UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-38112

ATHENEX, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**43-1985966**
State or other jurisdiction of incorporation or organization	**(I.R.S. Employer Identification No.)**
1001 Main Street, Suite 600 Buffalo, NY	
United States	**14203**
(Address of principal executive offices)	**(Zip Code)**

(716) 427-2950

Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol**	**Name of Exchange on Which Registered**
Common Stock, par value $0.001 per share	**ATNX**	**The Nasdaq Global Select Market**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of common equity held by non-affiliates of the registrant calculated based on the closing price of $4.62 of the registrant's common stock as reported on The Nasdaq Global Market on June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $380 million.

As of March 8, 2022, 110,397,818 shares of common stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2022 annual meeting of stockholders are incorporated by reference into Part III Items 10, 11, 12, 13 and 14 of this Form 10-K.

SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and section 27A of the Securities Act of 1933, as amended (the "Securities Act") and the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Annual Report. These forward-looking statements may include, but are not limited to, statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, clinical development activities, the timing and results of clinical trials and potential regulatory approval and commercialization of product candidates. In some cases, forward-looking statements may be identified by terminology such as "believe," "may," "will," "should," "predict," "goal," "strategy," "potential," "estimate," "continue," "anticipate," "intend," "indicate," "could," "would," "project," "plan," "expect," "seek," "strategy," "mission," "outlook" and similar expressions and variations thereof. These words are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations, except as required by law.

Unless the context indicates otherwise, as used in this Annual Report, the terms "Athenex," the "Company," "we," "us," and "our" refer to Athenex, Inc., a Delaware corporation, and its subsidiaries taken as a whole, unless otherwise noted.

Risk Factors Summary

The following factors are among the principal risks we face. For a more detailed description of the risks material to our business, see "Part I-Item 1A-Risk Factors" in this Annual Report on Form 10-K. The following summary should not be considered an exhaustive summary of the material risks we face and should be read in conjunction with the "Risk Factors" section and the other information in this Annual Report. Some of the factors that could cause our results to differ materially from our expectations or beliefs include, without limitation:

- the impact of the COVID-19 pandemic and other macroeconomic factors, like the war in Ukraine, on our business, including our commercial operations and clinical development activities;
- the substantial doubt about our ability to continue as a going concern and the volatility of our financial results;
- our strategic pivot to focus on our cell therapy platform and our plan to dispose of non-core assets;
- our ability to obtain additional financing to fund our operations and to refinance, extend or repay our substantial indebtedness owed to our senior secured lender;
- the uncertainty of ongoing legal proceedings;
- the early stage of development of the majority of our primary clinical candidates;
- the novel approach to some of our drug candidates, which may delay or impede our ability to achieve regulatory approval or market acceptance;
- costs and delays if our drug candidates fail to demonstrate safety and efficacy;
- our failure to identify or discover additional drug candidates or to prioritize development of certain product candidates;

- the unpredictable and lengthy regulatory approval processes of the FDA, NMPA and other regulatory authorities, including whether the FDA accepts data from clinical trials outside of the United States;
- ongoing regulatory obligations, which may result in significant additional expenses, for Klisyri® and other product candidates;
- the delay or prevention of regulatory approval or limitation of the commercial profile of an approved label due to undesirable adverse events caused or that may be caused by our approved drugs and drug candidates;
- our dependence on the efforts of Almirall S.A. for the commercialization of Klisyri;
- our limited experience in manufacturing and marketing proprietary drug products;
- the limited market for orphan drugs;
- if Klisyri or any other drug candidates become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives;
- competition from brand and generic drug products;
- the impact of legal, regulatory or legislative strategies that limit our ability to generate revenue;
- the material weakness in our internal control over financial reporting;
- regulatory and customer scrutiny of compounded preparations and the pharmacy compounding industry;
- our ability to successfully protect our intellectual property rights, a significant portion of which are pending patent applications, and defend against claims of infringement by others;
- our ability to protect the confidentiality of our trade secrets;
- our ability to comply with obligations in license agreements and maintain the rights that are important to our business;
- our reliance on third parties to conduct preclinical studies and clinical trials and manufacture some of our drug candidate supplies;
- our dependence on a limited number of pharmaceutical wholesalers to generate revenue;
- our dependence on our key personnel;
- our dependence on public-private partnerships and reliance on counterparties to meet their obligations;
- the impact of conflicts of interest and transactions with affiliates and related parties that were not negotiated at arms' length;
- if we or our third party service providers suffer security breaches;
- the impact of claims in excess of our insurance coverage, including product liability lawsuits;
- the interruption of our business or production at our manufacturing facilities;
- changes in political and economic policies of the Chinese government, or changes in the interpretation and enforcement of laws, rules and regulations in China; and
- compliance with tax laws, including whether we may be subject to Chinese income tax on our global income.

PART I

Item 1. Business.

Overview

Athenex, Inc., together with its subsidiaries ("Athenex," the "Company," "we," "us" or "our"), is a global biopharmaceutical company dedicated to becoming a leader in the discovery, development and commercialization of next generation drugs for the treatment of cancer. Our mission is to improve the lives of cancer patients by creating more effective, safer and tolerable treatments. We are organized around three platforms, an Oncology Innovation Platform, a Commercial Platform and a Global Supply Chain Platform. Our current clinical pipeline in the Oncology Innovation Platform is derived from the following core technologies: (1) Cell Therapy, (2) Orascovery, based on a P-glycoprotein ("P-gp") pump inhibitor, and (3) Src Kinase inhibition. We have assembled a strong and experienced leadership team and have established global operations across the pharmaceutical value chain to execute our goal of becoming a global leader in bringing innovative cancer treatments to the market and improving health outcomes.

Significant Developments in the Oncology Innovation Platform

Cell Therapy

Through our acquisition of Kuur Therapeutics, Inc. (formerly known as Cell Medica, "Kuur") in 2021, we acquired rights to intellectual property to further the development of autologous and allogeneic, or "off-the-shelf", natural killer T ("NKT") cell immunotherapies for the treatment of solid and hematological malignancies. We are advancing the following product candidates: KUR-501, KUR-502, and KUR-503.

KUR-501 is an autologous product in which NKT cells are engineered with a chimeric antigen receptor ("CAR") targeting GD2 ("GINAKIT" cells). GD2 is expressed on almost all neuroblastoma tumors and certain other malignancies. KUR-501 is currently being evaluated in a phase 1 clinical trial (GINAKIT2) treating children with relapsed-refractory ("R/R") high risk neuroblastoma. In May 2021, we presented an interim data update from the first eleven evaluable patients at the American Society of Gene & Cell Therapy ("ASGCT"). During this initial evaluation, the safety profile of KUR-501 was manageable, and there was no dose limiting toxicity ("DLT"). No patients experienced grade 2 or higher toxicities related to KUR-501. There were no grades 3-5 cytokine release syndrome ("CRS") and no evidence of immune effector cell-associated neurotoxicity syndrome ("ICANS") in any of the patients. Grades 3-4 adverse events ("AEs"), reported regardless of relationship to KUR-501, have included anemia, leukopenia, lymphopenia, neutropenia, thrombocytopenia, abdominal distension, acute gastroenteritis, liver enzyme increase, vomiting, bone pain, headache, neck pain, fever, urinary tract infection, altered mental status, and hypoxia. As this clinical development program is still in the early stages, we do not yet have meaningful statistics on safety, including AEs, to report. Observed responses included one complete response ("CR") and one partial response ("PR"). Four additional patients have exhibited stable disease ("SD"). We also observed long-term persistence of NKT cells expressing CAR. Importantly, we observed NKT cell localization to the tumor site.

KUR-502 is an allogeneic ("off-the-shelf") product in which NKT cells are engineered with a CAR targeting CD19. KUR-502 is currently being evaluated in a phase 1 clinical trial (ANCHOR) treating adults with R/R CD19 positive malignancies, including B cell lymphoma, acute lymphoblastic leukemia ("ALL"), and chronic lymphocytic leukemia ("CLL"). In December 2021, we presented an interim data update on the first five evaluable patients at the American Society of Hematology ("ASH") annual meeting. Tumor biopsies showed presence of NKT cells expressing CARs in the disease sites, indicating that the KUR-502 cells are able to traffic to the tumor. The safety profile was manageable with no DLT. There was one case of grade 1 CRS, no ICANS, and no graft versus host disease ("GvHD") attributable to KUR-502. Grades 3-4 AEs, reported regardless of relationship to KUR-502, have included lymphopenia, leukopenia, neutropenia, thrombocytopenia, liver enzyme elevation, bilirubin elevation, anemia, diarrhea, hypoalbuminemia, and myositis. As this clinical development program is still in the early stages, we do not yet have meaningful statistics on safety, including AEs, to report. Of the first five evaluable patients, the overall response rate was 80%, and the complete response rate was 60%.

KUR-503 is an allogeneic ("off-the-shelf") product in which NKT cells are engineered with a CAR targeting glypican-3 ("GPC3"). GPC3 is a molecule that is highly expressed on most hepatocellular carcinomas ("HCC") but not normal liver or other non-neoplastic tissue. KUR-503 is currently in preclinical development, and we are planning to submit an IND by the first half of 2023.

We continue to advance TCR affinity-enhancing specific T-cell ("TAEST") therapy with our drug candidate, TCRT-ESO-A2. TCRT-ESO-A2 is an autologous T cell receptor ("TCR")-T cell therapy targeting solid tumors that are NY-ESO-1 positive in HLA-A*02:01 positive patients. A phase 1 clinical trial treating adults with advanced solid tumors expressing NY-ESO-1 is currently open enrolling.

Orascovery

Our Orascovery technology is based on the novel P-gp pump inhibitor molecule, encequidar. Oral administration of encequidar in combination with established chemotherapy agents such as paclitaxel, irinotecan, docetaxel, topotecan and eribulin has been shown

to improve the absorption of these agents by blocking the P-gp pump in the intestinal wall. Oral paclitaxel and encequidar ("Oral Paclitaxel"), is our lead asset in our Orascovery platform.

Significant developments in our Orascovery platform in 2021 include the following:

On February 26, 2021, we received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding our New Drug Application ("NDA") for Oral Paclitaxel for the treatment of metastatic breast cancer ("mBC").

In June 2021, we presented data on Oral Paclitaxel for the treatment of mBC at the American Society for Clinical Oncology 2021 (ASCO2021) Virtual Scientific Program. Results of a post-hoc subgroup efficacy analysis based on additional tumor subtype data were presented.

In June 2021, we presented data from an open-label, two-way crossover phase 1 pharmacokinetic study of oral docetaxel and encequidar ("Oral Docetaxel") vs IV docetaxel, at the ASCO2021 Virtual Scientific Program. The data demonstrated the drug was well tolerated with no dose limiting toxicities, or drug-related serious adverse events at the doses tested. The mean absolute bioavailability was 15.9% (range 8% to 25%) with PK exposure becoming non-linear at 300 mg/m2.

In September 2021, we presented interim data from a study of Oral Paclitaxel in combination with pembrolizumab at the European Society for Medical Oncology ("ESMO") Virtual Congress 2021. The safety data helps establish Part B dose expansion and Phase 2 dose. The data showed encouraging anti-tumor activity in non-small cell lung cancer patients who failed prior PD1/PDL1 therapies.

Following the CRL, we held two Type A meetings with the FDA to discuss the deficiencies raised in the CRL, review a proposed design for a new clinical trial intended to address the deficiencies raised in the CRL, and discuss the potential regulatory path forward for Oral Paclitaxel in metastatic breast cancer ("mBC") in the U.S. In October 2021, after careful consideration of the FDA feedback, we determined to redeploy our resources to focus on other ongoing studies of Oral Paclitaxel and our Cell Therapy platform.

On November 29, 2021, we announced the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") validation of the Marketing Authorization Application ("MAA") for Oral Paclitaxel, for review. The Phase 3 study of Oral Paclitaxel in MBC (KX-ORAX-001) served as the basis of the MAA.

In December 2021, we presented a subgroup analysis from the Phase 3 study of Oral Paclitaxel in mBC patients, at the 2021 San Antonio Breast Cancer Symposium ("SABCS"). Analysis of safety data demonstrated that patients with elevated liver tests were at increased risk of neutropenia related toxicities. Post hoc analysis of this subgroup of patients with hepatic impairment was conducted and showed a median survival rate of 18.9 months in patients treated with Oral Paclitaxel vs 10.1 months in those treated with IV Paclitaxel, with a hazard ratio of 0.59.

We are continuing to evaluate Oral Paclitaxel in combination with check point inhibitors.

Src Kinase Inhibition

Our Src Kinase inhibition platform technology is based on novel small molecule compounds that have multiple mechanisms of action, including the inhibition of the activity of Src Kinase and the inhibition of tubulin polymerization, which may limit the growth or proliferation of cancerous cells. We believe the combination of these mechanisms of action provides a broader range of anti-cancer activity compared to either mechanism of action alone. Our lead product candidate on our Src Kinase inhibition platform is tirbanibulin (formerly known as KX2-391 and KX-01) ointment, which we are advancing for the treatment of actinic keratosis ("AK") and skin cancer.

Significant developments in our Src Kinase inhibition platform in 2021 include the following:

The New England Journal of Medicine published the pivotal Phase 3 trial results on Klisyri® for the topical treatment of AK of the face or scalp in the February 11, 2021 issue.

On February 15, 2021, we entered into the Second Amendment to the 2011 license agreement with PharmaEssentia Corp. ("PharmaEssentia") for tirbanibulin ointment (the "Second Amendment to the PharmaEssentia Agreement"). The Second Amendment to the PharmaEssentia Agreement expands the territory to include Japan and South Korea and includes a license to use the intellectual property for additional dermatology indications and skin cancer in the existing territories.

On February 18, 2021, our partner Almirall S.A. ("Almirall") launched Klisyri® for AK in the US.

On May 21, 2021, we announced our partner Almirall S.A. received a positive opinion from the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") for the regulatory approval of Klisyri®, indicated for the topical treatment of AK of the face or scalp.

On July 19, 2021, our partner Almirall received approval from the European Commission to market Klisyri®, indicated for the topical treatment of AK of the face or scalp in adults.

On July 26, 2021, we announced that we entered into licensing agreements and strategic partnerships with Seqirus Pty Ltd ("Seqirus"), a subsidiary of CSL Limited, and AVIR Pharma Inc. ("AVIR") for tirbanibulin. Under the terms of the agreements, Seqirus will have an exclusive license to commercialize tirbanibulin in Australia and New Zealand, and AVIR will have an exclusive license to commercialize tirbanibulin in Canada.

On September 27, 2021, we announced our partner Almirall had launched Klisyri® in Germany and the UK, as part of a phased European launch.

Mission and Strategy

Our company's mission is to become a leader in bringing innovative cancer treatments to the market and to improve patient health outcomes. Historically, we had focused development of our Orascovery platform which is based on a technology that converts IV chemotherapy to oral chemotherapy. We conducted a large phase 3 clinical trial in metastatic breast cancer comparing Oral Paclitaxel to IV paclitaxel, which was the basis of our NDA submission. Unfortunately, in February 2021, we received a CRL from the FDA which asked for an additional clinical study to support approval. After careful evaluation and prioritization of our research and development ("R&D") pipeline, we have decided to focus our R&D resources on our innovative cell therapy platform, which is based on NKT cells. NKT cells have unique biology that has potential advantages over current T cell and NK cell based technologies. We believe these advantages include the following:

(1) There is still a major unmet need in hematological and solid tumors in that even in those indications where autologous CAR-T cells have been previously approved, up to 60% of patients receiving CAR-T therapy do not achieve long term durable responses.

(2) Cellular therapies have generally not been effective in the treatment of solid tumors. We believe NKT cells are an ideal platform for treatment of solid tumors because NKT cells home to tumors, and we have data demonstrating that CAR-NKT cells are superior in tumor homing compared to CAR-T cells.

(3) Our allogeneic ("off-the-shelf") CAR-NKT cell therapy products may be produced at larger scale than autologous products, potentially at lower cost.

(4) Our allogeneic CAR-NKT cells are manufactured starting with the lymphocytes of healthy donors. Use of healthy donors, rather than patients (who are the source of autologous cell therapy starting materials), results in a more robust and consistent product, because patient lymphocytes are usually dysfunctional due to previous cancer therapy.

NKT cells demonstrate anti-tumor activity, even without a CAR. This is because NKT cells can kill immune suppressive cells in the local tumor microenvironment. Thus, when we add a CAR to NKT cells they are now equipped with two different anti-tumor mechanisms, which may lead to more potent anti-tumor activity and reduce the potential for relapse.

Advancing KUR-501 CAR-NKT Targeting GD2 – KUR-501 is an autologous product in which NKT cells are engineered with a CAR targeting GD2 and is currently being evaluated in a phase 1 clinical trial (GINAKIT2) treating children with R/R high risk neuroblastoma. Neuroblastoma is a rare pediatric cancer and patients with R/R high risk neuroblastoma have very poor outcomes. Therefore, we believe there is a significant unmet need for better treatment options. Interim data presented at the American Society of Gene and Cell Therapy (ASGCT) 2021 Annual Meeting for the first eleven evaluable patients, showed long-term persistence of CAR-NKT cells and CAR-NKT cell localization at the tumor site. Responses were observed in two patients, including one CR, one PR, and four patients achieved SD. The safety profile of KUR-501 was manageable and the product is being administered in the outpatient setting. GINATKIT2 will continue enrolling patients at higher dose level cohorts with a goal to identify an optimal dose that we may take into a pivotal study.

Advancing KUR-502 CAR-NKT Targeting CD19 – Early data, as presented at the ASH annual meeting in December 2021, indicated that, of the first five evaluable patients, there was a promising overall response rate of 80% with a complete response rate of 60%. KUR-502 is an allogeneic, "off-the-shelf" product in which NKT cells are engineered with a CAR targeting CD19. Today, autologous CAR-T cell treatments are available to patients, but the patient-to-patient variability and long manufacturing lead times limit patient care options. As an allogeneic "off-the-shelf" product, KUR-502 leverages economies of scale and has the potential to significantly increase patient access to innovative CAR-NKT treatments. Our aim is to expand the phase 1 (ANCHOR) clinical trial treating adults with R/R CD19 positive malignancies currently being conducted at the Baylor College of Medicine ("BCM") to a phase 1 multicenter clinical trial (ANCHOR2).

Focusing on Specific Programs of Oral Paclitaxel – For Oral Paclitaxel, while our MAA submission is currently under review by the U.K. MHRA, we have focused our efforts on our ongoing combination clinical trials with checkpoint inhibitors where we believe there is an opportunity. Oral Paclitaxel is currently being evaluated in combination with pembrolizumab in non-small cell lung cancer ("NSCLC"); and dostarlimab +/- carboplatin in neoadjuvant breast cancer, as part of the I-SPY TRIAL (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis 2) ("I-SPY 2 TRIAL").

Licensing and Partnership Opportunities **–** We continue to increase the global reach of tirbanibulin 1% ointment by maintaining strong global partnerships with existing partners such as Almirall, Seqirus, and AVIR and by evaluating other strategic territories to launch the product. Our team will continue to work closely with our partners to explore additional treatment regimens and indications for tirbanibulin 1% ointment.

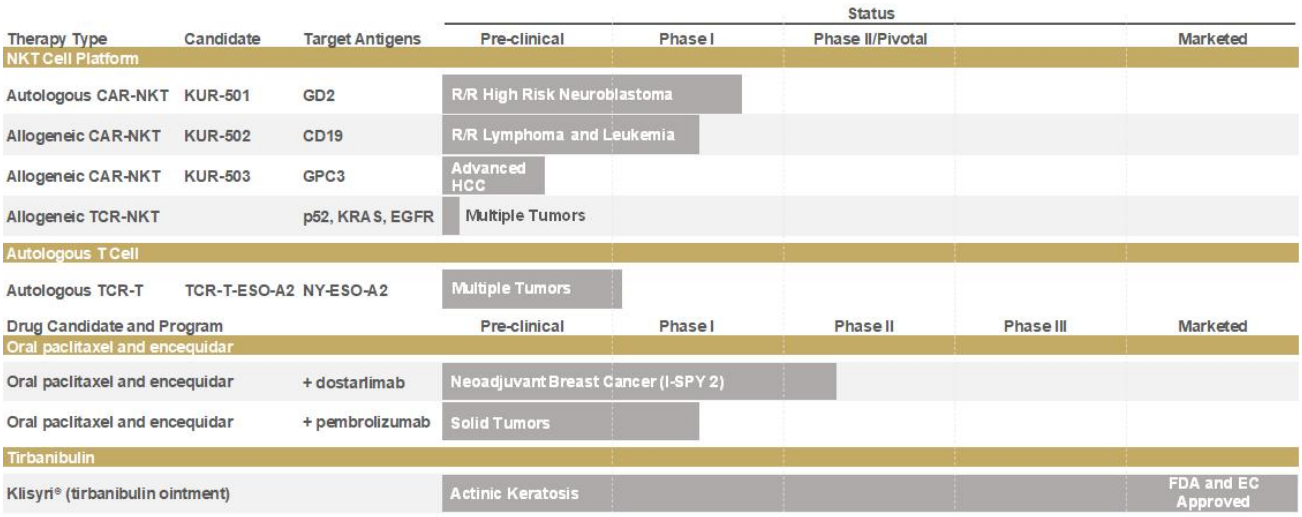
We will pursue strategic licensing and partnership opportunities for our small molecule programs and target opportunities that will create potential value for stockholders and support our business strategy and mission.

Operating Segments

We have organized our business model into three platforms: (1) our Oncology Innovation Platform, dedicated to the research and development of our proprietary drugs; (2) our Commercial Platform, focused on the sales and marketing of our specialty drugs and the market development of our proprietary drugs; and (3) our Global Supply Chain Platform, dedicated to providing a stable and efficient supply of active pharmaceutical ingredients ("API") for our clinical and commercial efforts. Athenex has global operations with offices and facilities in Buffalo and Clarence, New York; Cranford, New Jersey; Houston, Texas; Chicago, Illinois; Hong Kong; Taipei, Taiwan; multiple locations in Chongqing, China; Manchester, United Kingdom; Guatemala City, Guatemala and Buenos Aires, Argentina.

Our Oncology Innovation Platform

Within our Oncology Innovation Platform, we have three different technologies: (1) Cell therapy (2) Orascovery, based on a P-glycoprotein (P-gp) pump inhibitor, and (3) Src Kinase inhibition. The following table summarizes the development status of our current pipeline of product candidates in our Oncology Innovation Platform as of March 1, 2022:



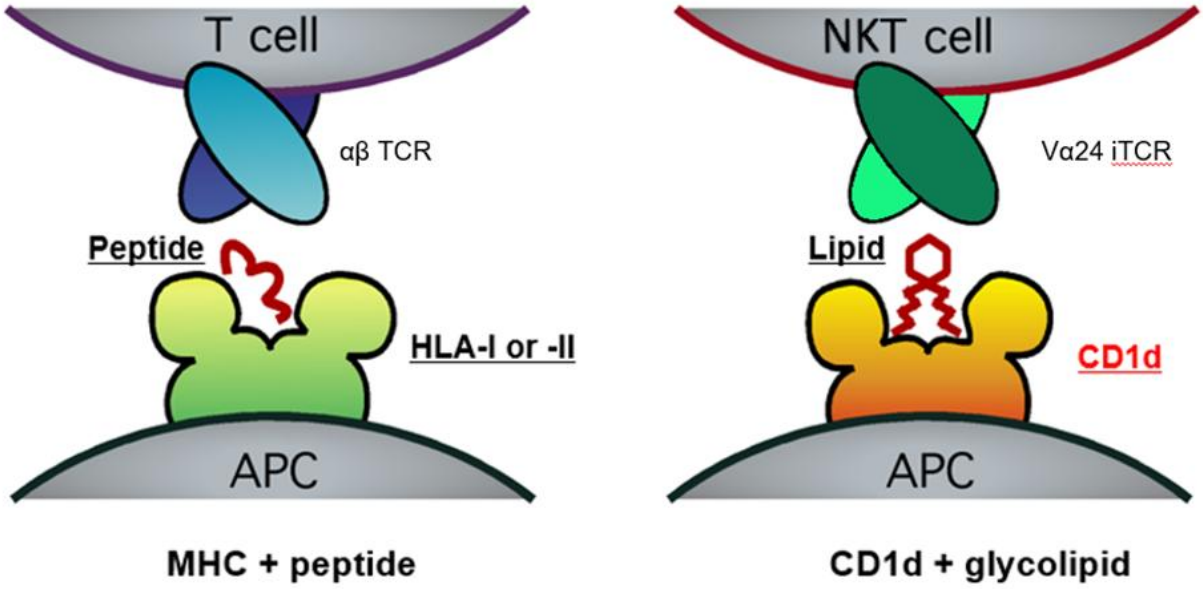
We collaborate with a number of biotechnology pharmaceutical companies, including Hanmi Pharmaceutical Co., Ltd. ("Hanmi"), Eli Lilly and Company ("Lilly"), Almirall, Guangzhou Xiangxue Pharmaceutical Co., Ltd. ("Xiangxue"), ZenRx Limited ("ZenRx") and PharmaEssentia, to support the development of our clinical pipeline globally and explore additional indications. For additional information, please see "*Business—License and Collaboration Agreements*".

Our Cell Therapy Platform

NKT cells are a core aspect of our cell therapy platform. NKT cells are a subset of lymphocytes that share properties of both innate and adaptive immune cells. NKT cells acquire effector memory functions immediately after exiting the thymus and, thus, behave similarly to innate immunity cells like natural killer ("NK") cells. Within the immune system, NKT cells have an important function, acting among the first cells to respond to either infection or stress in the tissues.

The target recognition for both NKT and T-cells is strictly restricted and antigen specific. Although both NKT and T-cells express TCRs, their models for recognition of antigen (target) are distinct. Both T-cells and NKT cells recognize target antigens in

association with other molecules, a phenomenon called “restriction.” T-cell TCRs are restricted by either human leukocyte antigen (HLA) class I or class II whereas NKT cell TCRs are restricted by CD1d, which is related to class I HLA in structure. The CD1d molecule is identical in all people (monomorphic) while HLA class I and II molecules are polymorphic (see following figure). T-cells utilize a wide variety of different TCRs, whereas type 1 NKT cells (which we use) employ an invariant TCR (iTCR). As a result, without major genetic engineering, the majority of T-cell products must be limited to autologous use, given the potential for toxicity if T-cell products are infused into a genetically different recipient (e.g., GvHD). In contrast, because CD1d is the same in all individuals, and NKT cells express an iTCR restricted by CD1d, the potential for GvHD toxicity is minimal. We believe that this provides us a promising basis to use NKT cells for an “off-the-shelf” product, without the need for complex genetic engineering to prevent GvHD.



Clinical Development

KUR-501 is an autologous product in which NKT cells are engineered with a CAR targeting GD2. Neuroblastoma is a pediatric cancer, and we believe there is a significant unmet need as the patient prognoses are often poor and treatment options are limited. KUR-501 is currently being evaluated in a phase 1 clinical trial (GINAKIT2) treating children with R/R high risk neuroblastoma. In May 2021, we presented an interim data update from the first eleven evaluable patients at ASGCT. During this initial evaluation, the safety profile of KUR-501 was manageable, and there was no DLT. No patients experienced grade 2 or higher toxicities related to KUR-501. There were no grades 3-5 CRS and no evidence of ICANS in any of the patients. Grades 3-4 AEs, reported regardless of relationship to KUR-501, have included anemia, leukopenia, lymphopenia, neutropenia, thrombocytopenia, abdominal distension, acute gastroenteritis, liver enzyme increase, vomiting, bone pain, headache, neck pain, fever, urinary tract infection, altered mental status, and hypoxia. As this clinical development program is still in the early stages, we do not yet have meaningful statistics on safety, including AEs, to report. Observed responses included one CR and one PR. Four additional patients have exhibited SD. We also observed long-term persistence of NKT cells expressing CAR. Importantly, we observed NKT cell localization to the tumor site. GINAKIT2 is supported by Athenex and is being conducted by Athenex’s collaborator, the Baylor College of Medicine ("BCM”). GINAKIT2 is currently recruiting patients.

KUR-502 is an allogeneic (“off-the-shelf”) product in which NKT cells are engineered with a CAR targeting CD19. In addition to the CAR, KUR-502 is genetically engineered to down regulate surface expression of HLA class I and class II proteins, resulting in reduced recognition and elimination by the host immune system following infusion. Therefore, unlike KUR-501, the KUR-502 CAR NKT product is manufactured from NKT cells isolated from healthy donors. Today, there are autologous CAR-T cell treatments available to patients, however, these treatments are limited by manufacturing lead time and variable final product quality due to their patient specific starting material (e.g., leukapheresis). As an “off-the-shelf” product, KUR-502 is designed to minimize manufacturing impact and increase patient accessibility. KUR-502 is currently being evaluated in a phase 1 (ANCHOR) clinical trial treating adults with R/R CD19 positive malignancies, including B cell lymphoma, ALL, and CLL. The single-arm study evaluates three dose levels of KUR-502 with patients receiving pre-dose lymphodepletion chemotherapy consisting of cyclophosphamide and fludarabine. Interim data showed the presence of NKT cells expressing CARs in the disease sites, indicating that the KUR-502 cells are able to traffic to the tumor. The safety profile was manageable with no DLT, only one case of grade 1 CRS, no ICANS, and no GvHD

attributable to NKT cells expressing CAR. Grades 3-4 AEs, reported regardless of relationship to KUR-502, have included lymphopenia, leukopenia, neutropenia, thrombocytopenia, liver enzyme elevation, bilirubin elevation, anemia, diarrhea, hypoalbuminemia, and myositis. As this clinical development program is still in the early stages, we do not yet have meaningful statistics on safety, including AEs, to report. Of the first five evaluable patients, the overall response rate was 80%, and the complete response rate was 60%. Given that these patients were heavily pretreated, including with prior autologous CAR-T cell treatment, we believe the early response data suggests that KUR-502 may yield high efficacy at low dose levels. The study is ongoing. ANCHOR is supported by Athenex and is being conducted by Athenex's collaborator, BCM. ANCHOR is currently recruiting patients.

KUR-503 is an allogeneic ("off-the-shelf") product in which NKT cells are engineered with a CAR targeting GPC3. GPC3 is a molecule that is highly expressed on most HCC but not normal liver or other non-neoplastic tissue. KUR-503 is currently in preclinical development, and we are planning to submit an IND by the first half of 2023.

We continue to advance TAEST therapy with our drug candidate, TCRT-ESO-A2. TCRT-ESO-A2 is an autologous TCR-T cell therapy targeting solid tumors that are NY-ESO-1 positive in HLA-A*02:01 positive patients. A phase 1 clinical trial treating adults with advanced solid tumors expressing NY-ESO-1 is currently open enrolling.

Our Orascovery Platform

Our Orascovery platform technology is based on the novel oral P-gp pump inhibitor molecule, encequidar. The P-gp pump is a plasma membrane efflux protein on the cells which forms a localized drug transport system. In the intestine it limits the oral absorption of a large number of drugs, including widely used P-gp substrate cancer chemotherapeutic drugs such as paclitaxel, irinotecan, docetaxel and eribulin, thus restricting their current dosing to IV administration.

Mechanism of Action - P-gp Inhibition

Encequidar is a P-gp pump inhibitor and an oral absorption enhancer that prevents the P-gp pump-mediated efflux of chemotherapy agents back into the gastrointestinal tract. P-gp plays an important physiologic role as a transporter protein at multiple barrier sites, including the gastrointestinal tract and the blood brain barrier ("BBB"). The demonstrated role of P-gp in limiting intestinal absorption of multiple cancer chemotherapies highlighted the potential utility of a small molecule P-gp inhibitor for enabling oral administration of P-gp substrate drugs otherwise restricted to IV dosing. Encequidar was originally identified by Hanmi as a highly selective and potent P-gp inhibitor, capable of elevating the oral bioavailability of paclitaxel from less than 5% (in the absence of encequidar) to 41% in rats. Encequidar is distinct from previously developed small molecule P-gp inhibitors because it is designed to not be systemically absorbed in the gastrointestinal tract following oral administration with only small amounts detectable in the plasma even after relatively high doses. This unique property makes encequidar a good candidate for co-administration with P-gp substrate drugs, such as paclitaxel, which normally exhibit poor oral bioavailability and are therefore limited to IV routes of dosing.

Clinical Development

In three separate pharmacokinetics ("PK") studies of encequidar conducted in healthy subjects, a total of 81 individuals received single oral doses of encequidar tablets in single doses of up to 900 mg, and 30 individuals were enrolled in multiple dose cohorts with treatment groups receiving encequidar tablets ranging from 60 to 360 mg per day for five days. Encequidar was well-tolerated, with mostly mild gastrointestinal adverse effects. No serious adverse events ("SAEs") were reported. At the current clinical dose of 15 mg given once daily for up to five days, the maximal concentration of the drug in plasma ("Cmax") in systemic circulation is low. Drug-drug interaction studies of encequidar with digoxin and dabigatran have been conducted, and the metabolism and routes of excretion in humans has been determined.

Our Orascovery Product Candidates

Oral Paclitaxel and Encequidar

Overview

IV paclitaxel is used widely for the treatment of breast, ovarian, and lung cancer. Due to its poor solubility, paclitaxel is usually dissolved in ethanol and polyethoxylated castor oil, which is a major cause of IV hypersensitivity reactions. As a result, premedication with high dose steroids and antihistamines is required to minimize these adverse reactions. Additional common toxicities associated with IV administration of paclitaxel include neuropathy, neutropenia and alopecia. These side effects limit dose intensification and often require reduction in dosing.

Oral Paclitaxel is our lead drug candidate in our Orascovery Platform and is initially being developed for the treatment of patients with metastatic breast cancer. We conducted a pivotal, randomized Phase 3 study of Oral Paclitaxel monotherapy versus IV paclitaxel monotherapy which met its primary endpoint of confirmed response rate in patients receiving Oral Paclitaxel. On February 26, 2021, we received a CRL from the FDA regarding our NDA for Oral Paclitaxel. Following the CRL, we held two Type A meetings with the FDA to discuss the deficiencies raised in the CRL, review a proposed design for a new clinical trial intended to address the deficiencies raised in the CRL, and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S. In October 2021, after careful consideration of the FDA feedback, we determined to redeploy our resources to focus on other ongoing studies of Oral Paclitaxel and our Cell Therapy platform. We are also evaluating Oral Paclitaxel as a monotherapy treatment for patients with cutaneous angiosarcoma, and in combination with pembrolizumab for advanced solid malignancies including gastric or gastroesophageal or non-small cell lung cancer. A study is also being conducted in combination with GlaxoSmithKline's ("GSK") dostarlimab in the neoadjuvant chemotherapy setting for breast cancer.

Clinical Development by Indication

Metastatic Breast Cancer

Phase 3 Study

Our Phase 3 pivotal study of Oral Paclitaxel in patients with metastatic breast cancer was a randomized, active-controlled clinical trial comparing Oral Paclitaxel monotherapy against IV paclitaxel monotherapy. The trial randomized subjects in a 2:1 ratio to

Oral Paclitaxel, and was designed to compare the safety and efficacy of Oral Paclitaxel with IV paclitaxel. The primary endpoint was ORR (confirmed by scans at two consecutive timepoints) as assessed by RECIST v1.1 criteria, a generally accepted method for assessing tumor response. Blinded assessments of tumor response were made by independent radiologists.

A total of 402 metastatic breast cancer patients were enrolled (Oral Paclitaxel=265 vs. IV paclitaxel=137), which represented the ITT population.

In the final analysis of the primary endpoint of the study, Oral Paclitaxel (205 mg/m2 per day 3 days/week) showed a statistically significant improvement in ORR. Based on ITT analysis, Oral Paclitaxel showed a statistically significant improvement in ORR over IV paclitaxel, with 35.8% ORR, compared to 23.4% for IV paclitaxel, a difference of 12.4% (p=0.011).

Secondary endpoints in the study included PFS and OS. In December 2020, we presented updated PFS and OS data at the 2020 SABCS. In the ITT population, the median PFS showed a benefit for Oral Paclitaxel versus IV paclitaxel (8.4 months vs. 7.4 months, respectively; hazard ratio (HR) = 0.768; 95% confidence interval (CI): 0.584, 1.01; p = 0.046). The median OS data demonstrated a trend favoring Oral Paclitaxel versus IV paclitaxel (22.7 months vs. 16.5 months, respectively; HR = 0.794; 95% CI: 0.607, 1.037; p = 0.082).

Based on data presented at the 2019 SABCS: 31.1% of IV paclitaxel patients experienced grade 2 or above neuropathy versus 7.6% of Oral Paclitaxel patients. The results also showed lower incidence of alopecia compared to IV paclitaxel, with 28.8% of the Oral Paclitaxel group experiencing alopecia versus 48.2% of the IV paclitaxel group in treatment-emergent adverse events of interest. For other treatment-emergent adverse events of interest, there was a higher incidence of neutropenia with CTCAE grade ≥ 3 (29.9% vs. 28.1%; with Grade 4 14.8% vs 8.9%) and gastro-intestinal side effects, such as diarrhea with CTCAE grade ≥ 3 (5.3% vs. 1.5%) and vomiting or nausea with CTCAE grade ≥ 3 (6.8% vs. 0.7%), in the Oral Paclitaxel group as compared to the IV paclitaxel group.

Based on data presented at the 2020 SABCS: all grades of neuropathy were observed in 22% of Oral Paclitaxel patients versus 64% of IV paclitaxel patients, and grade 3 neuropathy was observed in 2% of Oral Paclitaxel patients versus 15% of IV paclitaxel patients. Also presented were data on the effect of prophylactic treatments on the incidence and severity of gastrointestinal-related adverse events. After approximately 30% of patients were enrolled, the Phase 3 trial protocol was amended to allow patients randomized to the Oral Paclitaxel arm to receive prophylactic pre-medications for gastrointestinal side effects. Overall gastrointestinal (GI)-related adverse events (AEs) were less frequent in the IV paclitaxel arm. GI-related AEs improved in the Oral Paclitaxel arm following the amendment, as measured by lower incidences of grade 2 vomiting before and after amendment (24% vs. 7%) and grade 2 diarrhea before and after amendment (27% vs. 16%).

On February 26, 2021, we received a CRL from the FDA regarding our NDA for Oral Paclitaxel for the treatment of metastatic breast cancer. Following the CRL, we held two Type A meetings with the FDA to discuss the deficiencies raised in the CRL, review a proposed design for a new clinical trial intended to address the deficiencies raised in the CRL, and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S. In October 2021, after careful consideration of the FDA feedback, we determined to redeploy our resources to focus on other ongoing studies of Oral Paclitaxel and our Cell Therapy platform.

On November 29, 2021, we announced the U.K. MHRA validation of the MAA for Oral Paclitaxel, for review. The Phase 3 study of Oral Paclitaxel in MBC (KX-ORAX-001) served as the basis of the MAA.

Angiosarcoma

We have also been developing Oral Paclitaxel for the treatment of cutaneous angiosarcoma. Angiosarcomas are rare, aggressive and heterogeneous tumors accounting for approximately 2% of all soft tissue sarcomas. Only limited treatment options for advanced disease exist with poor outcomes and low 5-year survival rates.

We commenced a study of Oral Paclitaxel monotherapy in the treatment of angiosarcoma in December 2018. At the ASCO 2020 Virtual Scientific Program, we announced interim data from an ongoing Phase 2 clinical trial in which Oral Paclitaxel monotherapy showed encouraging efficacy and tolerability in elderly patients with unresectable cutaneous angiosarcoma, an aggressive malignancy with poor prognosis. The interim results reflect data from 22 evaluable patients out of 26 enrolled patients. The interim data showed a clinical benefit rate (CR+PR+SD) of 100% in 22 evaluable patients who reached their first post treatment efficacy evaluation. All 22 patients experienced reduction in tumor size. Complete responses (CR) were observed in 27.3% of patients (6/22), partial responses (PR) were observed in 22.7% of patients (5/22), and stable disease was observed in 50% of patients (11/22). Oral Paclitaxel has been generally well tolerated in this predominantly elderly population. The study is ongoing and the enrollment goal has been reached.

Combination studies

Oral Paclitaxel in combination with pembrolizumab

We have an ongoing Phase 1/2 clinical study to assess the safety, tolerability and activity of Oral Paclitaxel in combination with an anti-programmed cell death protein 1 (anti-PD1) antibody (pembrolizumab) in patients with advanced solid malignancies who have

failed treatment with checkpoint inhibitors. The study is being conducted in patients with gastric or gastroesophageal or non-small cell lung cancer that have previously failed treatment with a checkpoint inhibitor. Part 2 of the study in patients with non-small cell lung cancer has initiated.

I-SPY 2 TRIAL (Oral Paclitaxel in combination with dostarlimab +/- carboplatin)

In September 2020, we and Quantum Leap Healthcare Collaborative (Quantum Leap) announced the launch of two new study arms of the I-SPY 2 TRIAL to evaluate Oral Paclitaxel with GSK's dostarlimab, an investigational antibody binding PD-1, in the neoadjuvant chemotherapy setting. Quantum Leap is the trial sponsor and manages all study operations, and Athenex provides Oral Paclitaxel. The goal of this study is to evaluate the safety and efficacy of oral paclitaxel plus encequidar with dostarlimab +/- carboplatin in Stage 2/3 HER2- breast cancer patients and plus trastuzumab in HER2+ patients, followed, by doxorubicin plus cyclophosphamide chemotherapy and surgical resection. The primary objective is to determine whether this regimen increases the probability of pathologic complete response (pCR) over standard neoadjuvant chemotherapy alone for any of the tumor subtypes established at trial entry, and to determine the predictive probability of success in a subsequent Phase 3 trial. The study is ongoing.

Other Indications

We are conducting an MTD (maximum tolerated dose) study of Oral Paclitaxel in combination with ramucirumab in patients with advanced gastric cancer in the U.S. and Asia through a clinical trial collaboration with Lilly. We commenced a study of up to 32 patients in a dose escalation part of the trial with a dose expansion of Oral Paclitaxel in combination with a fixed dose of ramucirumab in July 2017.

The objective of our Phase 1 study was to define the MTD of daily Oral Paclitaxel dosing, starting at 200 mg/m2 for three days in a week, in combination with ramucirumab, which will be dosed every other week. In the first part of the study, 17 subjects were enrolled at doses ranging from 200-300 mg/m2. We defined the MTD dose of Oral Paclitaxel as 200 mg/m2 daily for three consecutive days weekly in combination with ramucirumab. Dose limiting toxicities ("DLTs") included febrile neutropenia, grade 4 neutropenia and grade 3 gastric hemorrhage. The most frequently reported adverse events were vomiting (70%), neutropenia (59%), decreased appetite (53%), nausea (24%) and mucositis (24%). Enrollment is completed and long term survival follow up has been stopped.

Overview of Safety Observations in Oral Paclitaxel Studies

Studies to date have indicated that Oral Paclitaxel does not result in hypersensitivity reactions when given without premedication for hypersensitivity type reactions, in contrast to the premedication requirement for IV paclitaxel, namely steroids and antihistamines. No new toxicity, apart from those typically observed with paclitaxel, was observed. Infusion related reactions, including hypersensitivity type reactions, have not been observed in patients administered Oral Paclitaxel. Additionally, severe toxicities associated with IV administration of paclitaxel, including neuropathy and alopecia, are at a lower incidence and severity for Oral Paclitaxel.

As of December 31, 2021, approximately 16% of patients treated in clinical studies with Oral Paclitaxel experienced SAEs that were considered to be related to the study treatment. The most common were neutropenia in approximately 3% of patients and febrile neutropenia in approximately 4.7% of patients; pneumonia in approximately 2.7% of patients; septic shock in approximately 1.7% of patients; sepsis in 1.5% of patients; dehydration in approximately 1.2% of patients; gastroenteritis, anemia, diarrhea, mucositis, gastrointestinal bleeding, vomiting, nausea and hypokalaemia, pneumonitis, colitis, tachycardia and atrial fibrillation, each in less than one percent of patients. Other serious treatment-related infections were reported in approximately 1.7% of patients. Approximately 3.3% of patients had other treatment-related SAEs (one patient each including rectal bleeding, altered state of consciousness, cardiac arrest, cardiogenic shock, hypotension, pancytopenia, multiorgan failure, renal failure, pleural effusion, supraventricular tachycardia, respiratory failure, malnutrition, dyspnoea, cardiac failure, upper abdominal pain, fatigue, decreased appetite, pulmonary tuberculosis and peripheral sensory neuropathy).

Oral Irinotecan and Encequidar

Current and Planned Clinical Development

A Phase 1 MTD study has been clinically completed. This study is to determine the MTD of Oral Irinotecan, when given once every three weeks, in subjects with advanced malignancies. We have identified a dosing regimen suitable for Phase 2. However, further development of Oral Irinotecan has been suspended at this time.

Overview of Safety Observations in Oral Irinotecan Studies

In our Oral Irinotecan clinical studies to date, the SAEs observed that were deemed to be at least possibly related to Oral Irinotecan include diarrhea, rash, gastrointestinal hemorrhage, anorexia, vomiting, nausea, enteritis, asthenia, neutropenia, increased alanine aminotransferase, increased aspartate aminotransferase, and C diff infection. As the clinical development program is still in its early stages, we do not yet have meaningful statistics on safety, including adverse events, to report.

Oral Docetaxel and Encequidar

Current and Planned Clinical Studies

A Phase 1 dose escalation U.S. based trial for Oral Docetaxel in patients with various solid tumors given once every three weeks is ongoing. Another Phase 1 study to identify the absolute bioavailability of Oral Docetaxel in prostate cancer patients has been completed. Based on Phase 1 results so far, we believe that we can achieve similar exposure to IV docetaxel with one to three days of dosing every three weeks. Alternative schedules such as weekly or 2 of 3 weeks are also being explored. Further development of Oral Docetaxel has been suspended at this time.

Overview of Safety Observations in Oral Docetaxel Studies

We expect that the overall safety profile of Oral Docetaxel will be similar to that of IV docetaxel, with differences related to the route of administration. As with Oral Paclitaxel, premedication has not been required and hypersensitivity type reactions have not been observed. As of December 31, 2021, in our Oral Docetaxel clinical studies, the SAEs observed that were deemed to at least possibly related to Oral Docetaxel include gastrointestinal toxicity; vomiting, nausea and diarrhea in 1 subject.

Oral Topotecan and Encequidar

A Phase 1 clinical trial in advanced malignancies for Oral Topotecan has completed enrollment. Further development of Oral Topotecan has been suspended at this time. As the clinical development program has enrolled few patients, we do not have meaningful statistics on safety, including adverse events, to report.

Oral Eribulin and Encequidar

In October 2018, the FDA allowed our IND application for Oral Eribulin. A Phase 1 study commenced in 2019 to assess the safety, MTD, DLT and absolute bioavailability of Oral Eribulin in subjects with solid tumors. Enrollment into the trial has been suspended, and no further trials are planned at this time. As few patients were enrolled into the trial, we do not have meaningful statistics on safety, including adverse events, to report.

Our Src Kinase Inhibition Platform

Our Src Kinase inhibition platform technology is based on novel small molecule compounds that have multiple mechanisms of action, including the inhibition of the activity of Src Kinase and the inhibition of tubulin polymerization, which may limit the growth or proliferation of cancerous cells. We believe the combination of these mechanisms of action provides a broader range of anti-cancer activity compared to either mechanism of action alone. Our lead product candidate on our Src Kinase inhibition platform is tirbanibulin ointment. Our other clinical candidates in this platform include tirbanibulin oral and KX2-361.

Tirbanibulin

Mechanism of Action

Tirbanibulin, formerly known as KX2-391 or KX-01, is a novel small molecule that we discovered and developed, which demonstrates at least two mechanisms of action (“MOAs”) relevant to the potential control of cancer and hyper-proliferative disorders: (1) Src tyrosine kinase inhibition (non-ATP competitive) and (2) tubulin polymerization inhibition. Src Kinase, a tyrosine kinase protein involved in regulating cell growth, is strongly implicated in metastasis. Inhibiting Src Kinase may limit the growth or proliferation of cancerous cell types. Src plays a role in regulating multiple aspects of tumor development, growth and metastases, and its inhibition limits such tumor activity. Interfering with tubulin polymerization activity is a clinically validated mechanism for treating cancer. For both targets tirbanibulin binds at a novel binding site. Taken together, these two MOAs may provide for a potent means of treating cancer and other hyper-proliferative disorders.

Tirbanibulin Ointment

Tirbanibulin is a compound developed under our Src Kinase inhibition platform that, as a free base, has advantageous physical properties for topical ointment formulations.

Actinic Keratosis

In December 2020, the FDA approved Klisyri® (tirbanibulin), a microtubule inhibitor, for the topical treatment of AK on the face or scalp. The FDA approved Klisyri based on data from two pivotal, randomized, double-blind, vehicle-controlled Phase 3 trials (KX01-AK-003 and KX01-AK-004) that evaluated the efficacy and safety of tirbanibulin ointment 1% (10mg/g) in adults with AK of the face or scalp. In July 2021, our partner Almirall received approval from the European Commission to market Klisyri® in the same indication. Klisyri® has launched in the US and in certain European countries. Our partner, PharmaEssentia, has initiated trials of tirbanibulin ointment for the treatment of AK, in Japan.

Psoriasis

Tirbanibulin ointment has shown encouraging preclinical results in treating psoriasis, a chronic autoimmune skin disease that speeds up the growth cycle of skin cells. Psoriasis causes localized or generalized patches of red papules and plaques, covered with white or silver scales and itching. A Phase 1 clinical trial of tirbanibulin ointment 1% in psoriasis, performed by our partner PharmaEssentia, has been completed.

Tirbanibulin Oral

Development of our oral formulation of tirbanibulin has been suspended at this time.

KX2-361

KX2-361, formerly known as KX-02, is the second compound we developed using our Src Kinase inhibition platform technology. KX2-361 is a closely related structural analog of tirbanibulin and has been observed to have a similar dual MOA of inhibition of Src activity and microtubule polymerization. Although KX2-361 is an analog of tirbanibulin, it has significantly different physical properties. These properties are designed to allow KX2-361 freely cross the BBB such that the concentration in the brain is equal to, or somewhat greater than, that in the plasma. This trait is uncommon for oncology drugs and highlights the potential for KX2-361 as a novel therapy for unmet medical needs such as brain cancers, including glioblastoma and brain metastases. KX2-361's multiple MOAs along with its ability to cross the BBB, make it a novel molecule for the treatment of brain tumors. The FDA has granted Orphan Drug Designation to KX2-361 for the treatment of gliomas.

KX2-361 is currently in the early stages of development. In our KX2-361 clinical studies to date, the SAEs observed were thromboembolic events, hyperuricemia and pulmonary embolism. As the clinical development program is still in its early stages, we do not yet have meaningful statistics on safety, including adverse events, to report.

Further development of KX2-361 has been suspended at this time.

Our Other Technologies

Arginine Deprivation Therapy

PT01, the arginine deprivation therapy product, is based on our pegylated genetically engineered human arginase. It targets cancer growth and survival by interrupting the supply of arginine to cancers with disrupted urea cycles such as melanoma, hepatocellular carcinoma and prostate cancer. Our proprietary arginase biologic product is well suited to deplete arginine from the tumors, while healthy cells, capable of producing their own arginine, are largely unaffected. We had enrolled subjects with advanced solid tumors in a study in the US that was intended to determine the dose limiting toxicities, safety, pharmacokinetics and pharmacodynamics of PT01 with administered as a weekly IV infusion. Enrollment into this trial has been suspended, and no further studies are planned at this time.

Proprietary Dual (CYP/P-gp) Inhibitor

We are developing a proprietary class of "dual" absorption enhancers that are intended to inhibit both the P-gp transporter and the cytochrome p450 3A ("CYP") enzymes within the gastrointestinal tract. These dual absorption enhancers may lead to better performing next-generation oral medicines in our pipeline of clinical products.

The development of these dual absorption enhancers is at the preclinical stage. Proof of concept, providing increased oral bioavailability in preclinical species, has been obtained with several absorption enhancers and candidate drugs. Currently additional filters such as patentability/freedom to operate, physical-chemical characterization, pre-formulation studies, manufacturing analysis and preliminary toxicity testing are being applied to our first group of lead candidates to facilitate election of an IND candidate.

Research and Development

We have drug discovery, drug formulation, clinical and regulatory development and API/drug product manufacturing facilities and capabilities around the world. The U.S. drug discovery, clinical and regulatory development and formulation research facilities are largely concentrated in Buffalo, New York and Cranford, New Jersey. The range of capabilities at these facilities includes medicinal chemistry, biochemistry, cell biology, formulation, chemical manufacturing and control, quality control, pharmacokinetics/ pharmacodynamics ("PK/PD") and data management, as well as pharmacovigilance, clinical development and regulatory expertise functions. Animal efficacy, PK/PD and toxicology studies are carried out at various contract research organizations, or CROs, around the world in order to facilitate the drug research and development process. We also have research, clinical development and regulatory capabilities in China, the U.K. and Latin America, as well as in Taiwan, where we also have built up data management facility. Our research and development center in Hong Kong concentrates on drug formulation development and evaluation. Our global research and development capabilities and facilities are well integrated with our research and development center in the U.S.

To date, we and our partners have conducted, or are conducting, clinical trials across sites in the U.S., South Korea, New Zealand, Taiwan, China, U.K., Australia, and various countries in Latin America, including Argentina, Guatemala, Honduras, Chile, Colombia, Ecuador, the Dominican Republic, and Peru.

Commercialization

Following the CRL of Oral Paclitaxel in mBC and the decision to redeploy resources to our Cell Therapy technologies and other ongoing studies of Oral Paclitaxel, we have suspended commercial activities for Oral Paclitaxel in the U.S., at this time. Outside of the U.S., we continue to evaluate marketing options, including using our internal resources, partnering with others, or out-licensing the product.

In February 2021 and September 2021, Klisyri® was launched in the U.S. and in Europe, respectively, for the treatment of AK by our partner Almirall. As of December 31, 2021, Klisyri® is available to patients in the U.S., Germany, United Kingdom, and Austria. In 2022, Almirall plans to continue to rollout the launch of Klisyri® throughout Europe. To increase the global reach of tirbanibulin 1% ointment, we have partnered with other third parties and anticipate commercialization efforts outside of the U.S. and E.U. to commence in 2023. For additional information, please see "*Business—License and Collaboration Agreements—Tirbanibulin—Almirall License Agreement*." We may also partner with third parties or consider using our internal resources to reach other geographic markets.

Our Commercial Platform

Our Commercial Platform includes our specialty pharmaceuticals business, and our manufacture and marketing of products subject to Section 503B of the Federal Food, Drug & Cosmetic Act ("FDCA").

Specialty Pharmaceuticals

Our Athenex Pharmaceutical Division ("APD") business develops and sources products through licensing agreements with various partners, whom we collectively refer to as our Global Partner network. Our team has unique commercial expertise in multisource injectable products and has developed a number of Global Partners that develop and manufacture multisource products for the U.S. market. We primarily market products to acute hospital group purchasing organizations, which supply to integrated healthcare networks ("IHNs"), clinics, and directly to physicians. As of December 31, 2021, APD markets 29 molecules with 54 SKUs. In addition, Athenex Pharma Solutions ("APS") markets 5 products with 16 SKUs as of December 31, 2021.

Agreements with Suppliers and Marketing Partners

Gland Term Sheets

From August 2016 to May 2017, we entered into four binding term sheets with Gland Pharma Ltd ("Gland") to market twenty-seven of Gland's products. Gland has obtained FDA approval for twenty-two of such products and has filed an abbreviated new drug application, or ANDA, in the U.S. for the remaining five products. For each of the licensed products, we will pay a license fee to Gland. Additionally, during the terms of the term sheets we have a profit-sharing arrangement pursuant to which we will pay to Gland between 0% and 60% of the net profits from sales of each of the licensed products, depending on the product. The initial term of each of the Gland term sheets is five years from the launch of each product licensed pursuant to the term sheet, subject to automatic renewal for additional two-year terms, unless terminated by either party upon provision to the other party at least 90 days' notice in advance of a renewal date. To date, none of the term sheets have been terminated.

MAIA Agreement

In December 2018, we entered into a distribution and supply agreement with MAIA Pharmaceuticals ("MAIA") effective as of October 3, 2018 whereby we acquired the exclusive license to a generic version of an approved product, which we began selling in January 2019. In connection with the execution of this agreement, we agreed to pay an upfront milestone payment in addition to profit sharing of 50% of the net profits from the sales of the licensed product. We also agreed to pay an additional milestone payment to MAIA in the event the FDA approves the ANDA for the licensed product. The initial term of the agreement is for seven years from the launch of the product and is subject to an automatic two-year renewal term unless terminated by either party upon at least 180 days' notice in advance of the renewal date.

In December 2019, the agreement with MAIA was amended to grant us the license to a branded product which MAIA holds the approved NDA. In connection with this amendment, we agreed to an upfront milestone payment and 56% of the net profits from sales

of the licensed product. Additionally, we agreed to increase MAIA's share of the net profits to 70% for both products until certain financial metrics are achieved and shall revert to the initial rates after those metrics are satisfied.

Ingenus Agreements

In September 2020, we entered into an asset purchase and sale agreement with Ingenus Pharmaceuticals, LLC ("Ingenus") whereby we purchased from Ingenus all of their right, title and interest in and to Glycopyrrolate Injection ("Glycopyrrolate") in the U.S. for $2 million and pursuant to which Ingenus transferred to us the ANDA for Glycopyrrolate.

In November 2020, we entered into a co-marketing, manufacturing and supply agreement with Ingenus pursuant to which Ingenus will be our exclusive supplier of the Cyclophosphamide Injection and granted us a license to market and sell the product to acute care group purchasing organizations (GPOs) and their entire memberships as provided by said GPOs, integrated delivery networks (IDNs) and to hospitals within the U.S. for a purchase price of $1 million. Under the agreement, we are entitled to 25% of the net profits from our sales of the product and we are entitled to a marketing allowance. The agreement has a 3-year term, which may be extended if we mutually agree.

In January 2021, we entered into a manufacture and supply agreement with Ingenus for Arsenic Trioxide Injection pursuant to which Ingenus will be our exclusive supplier of the product and granted us a license to market and sell the product to acute care GPOs and their entire memberships as provided by said GPOs, IDNs and to hospitals within the U.S. Under the agreement, we are entitled to 45% of the net profits from our sales of the product and we are entitled to a marketing allowance. The agreement has a 5-year term, which may be extended if we mutually agree.

Customers and Product Distribution

We distribute APD products primarily through pharmaceutical wholesalers and, to a lesser extent, specialty distributors that focus on particular therapeutic product categories, for use by a wide variety of end-users, including hospitals, integrated delivery networks and alternative site facilities. For the year ended December 31, 2021, the products we sold through our three largest wholesalers in the U.S., accounted for 49% of our total revenue.

We utilize an outside third-party logistics contractor to distribute our U.S. products. Since the inception of the launch of our specialty products, the third-party logistics provider has been handling all aspects of our product logistics efforts and related services for us, including warehousing and shipment services, order-to-cash services, contract administration services and chargeback processing. Our products are warehoused and distributed through a third-party logistics provider located in Memphis, Tennessee. Under our agreement with the third-party logistics provider, we maintain ownership of our finished products until sale to our customers. The initial term of the agreement is three years following the initial delivery date and will automatically renew for successive 12-month periods, unless either we or the other party give notice of intent to terminate at least 90 days in advance of such automatic renewal. We may also have the opportunity to terminate the agreement within 30 days of receiving notice of certain price increases by the third-party logistics provider. The agreement also contains customary termination rights for either party, such as in the event of a breach of the agreement.

We have also created a product portal, which allows APD and APS customers in each class to order from us online, and us to distribute directly from our manufacturing facilities. This portal was created primarily due to prohibitions on wholesaling, under Section 503B.

Global Supply Chain Platform

In 2015, we acquired Polymed Therapeutics Inc. ("Polymed") and Chongqing Taihao Pharmaceutical Co. Ltd., or Taihao. Taihao operates a cGMP high potency oncology API plant based in Chongqing, China ("Taihao API facility") and Polymed is the U.S. marketing entity for Taihao's API in North America and Europe.

We suspended production activities at our Taihao API facility in Chongqing, China, in May 2019, based on concerns raised by the Department of Emergency Management of Chongqing ("DEMC") related to the location of our plant. We subsequently resumed producing API at the Taihao API facility primarily for our ongoing clinical studies and commercial launches of proprietary drugs in accordance with local regulatory guidance, while we started building out Sintaho, a new API facility in Chongqing. In July 2021, we received verbal notice from the DEMC that we will be required to terminate the production activities at its Taihao API facility. We are continuing to engage in dialogue with the DEMC. While we are able to continue producing certain API at the Taihao API facility in limited quantities and a certain extent of our operations are now being conducted at Sintaho, we are in the process of moving the remainder of the operations and production activities to Sintaho and exploring other sources of API, in the event we are unable to reach an agreement with the DEMC for the continued production activities of the Taihao API facility.

A new API manufacturing facility in Chongqing, China ("New API Facility" or the "Sintaho facility") was constructed and commenced operations. The facility continues to conduct and complete product qualification activities.

In 2014, we acquired APS (formerly known as QuaDPharma, LLC), one of our suppliers based in Clarence, New York.

Strategic Public-Private Partnerships

To date, we have utilized a combination of acquisitions and public-private partnerships to internalize certain key components of our manufacturing and supply chain.

China Partnership

In October 2015, we entered into an agreement with Chongqing Maliu Riverside Development and Investment Co., LTD ("CQ"), which is wholly owned by the Finance Bureau of Banan district of Chongqing, and is authorized to be responsible for investments, financing, infrastructure construction, operations and management in the Chongqing Maliu Riverside Development Zone. Our agreement with CQ provides for the construction of an API plant and a formulation plant in China. After entering into the agreement, and pursuant to its terms, we established a China-based subsidiary that is responsible for the operations of both facilities in July 2016 and committed to a registration capital requirement of no less than $30.0 million. CQ is responsible for the construction of both facilities according to the U.S. cGMP standards. The land and buildings will be owned by CQ, and we will lease the facilities rent-free, for the first 10-year term, with an option to extend the lease for an additional 10-year term, during which, if we are profitable, we will pay a monthly rent of 5 Chinese Renminbi ("RMB") per square meter of space occupied. We are responsible for the costs of all equipment and technology for the facilities. In January 2021, we accepted the building and the lease became effective. We have finished equipment installation and testing, and commenced production. We have also committed to achieving certain operational, revenue and tax generation milestones within certain time periods once we commence operations. If we are unable to achieve these milestones, CQ will have the opportunity to terminate the agreement and dispose of the plants in its discretion.

The New API Facility commenced operations in January 2021 and is part of our strategy for vertical integration in order to capture value across the supply chain.

Our goal is to use our public-private partnerships as a capital efficient method for large scale cGMP manufacturing within our supply chain and to facilitate market access in China. We believe those facilities will be adequate and suitable for our operations for the foreseeable future.

New York State Partnership

On February 14, 2022, we completed the sale of our leasehold interest, and certain other related assets, in the new manufacturing facility in Dunkirk, New York (the "Dunkirk Facility") to ImmunityBio, Inc. ("ImmunityBio") for approximately $40.0 million. The Dunkirk Facility had been constructed in connection with our agreement with Fort Schuyler Management Corporation ("FSMC") a not-for-profit corporation affiliated with the State of New York, for a medical technology research, development, innovation and commercialization alliance (the "Alliance Agreement"). Under the Alliance Agreement, FSMC had been responsible for the costs of construction and equipment for the facility up to an aggregate of $200.0 million, plus any additional funds available from the previous $25.0 million grant, and FSMC would retain ownership of the facility and equipment. In a series of agreements with ImmunityBio, we sold our leasehold interest, our interest in certain leased manufacturing equipment and personal property and owned personal property and inventory at the Dunkirk Facility, and our rights in and obligations under our agreements relating to the Dunkirk Facility with the Empire State Development Corporation ("ESD"), FSMC and County of Chautauqua Industrial Development Agency ("CCIDA") and other parties.

Under the original Alliance Agreement, we had been committed to spending $1.52 billion on operational expenses in the first 10-year term of the Dunkirk Facility and any subsequent extension periods and to hiring 450 employees at our Dunkirk Facility within the first five years of operations, including hiring at least 300 new employees within 2.5 years of the Dunkirk Facility becoming operational. ImmunityBio assumed these capital expenditure and hiring obligations of ours in connection with the purchase of the leasehold interest in the Dunkirk Facility.

We also entered into a preliminary agreement with ImmunityBio, pursuant to which our APS division will have the ability to manufacture our 503B products at the Dunkirk Facility at prices to be determined on a product-by-product basis, provided that the pricing will not exceed ImmunityBio's costs plus a 15% margin. We expect to enter into a definitive preferred contract manufacturing agreement with ImmunityBio relating to the manufacture of our 503B products.

We did not assign any of our rights to our corporate headquarters in Buffalo, New York, in connection with the sale of the leasehold interest in the Dunkirk Facility and we retained all of our rights and obligations with respect to our corporate headquarters. Under the Alliance Agreement, FSMC agreed to pay up to $25.0 million for the construction of our North American headquarters and formulation lab and equipment in Buffalo, New York. We are sub-leasing the space from FSMC for a 10-year term expiring in October 2025, with an option to extend the term for an additional 10 years. Under the Alliance Agreement, we are obligated to spend $100.0 million in the Buffalo area over the initial 10-year term of the lease and an additional $100.0 million during the second 10-year term if we elect to extend the lease. We also committed to hiring 250 permanent employees in the Buffalo area within the first 5 years of completion of the project. As of December 31, 2021, we had hired 211 permanent employees in the Buffalo area. In the event we

are unable to hire enough employees in the Buffalo area or meet our other obligations under this agreement, FSMC may terminate the agreement and we may have to renegotiate our lease or relocate our North American headquarters.

License and Collaboration Agreements

Cell Therapy

Baylor College of Medicine Agreements

In October 2021, we simultaneously entered into the Second Amended and Restated Exclusive License and Option Agreement (the "Baylor License Agreement") and the Second Amended and Restated Co-Development Agreement (the "Baylor Co-Development Agreement," and together with the Baylor License Agreement, the "Baylor Agreements") with BCM, which were first entered into in 2016 between BCM and Kuur. Under the Baylor Co-Development Agreement, BCM is responsible for developing the cell therapy products using an annual budget paid by us and under the supervision of a joint steering committee composed of five BCM appointees and five of our appointees. The Baylor License Agreement grants us, among other rights, worldwide rights to research, sell, and commercialize NKT, NKT-CAR, and NKT process technology in the prevention, treatment, or modulation of cancer in humans as well as exclusive future oncology and non-oncology and field expansion options. The Baylor Agreements include execution fees, annual fees, royalties, and milestones. Under the Baylor License Agreement, we have agreed to pay BCM up to $128.5 million in the event defined development and sales milestones are achieved, along with tiered royalties at single digit rates based on annual net sales of licensed products and tiered percentages of sublicensing revenue ranging from mid-single digits to royalty rates in the mid-teens. The Baylor Agreements will remain in effect on a country-by-country basis until the expiration of (i) the date of expiration of the last such patent rights issued in such country; or (ii) in the event that no patents issue in such country, the day immediately following the tenth anniversary of the first commercial sale in such country. The agreements contain customary termination rights such as for material default or failure, insolvency, or convenience on a product-by-product basis.

TCR-T License Agreement

In June 2018, we entered into a Share Subscription Agreement with Xiangxue Life Sciences Ltd. ("XLifeSc"), a subsidiary of Xiangxue, to establish, operate and manage a joint venture named Axis Therapeutics Limited ("Axis") to offer certain goods and services worldwide except in China. Axis is owned 45% by XLifeSc and 55% by us.

Also in June 2018, Axis entered into a license agreement with XLifeSc (the "TCR-T License") where XLifeSc granted Axis an exclusive, sublicensable right and license to use XlifeSc's proprietary TCR-T to develop and commercialize therapeutic products for oncology indications worldwide except in China. Axis is responsible for all development, manufacturing and commercialization, and the related costs and expenses, of any product candidates resulting from the agreement. Pursuant to the TCR-T License, following an upfront payment and the achievement of the first regulatory milestone, Axis may be required to make additional cash payments to XLifeSc worth up to $108.0 million in the aggregate upon the occurrence of certain additional regulatory milestones to be achieved in the U.S., the EU, China, and Japan. In addition, XLifeSc is required to pay Axis royalty payments based on certain percentage of aggregate net income generated by sales of any products using the licensed intellectual property in China. The TCR-T License will remain in effect until the expiration of the patent rights licensed under the agreement. The agreement will terminate automatically if the shareholders agreement between XLifeSc and us is terminated. The TCR-T License also contains customary termination rights for either party, such as in the event of a breach of the agreement or the initiation of bankruptcy proceedings by the other party.

Orascovery

Eli Lilly and Company Agreement

In October 2016, we entered into a Clinical Trial Collaboration and Supply Agreement with Eli Lilly and Company ("Lilly") to jointly conduct a Phase 1b trial of Oral Paclitaxel in combination with Ramucirumab in patients with gastric, gastro-esophageal, and esophageal cancers. Under the terms of the agreement, we are the sponsor of the study and hold the study IND/clinical trial application ("CTA") while all clinical data generated under the study will is jointly owned by us and Lilly. The agreement will remain in effect until the study contemplated by the agreement has been completed. The agreement also contains customary termination rights for either party, such as in the event of a breach of the agreement by the other party, or in the event a regulatory authority takes any action against or raises any objection to the study.

Quantum Leap Healthcare Collaborative

In September 2020, we announced with Quantum Leap, the launch of two new study arms of the I-SPY 2 TRIAL, to evaluate the safety and efficacy of Oral Paclitaxel with dostarlimab +/- carboplatin in stage 2/3 HER2- breast cancer patients and plus trastuzumab in HER2+ patients, followed, if needed, by doxorubicin plus cyclophasamide chemotherapy (AC) and surgical resection of breast tissue.

The trial was designed to rapidly screen promising experimental treatments and identify those most effective in specific patient subgroups based on molecular characteristics (biomarker signatures). The trial is a unique collaborative effort by a consortium that includes the FDA, industry, patient advocates, philanthropic sponsors, and clinicians from 16 major U.S. cancer research centers. Under the terms of the collaboration agreement, Quantum Leap is the trial sponsor and manages all study operations, and Athenex provides Oral Paclitaxel.

Hanmi License Agreements and Related Out-Licenses

We entered into a series of license agreements, as amended from time to time, with Hanmi Pharmaceuticals Ltd. ("Hanmi") pursuant to which we obtained an exclusive, sublicensable license for development and commercialization activities utilizing Hanmi's patents and know-how related to the Orascovery platform worldwide except in South Korea, and a non-exclusive license to utilize the same intellectual property in manufacturing worldwide for sales inside those territories (the "Hanmi Agreements"). Under the Hanmi Agreements, we are responsible for all clinical studies and development and commercialization activities, and the related expenses, resulting from the agreements.

Under the Hanmi Agreements, we are obligated to pay Hanmi tiered royalty payments in the teens based on aggregate net sales of any products using the licensed intellectual property in the territory. These royalties will be reduced if competing generic products gain market share in the applicable country. We also granted to Hanmi a one-time right of first negotiation to purchase all of our rights in Oral Paclitaxel or Oral Irinotecan under the Hanmi Agreements during development and prior that, at Hanmi's discretion, requires us to negotiate in good faith the sale of our rights under such agreement to Hanmi at a purchase price determined by an internationally-recognized investment banking firm with an office in Hong Kong at any time prior to the earlier of (1) our first commercial sale of products using such technology or (2) receipt by Hanmi of written notice from our company of the sublicense of the rights in an applicable product to a third party.

The Hanmi Agreements expire on the earlier of (1) expiration of the last of Hanmi's patent rights licensed under the agreement or (2) invalidation of Hanmi's patent rights which are the subject of the agreement, provided that the term will automatically be extended for consecutive one-year periods unless either party gives notice to the other at least 90 days prior to expiration of the patent rights licensed under the agreement or before the then-current annual expiration date of the agreement. The patent rights licensed to us under the Hanmi Agreements have expiry dates ranging from in 2023 to 2033, unless the terms of such licensed patents are extended in accordance with applicable laws and regulations.

We have out-licensed certain of the rights we obtained under the Hanmi Agreements to third parties to develop and commercialize products from the Orascovery platform in certain territories. Under these out-licenses, we are entitled to receive payments and royalties from the licensees, (a portion of which we will be obligated to pay Hanmi under the Hanmi Agreements). These out-license agreements are described below:

- ZenRx: We granted ZenRx an exclusive, sublicensable license to develop and commercialize Oral Irinotecan and Oral Paclitaxel in Australia and New Zealand in April 2013, and a non-exclusive license to manufacture a certain compound for use only in Oral Irinotecan and Oral Paclitaxel. We may be entitled to receive up to an aggregate of $1.25 million in additional development, regulatory and sales milestone payments under the license agreement with ZenRx. We will also be eligible to receive tiered royalties in the teens on net sales of each product commercialized by ZenRx utilizing the intellectual property that is the subject of the ZenRx License. Such royalties will be reduced by 40% when competing generic products have 30% of the market share in the applicable country and will be eliminated entirely when competing generic products have 60% of the market share in the applicable country. As an incentive to ZenRx to further development and commercialization of Oral Irinotecan and Oral Paclitaxel in the territory, if ZenRx obtains certain regulatory approvals in the territory prior to regulatory approval of those products in either the U.S. or South Korea, we may be required to make payments to ZenRx, at ZenRx's option, either up to $0.6 million in cash or $0.35 million in cash plus $0.25 million worth of our common stock.
- PharmaEssentia: We granted PharmaEssentia an exclusive, sublicensable license for development and commercialization of Oral Paclitaxel, Oral Irinotecan, and Oral Docetaxel in Taiwan and Singapore pursuant to a license agreement in December 2013, as amended from time to time. We may be entitled to receive up to an aggregate of $7.5 million in additional development, regulatory and sales milestone payments under this license agreement with PharmaEssentia. We may be obligated to pay PharmaEssentia an aggregate of $0.5 million in incentives if PharmaEssentia achieves certain milestones within designated timeframes. We will also be eligible to receive tiered royalties in the mid-teens on net sales of each product commercialized by PharmaEssentia utilizing the intellectual property that is the subject of this agreement. Such royalties will be reduced by 40% when competing generic products have 30% of the market share in the applicable country and will be eliminated entirely when competing generic products have 60% of the market share in the applicable country.
- Xiangxue: We granted Xiangxue an exclusive license to develop and commercialize Oral Paclitaxel, Oral Irinotecan and tirbanibulin ointment in China, Hong Kong, and Macau for any oncological indications as well as other indications that

we mutually agree to pursue (the "Xiangxue License"). We may be eligible to receive future additional payments up to $138.5 million in the event defined regulatory and sales milestones are achieved, a payment of $20.0 million in the event of a change of control or assignment of rights involving Xiangxue, tiered royalties at rates ranging from the low teens to low twenties based on annual net sales of the licensed products in the territory covered by the license, and a percentage of sublicensing revenue. In November 2021, we regained the exclusive rights to develop and commercialize Oral Paclitaxel, Oral Irinotecan, and tirbanibulin ointment for Hong Kong and Macau for $1.5 million. Before the November 2021 amendment to the license agreement, we recognized revenue in the third quarter of 2020 for a $10.0 million milestone fee from Xiangxue upon meeting the first regulatory milestone under the license agreement, but Xiangxue was unable to make the full payment. We received $1.5 million from Xiangxue in February 2021. Consequently, the Company recorded a provision for the outstanding balance of $8.5 million and $0.4 million related to currency conversion in our financial statements for the three months and year ended December 31, 2020, respectively. We have not yet taken legal action against Xiangxue to enforce the provisions of the license, but we may exercise all rights and remedies available to us under the terms of the license and applicable law at any time.

Tirbanibulin

Almirall License Agreement

In December 2017, we entered into a license agreement with Almirall pursuant to which we granted to Almirall an exclusive, sublicensable license of certain of our intellectual property for the development and commercialization of pharmaceutical preparations containing tirbanibulin to treat and prevent skin disorders and diseases in humans in the U.S. and substantially all European countries (including Russia and Turkey). The first label indication is actinic keratosis. In the licensed territory, Almirall also holds a right of first negotiation to license any compound that we may develop in the future with the same mechanism of action as tirbanibulin and for topical administration for the treatment of skin disorders and diseases if we decide to collaborate with a third party regarding that newly developed compound.

Following the receipt of $50.0 million from Almirall in upfront and milestone payments, we may also be entitled to receive an aggregate of $70.0 million in additional milestone payments, as well as sales milestone payments that we estimate will likely total $155.0 million. Almirall will reward Athenex with additional sales milestones should the sales exceed the currently projected amounts. In addition, we are eligible to receive tiered royalty payments for a certain period starting at 15% based on annual net sales of the topical products commercialized by Almirall, utilizing the intellectual property subject to the license agreement, with incremental increases in royalty rates commensurate with increased sales. We may be required to reimburse Almirall in the event Almirall provides notice that certain clinical endpoints under the agreement are not met. Almirall may terminate the agreement in its entirety or with regard to a certain territory in its sole discretion by providing six months' notice to us. The agreement also contains customary termination rights for both parties, such as in the event of a breach of the agreement or if the other party defaults in performance of its obligations under the agreement.

Other Territories

In 2021, we entered into licensing agreements with strategic partners such as Seqirus and AVIR, to further the global development and commercialization of products containing tirbanibulin for topical administration. We granted Seqirus an exclusive license to commercialize tirbanibulin in Australia and New Zealand. We granted AVIR an exclusive license to commercialize tirbanibulin in Canada.

We granted PharmaEssentia an exclusive, sublicensable license to use any pharmaceutical preparation containing tirbanibulin for use in treating (i) AK in a territory that includes Taiwan, Japan, and South Korea, (ii) psoriasis and other nonmalignant skin conditions in a territory that includes Taiwan, Japan, South Korea, China, Hong Kong, Macau, Singapore, and Malaysia, and (iii) all other dermatology indications, including skin cancer, in a territory that includes Taiwan, Japan, South Korea, Singapore, and Malaysia. We may be entitled to an aggregate of up to $14.6 million in associated with the achievement of certain development and sales milestones, $0.25 million of which may be paid in the form of PharmaEssentia stock. We will also be eligible to receive tiered royalties ranging from the high single-digits to teens on net sales of each product commercialized by PharmaEssentia, which may be reduced accordingly upon the entrance of competing generic products. Prior to the expiration of the term of each agreement, PharmaEssentia may terminate the agreement in its sole discretion, by providing six months' notice to us. Subject to certain conditions, we may also terminate the agreement if PharmaEssentia fails to comply with certain development timelines set out in each of the agreements. The agreements also contain customary termination rights for either party, such as in the event of a breach of the agreement or the initiation of bankruptcy proceedings by the other party.

We granted Xiangxue an exclusive license to develop and commercialize ointment preparations of tirbanibulin ointment for certain indications, including actinic keratosis, for China, Hong Kong, and Macau. In November 2021, we regained the exclusive rights to develop and commercialize Oral Paclitaxel, Oral Irinotecan, and tirbanibulin ointment for Hong Kong and Macau for $1.5 million. We may be eligible to receive $40.0 million if the defined regulatory milestones are achieved, sales milestones up to $30.0

million when certain sales targets of tirbanibulin ointment among other products are met, and tiered royalties at rates starting from the low teens. The license may be terminated in its entirety upon the mutual agreement of the parties, by Xiangxue for convenience upon requisite notice, or by either party for material breach as set forth in the license. The license also will be terminated with respect to any licensed product for Xiangxue's failure to meet agreed upon regulatory milestones with respect to such licensed product.

Other Product Candidates

In June 2018, we entered into a license agreement with Avalon Polytom (HK) Ltd. ("Polytom"), an entity affiliated with Avalon Global Holdings Limited ("Avalon"), pursuant to which Polytom granted us an exclusive, sublicensable right and license to develop and commercialize products containing pegylated and cobalt-replaced arginase for the treatment of cancer in humans, apart from ophthalmic uses and use as eye drops, worldwide. Dr. Johnson Lau, our chief executive officer and chairman, and Dr. Manson Fok, one of our directors, collectively have a controlling interest in and serve on the board of directors of Avalon. Also in June 2018, we entered into a license and supply agreement with Avalon HepaPOC Limited ("HepaPOC"), an entity affiliated with Avalon, pursuant to which HepaPOC agreed to exclusively sell to us the meter and consumable strips that can be used to detect galactose concentrations in human blood and granted us an exclusive, sublicensable right and license to use and commercialize the meter and strips for conduct of liver function tests in humans taking our oncology drugs.

For KX2-361, in December 2011, we granted PharmaEssentia an exclusive, sublicensable license to use any pharmaceutical preparation containing KX2-361 for use in treating psoriasis or other non-malignant skin conditions in a territory that includes China, Taiwan, Macau, Hong Kong, Singapore, Malaysia, Japan and South Korea. In May 2012, we granted Xiangxue an exclusive, sublicensable license to use certain of our intellectual property to develop and commercialize products containing KX2-361 in all indications for brain tumors in China, Taiwan, Hong Kong, and Singapore.

Competition

The biopharmaceutical industry and the oncology subsector are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our product candidates, platforms and scientific expertise in the field of biotechnology and oncology provide us with competitive advantages, a wide variety of institutions, including large biopharmaceutical companies, specialty biotechnology companies, academic research departments and public and private research institutions, are actively developing potentially competitive products and technologies. We face substantial competition from biotechnology and biopharmaceutical companies developing oncology products. These competitors and their products generally fall within the following categories:

Cell Therapy: Adicet, Allogene, Appia Bio, Atara, Autolus, Biotherapeutics, Cellectis, Celyad, Crispr, Cytovia, Fate Therapeutics, MiNK Therapeutics, Nkarta, ONK Therapeutics, Precision Biosciences, Poseida, and Senti Bio;

Oral administration: Taxol, Abraxane, Cynviloq, Camptosar, Onivyde, Taxotere and Hycamtin; and

Src Kinase inhibitors: Picato and Temodar.

Many of the companies, either alone or with strategic partners, against which we are competing or against which we may compete in the future have significantly greater financial, technical and human resources, and clinical, regulatory, commercialization and manufacturing capabilities than we do. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites and patient registration for clinical studies, acquiring technologies complementary to, or necessary for, our programs and for sales in the API business. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or less expensive than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of our products' entry. We believe the factors determining the success of our programs will be the efficacy, safety and convenience of our product candidates and our access to supply of API.

Intellectual Property

We strive to protect and enhance the proprietary technologies, inventions, products and product candidates, methods of manufacture, methods of using our products and product candidates, and improvements thereof that are commercially important to our business. We protect our proprietary intellectual property position by, among others, filing patent applications in the U.S. and in

jurisdictions outside of the U.S. covering our proprietary technologies, inventions, products and product candidates, methods, and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how, continuing innovation, and licensing opportunities to develop, strengthen and maintain our proprietary intellectual property position.

Granted patents and pending patent applications related to our platforms and product candidates cover such aspects as composition-of-matter claims to our lead product candidates and their analogs, claims to pharmaceutical compositions comprising such candidates, and claims to methods of making and method of treatment using such candidates. As of February 2, 2022, related to the Src Kinase inhibition platform, we owned approximately 200 granted patents and over 100 pending patent applications, including nine allowed patent applications worldwide. Not accounting for any patent term adjustment, patent term extension or terminal disclaimer, and, assuming that all annuity and/or maintenance fees are paid, the patents and, if granted, patent applications, will expire from 2025 to 2040.

In addition, we have in-licensed various patent, pending patent applications, and technologies. Notably, pursuant to our collaboration with the Center for Cell and Gene Therapy at BCM, in October 2021, we announced the allowance of the first U.S. patent related to our CAR-NKT cell therapy, including a composition-of-matter claim comprising a plurality of genetically modified CD62L-positive human NKT cells comprising at least one CAR. In November 2021, we licensed a portfolio of TCRs that recognize “hotspot” mutations in p53, KRAS, and EGFR genes and methods of isolating T-cells that are reactive to p53 and KRAS specific mutated antigens from the National Cancer Institute (NCI), an institute of the National Institutes of Health (NIH). We continue to maintain licenses for patents related to TCR T-cell therapy, the Orascovery platform, and PEGylation of arginases and their use as anti-cancer and anti-viral therapies.

The term of individual patents depends upon the laws of the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. In the U.S., the term of a patent may be lengthened by patent term adjustment to compensate the patentee for administrative delays by the U.S. Patent and Trade Office ("USPTO") in examining and granting the patent or may be shortened if the patent is terminally disclaimed over an earlier-filed patent. In addition, a patent term may be extended to restore a portion of the term effectively lost as a result of FDA regulatory review. However, the restoration period cannot be longer than five years and cannot extend the remaining term of a patent beyond a total of fourteen years from the date of FDA approval, and only one patent applicable to an approved drug may be extended. Similar extensions as compensation for regulatory delays are available in Europe and other jurisdictions. We have sought patent term extensions in the U.S. and Supplementary Protection Certificates in Europe and intend to seek similar regulatory extensions in other jurisdictions when available. However, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and we cannot predict the length of the extensions even if they are granted. The actual protection afforded by a patent varies on a claim-by-claim basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. For a granted patent to remain in force most countries require the payment of annuities or maintenance fees, either yearly or at certain intervals during the term of a patent. If an annuity or maintenance fee is not paid, the patent may lapse irrevocably.

Government Regulation and Product Approval

Governmental authorities in the U.S., at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, approval, quality control, labeling, packaging, promotion, storage, advertising, distribution, post-approval monitoring, marketing and export and import of products such as those we are developing. In order to be lawfully marketed in the U.S., our therapeutic drug candidates and compounded products must comply with either Section 503B (outsourcing facility) or Section 505 (new drug approval) of the FDCA as applicable, and they will be subject to similar premarket requirements in other countries. The process of obtaining regulatory approvals and ensuring compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

U.S. Government Regulation

In the U.S., the FDA regulates drugs under the FDCA and its implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development or approval process, or after approval, may subject an applicant to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning or untitled letters;
- seizures or administrative detention of product;

- total or partial suspension of production or distribution; or
- injunctions, fines, restitution, disgorgement, refusal of government contracts, or civil or criminal penalties.

NDA approval processes

The process required by the FDA before a therapeutic drug product may be marketed in the U.S. generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies conducted in accordance with GLPs and other applicable regulations;
- submission to the FDA of an IND application, which must be authorized before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with federal regulations and Good Clinical Practices, or GCPs, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors, to establish the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product candidate is produced to assess readiness for commercial manufacturing and conformance to the manufacturing-related elements of the application, to conduct a data integrity audit, and to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to assure the product candidate's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical or nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Such studies must generally be conducted in accordance with the FDA's GLPs. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND application. Some nonclinical testing may continue even after the IND application is submitted. In addition to including the results of the nonclinical studies, the IND application will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND application automatically becomes effective thirty days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND and may affect one or more specific studies or all studies conducted under the IND application. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and API imported into the U.S. are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the U.S. may be subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP requirements, which include, among other things, the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness endpoints to be evaluated. Each protocol, and any subsequent material amendment to the protocol, must be submitted to the FDA as part of the IND application, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must report to the FDA serious and unexpected adverse reactions in a timely manner. Reporting requirements also apply to, among other things, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure and any findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product candidate. An institutional review board, or IRB, with jurisdiction at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined.

- Phase 1—The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some therapeutic candidates for severe or life-threatening diseases, such as cancer, especially when the product candidate may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2—Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3—Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling.

A pivotal study is a clinical study that adequately meets regulatory agency requirements for the evaluation of a product candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are also Phase 3 studies but may be Phase 2 studies, with the agreement of FDA, if the trial design provides a reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need.

In the case of a 505(b)(2) NDA, which is a marketing application in which the sponsor may rely on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted, some of the above-described studies and nonclinical studies may not be required or may be abbreviated. The applicant may rely upon the FDA's prior findings of safety and efficacy for a previously approved product or on published scientific literature in support of its application. Bridging studies, including clinical studies, may be needed, however, to demonstrate that it is scientifically appropriate to rely on the findings of the studies that were previously conducted by other sponsors to the drug that is the subject of the marketing application.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

The outcome of human clinical trials is inherently uncertain, and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed or may not be completed at all. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

During the development of a new product candidate, sponsors are given opportunities to meet with the FDA at certain points; specifically, prior to the submission of an IND, at the end of Phase 2 and before an NDA application is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trials that they believe will support the approval of the new therapeutic. A sponsor may request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the product candidate was identified after the testing began.

Post-approval trials, sometimes referred to as "Phase 4" clinical trials, may be required after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and the manufacturer must develop methods for testing the quality, purity and potency of the product candidate. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its proposed shelf-life.

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests and other control mechanisms, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. An NDA must also contain data to assess the safety and effectiveness of the product for the claimed indication in all relevant pediatric populations. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for each prescription

drug. Fee waivers or reductions are available in certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation or where the applicant is a small business submitting its first human therapeutic application for review. Product candidates that are designated as orphan drugs are also not subject to user fees unless the application contains an indication other than an orphan indication.

Within sixty days following submission of an NDA, FDA reviews the application to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to accept any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA files it. Once the submission is filed, the FDA begins an in-depth substantive review of the NDA. The FDA has agreed to certain performance goals in the review of NDAs. FDA seeks to review NDAs for standard review products that are not new molecular entities, or NMEs, within ten months of the date the NDA is submitted, while FDA seeks to review NDAs for standard review NMEs within ten months of the date FDA files the NDA. FDA seeks to review NDAs for priority review products that are not NMEs within six months of the date the NDA is submitted, while FDA seeks to review NDAs for priority review NMEs within six months of the date FDA files the NDA. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, plan is necessary to assure the safe use of the product. If the FDA concludes that a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS plan prior to approval. The FDA has authority to require a REMS plan when necessary to ensure that the benefits of a drug outweigh the risks. In determining whether a REMS plan is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. A REMS plan may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the risks, limitations on who may prescribe or dispense the drug or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS plan must include a timetable to assess the strategy at eighteen months, three years and seven years after the strategy's approval.

The FDA may also require a REMS plan for a drug that is already on the market if it determines, based on new safety information, that a REMS plan is necessary to ensure that the product's benefits outweigh its risks.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are compliant with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA does not satisfy its regulatory criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than the applicant. If the agency decides not to approve the NDA in its then present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the NDA identified by the FDA, with no implication regarding the ultimate approvability of the application or the timing of any such approval, if ever. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant must either resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or appeal the decision.

Even if a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as "Phase 4" clinical trials, designed to further assess a drug's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, accelerated approval and breakthrough therapy designation, which are intended to expedite or simplify the process for reviewing therapeutic candidates, or provide for the approval of a product candidate on the basis of a surrogate endpoint. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will be lengthened. Generally, therapeutic candidates that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of therapeutic candidates to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give therapeutic candidates that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months of the date that FDA files the NDA as compared to a standard review time of ten months of the date that FDA files the NDA.

Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated product candidate and expedite review of the application for a product candidate designated for priority review. Under the Fast Track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. The Fast Track program and FDA's accelerated approval regulations, which are described in Subpart H of 21 CFR Part 314, provide for an earlier approval for a new product candidate that is (1) intended to treat a serious or life-threatening disease or condition; (2) generally provides a meaningful advantage over available therapies and (3) demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, and is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA will require that a sponsor of a product candidate receiving accelerated approval perform post-marketing studies to verify and describe the predicted effect on IMM or other clinical endpoint. The product may be subject to accelerated withdrawal procedures under certain circumstances.

In addition to the Fast Track, accelerated approval and priority review programs discussed above, a sponsor may seek a breakthrough therapy designation. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or conditions, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A breakthrough therapy designation conveys all of the Fast Track program features, as well as more intensive FDA guidance on an efficient drug development program and a commitment from FDA to involve senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review.

Abbreviated New Drug Applications for Generic Drugs and 505(b)(2)NDAs

NDA applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic or 505(b)(2) applicants in support of approval of an ANDA, or a 505(b)(2) application. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way can often be substituted by pharmacists under prescriptions written for the original listed drug. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness but where some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) applicant may be able to rely on published literature or on FDA's previous findings of safety and effectiveness for an approved drug. A 505(b)(2) NDA may be submitted for changes to a previously approved drug, including, for example, in the dosage form, route of administration, or indication.

The ANDA or 505(b)(2) applicant is required to make a certification to the FDA concerning any patents listed for the approved NDA product in the FDA's Orange Book. Specifically, the ANDA or 505(b)(2) applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA or 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the ANDA or 505(b)(2) product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) application has been received by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within forty-five days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of thirty months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA or 505(b)(2) application will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of fourteen years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND application and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that this review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, if available, we intend to apply for restorations of patent term for some of our currently owned patents beyond their current expiration dates, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA; however, there can be no assurance that any such extension will be granted to us.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA, submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA under 505(b)(1) of the FDCA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to therapeutic candidates intended to treat a rare disease or condition, which is generally a disease or condition that affects either (1) fewer than 200,000 individuals in the U.S., or (2) more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a product candidate for this type of disease or condition will be recovered from sales in the U.S. for that product candidate. Orphan Drug Designation must be requested before submitting an NDA. We have received Orphan Drug Designation for KX2-361 for the treatment of gliomas and Oral Paclitaxel for the treatment of angiosarcomas. After the FDA grants Orphan Drug Designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product candidate that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product candidate is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except under limited circumstances, for seven years. Orphan drug exclusivity, however, could also block the approval of one of our therapeutic candidates for seven years if a competitor obtains approval of the same drug for the same disease or condition as defined by the FDA or if our product candidate is determined to be

contained within the competitor's product candidate for the same indication or disease. Orphan drug exclusivity does not prevent FDA from approving the same drug for a different disease or a different drug for the same disease.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act (BPCA), certain therapeutic candidates may obtain an additional six months of exclusivity if the sponsor submits information requested in writing by the FDA, referred to as a Written Request, relating to the use of the active moiety of the product candidate in children. Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly responds to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied. If the FDA determines that information relating to the use of the new drug in the pediatric population may produce health benefits in the population, the clinical study is deemed to fairly respond to the FDA's request and the reports of FDA-requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection covering the product are extended by six months. In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for most therapeutic candidates, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product candidate is safe and effective. The FDA may grant a waiver or a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the product candidate is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. The law requires the FDA to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. It further requires the FDA to post the PREA Non-Compliance letter and sponsor's response.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product candidate reaches the market. Later discovery of previously unknown problems with a product candidate may result in restrictions on the product candidate or even complete withdrawal of the product candidate from the market. After approval, some types of changes to the approved product candidate, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval in a supplemental NDA, or sNDA. An sNDA must contain all of the information necessary to support the change. In the case of a new indication, that information usually consists of at least one clinical trial, and often more. Like an NDA, FDA determines whether the sNDA is sufficiently complete to permit review before it files the sNDA. FDA then reviews the sNDA. Like an NDA, FDA can either approve the sNDA or issue a complete response letter outlining the deficiencies in the sNDA. In addition, the FDA may under some circumstances require testing and surveillance programs to monitor the effect of approved therapeutic candidates that have been commercialized, and the FDA under some circumstances has the power to prevent or limit further marketing of a product candidate based on the results of these post-marketing programs.

Any therapeutic candidates manufactured or distributed pursuant to FDA approvals for prescription drugs are subject to continuing regulation by the FDA, including, among other things:

- reporting and record-keeping requirements;
- reporting of adverse experiences;
- providing the FDA with updated safety and efficacy information;
- product sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes and
- complying with FDA promotion and advertising requirements, which include, among other things, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in or consistent with the product's approved labeling, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet.

Therapeutic manufacturers and other entities involved in the manufacturing of approved therapeutic products are required to register their establishments with the FDA and obtain licenses in certain states and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws. The FDA periodically inspects manufacturing facilities

to assess compliance with cGMP, which imposes extensive procedural, substantive and record-keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations would also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers used. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed under certain limited circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. The government recently released a regulation and policy to expand and enhance the requirements related to registering and reporting the results of which may result in greater enforcement of these requirements in the future.

Regulation of Outsourcing Facilities

Pharmaceutical drug compounding is a practice in which a licensed pharmacist, a licensed physician, or in the case of an outsourcing facility, a person under the direct supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication. We are engaged in the compounding of sterile drugs as an outsourcing facility registered with FDA under FDCA Section 503B. Title I of the Drug Quality and Security Act, the Compounding Quality Act, or CQA, allows a facility that compounds sterile drugs to register with FDA as an outsourcing facility. Once registered (which includes payment of an annual fee, among other requirements), an outsourcing facility must meet certain conditions in order to be statutorily exempt from the FDCA's new drug approval requirements, the requirement to label products with adequate directions for use, and certain product tracing and serialization requirements. Under the CQA, a drug must be lawfully compounded in compliance with the provisions set forth in Section 503B including FDA's cGMP regulations and related cGMP guidance for outsourcing facilities in order to remain eligible for the statutory exemptions. The outsourcing facility must also bi-annually report specific information about the products that it compounds, including a list of all of the products it compounded during the previous six months pursuant to Section 503B(b)(2). The source of any bulk substance active ingredient used in compounding must be a Section 510-registered manufacturer, and the substances must be accompanied by a Certificate of Analysis. If the outsourcing facility compounds using bulk drug substances, the bulk drug substances must either appear on FDA's "interim" Category 1 list of bulk substances that may be used in compounding under Section 503B, which are bulk drug substances for which FDA has determined there is a clinical need for use in compounding. Drugs may also be compounded if an FDA-approved drug product appears on FDA's published drug shortage list.

FDA has not yet finalized its list of bulk drug substances for which there is a clinical need. Provided certain conditions are met, FDA will exercise enforcement discretion concerning interim Category 1 substances pending evaluation of the substances for inclusion on FDA's final list of bulk drug substances for which there is a clinical need.

In addition, an outsourcing facility must meet other conditions described in the CQA, including reporting adverse events pursuant to Section 503B(b)(5) of the FDCA, and labeling its compounded products with certain information pursuant to Section 503B(a)(10). Outsourcing facilities are prohibited from transferring or otherwise selling compounded drugs through a wholesale distributor, or from compounding drugs that are essentially copies of commercially available, FDA-approved drugs. Outsourcing facilities are subject to FDA inspection, and FDA conducts inspections on a risk-based frequency under Section 503B(b)(4).

Pharmaceutical Coverage, Reimbursement and Pricing

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval or compound. In the U.S., sales of any products for which we may compound or receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include managed care providers, private health insurers and other organizations as well as government payors such as Medicare, Medicaid, TRICARE and the Department of Veterans Affairs.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list or formulary which might not include all of the FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. However, under Medicare Part D—Medicare's outpatient prescription drug benefit—there are protections in place to ensure coverage and reimbursement for oncology products and all Part D prescription drug plans are required to cover substantially all anti-cancer agents. However, a payor's decision to provide coverage for a product

does not imply that an adequate reimbursement rate will be available. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our drug candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover an approved product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

Government Programs

Medicaid, the 340B Drug Pricing Program, and Medicare

Federal law requires that a pharmaceutical manufacturer, as a condition of having its products receive federal reimbursement under Medicaid and Medicare Part B, must pay rebates to state Medicaid programs for all units of its covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by a state Medicaid program under either a fee-for-service arrangement or through a managed care organization. This federal requirement is effectuated through a Medicaid drug rebate agreement between the manufacturer and the Secretary of Health and Human Services. The Centers for Medicare & Medicaid Services ("CMS") administers the Medicaid drug rebate agreements, which provide, among other things, that the drug manufacturer will pay rebates to each state Medicaid agency on a quarterly basis and report certain price information on a monthly and quarterly basis. The rebates are based on prices reported to CMS by manufacturers for their covered outpatient drugs. For innovator products, that is, drugs that are marketed under approved NDAs, the basic rebate amount is the greater of 23.1% of the average manufacturer price ("AMP") for the quarter or the difference between such AMP and the best price for that same quarter. The AMP is the weighted average of prices paid to the manufacturer (1) directly by retail community pharmacies and (2) by wholesalers for drugs distributed to retail community pharmacies. The best price is essentially the lowest price available to non-governmental entities. Innovator products are also subject to an additional rebate that is based on the amount, if any, by which the product's current AMP has increased over the baseline AMP, which is the AMP for the first full quarter after launch, adjusted for inflation. For non-innovator products, generally generic drugs marketed under approved abbreviated new drug applications, the basic rebate amount is 13% of the AMP for the quarter. Non-innovator products are also subject to an additional rebate. The additional rebate is similar to that discussed above for innovator products, except that the baseline AMP quarter is the fifth full quarter after launch (for non-innovator multiple source drugs launched on April 1, 2013 or later) or the third quarter of 2014 (for those launched before April 1, 2013). To date, the rebate amount for a drug has been capped at 100% of the AMP; however, effective January 1, 2024, this cap will be eliminated, which means that a manufacturer could pay a rebate amount on a unit of the drug that is greater than the average price the manufacturer receives for the drug.

The terms of participation in the Medicaid drug rebate program impose an obligation to correct the prices reported in previous quarters, as may be necessary. Any such corrections could result in additional or lesser rebate liability, depending on the direction of the correction. In addition to retroactive rebates, if a manufacturer were found to have knowingly submitted false information to the government, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

A manufacturer must also participate in a federal program known as the 340B drug pricing program in order for federal funds to be available to pay for the manufacturer's drugs under Medicaid and Medicare Part B. Under this program, the participating manufacturer agrees to charge certain federally funded clinics and safety net hospitals no more than an established discounted price for its covered outpatient drugs. The formula for determining the discounted price is defined by statute and is based on the AMP and the unit rebate amount as calculated under the Medicaid drug rebate program, discussed above. Manufacturers are required to report pricing information to the Health Resources and Services Administration ("HRSA") on a quarterly basis. HRSA has also issued regulations relating to the calculation of the ceiling price as well as imposition of civil monetary penalties for each instance of knowingly and intentionally overcharging a 340B covered entity.

Federal law also requires that manufacturers report data on a quarterly basis to CMS regarding the pricing of drugs that are separately reimbursable under Medicare Part B. These are generally drugs, such as injectable products, that are administered "incident to" a physician service and are not generally self-administered. The pricing information submitted by manufacturers is the basis for reimbursement to physicians and suppliers for drugs covered under Medicare Part B. As with the Medicaid drug rebate program, federal law provides for civil monetary penalties for failing to provide required information, late submission of required information, and false information.

Medicare Part D provides prescription drug benefits for seniors and people with disabilities. Medicare Part D beneficiaries had a gap in their coverage (between the initial coverage limit and the point at which catastrophic coverage begins) where Medicare did not cover their prescription drug costs, known as the coverage gap. However, by 2020, Medicare Part D beneficiaries will pay 25% of

drug costs after they reach the initial coverage limit - the same percentage they were responsible for before they reached that limit - thereby closing the coverage gap. Most of the cost of closing the coverage gap is being borne by innovator companies and the government through subsidies. Each manufacturer of a drug approved under an NDA is required to enter into a Medicare Part D coverage gap discount agreement and provide a 70% discount on those drugs dispensed to Medicare beneficiaries in the coverage gap, in order for its drugs to be reimbursed by Medicare Part D.

Federal Contracting/Pricing Requirements

Manufacturers are also required to make their covered drugs, which are generally drugs approved under NDAs, available to authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration. The law also requires manufacturers to offer deeply discounted FSS contract pricing for purchases of their covered drugs by the Department of Veterans Affairs, the Department of Defense ("DoD"), the Coast Guard, and the Public Health Service (including the Indian Health Service) in order for federal funding to be available for reimbursement or purchase of the manufacturer's drugs under certain federal programs. FSS pricing to those four federal agencies for covered drugs must be no more than the Federal Ceiling Price ("FCP"), which is at least 24% below the Non-Federal Average Manufacturer Price ("Non-FAMP") for the prior year. The Non-FAMP is the average price for covered drugs sold to wholesalers or other middlemen, net of any price reductions.

The accuracy of a manufacturer's reported Non-FAMPs, FCPs, or FSS contract prices may be audited by the government. Among the remedies available to the government for inaccuracies is recoupment of any overcharges to the four specified federal agencies based on those inaccuracies. If a manufacturer were found to have knowingly reported false prices, in addition to other penalties available to the government, the law provides for civil monetary penalties of $100,000 per incorrect item. Finally, manufacturers are required to disclose in FSS contract proposals all commercial pricing that is equal to or less than the proposed FSS pricing, and subsequent to award of an FSS contract, manufacturers are required to monitor certain commercial price reductions and extend commensurate price reductions to the government, under the terms of the FSS contract Price Reductions Clause. Among the remedies available to the government for any failure to properly disclose commercial pricing and/or to extend FSS contract price reductions is recoupment of any FSS overcharges that may result from such omissions.

Tricare Retail Pharmacy Network Program

The DoD provides pharmacy benefits to current and retired military service members and their families through the Tricare healthcare program. When a Tricare beneficiary obtains a prescription drug through a retail pharmacy, the DoD reimburses the pharmacy at the retail price for the drug rather than procuring it from the manufacturer at the discounted FCP discussed above. In order for the DoD to realize discounted prices for covered drugs (generally drugs approved under NDAs), federal law requires manufacturers to pay refunds on utilization of their covered drugs sold to Tricare beneficiaries through retail pharmacies in DoD's Tricare network. These refunds are generally the difference between the Non-FAMP and the FCP and are due on a quarterly basis. Absent an agreement from the manufacturer to provide such refunds, DoD will designate the manufacturer's products as Tier 3 (non-formulary) and require that beneficiaries obtain prior authorization in order for the products to be dispensed at a Tricare retail network pharmacy. However, refunds are due whether or not the manufacturer has entered into such an agreement.

Branded Pharmaceutical Fee

A branded pharmaceutical fee is imposed on manufacturers and importers of branded prescription drugs, generally drugs approved under NDAs. The fee is $2.8 billion in 2019 and subsequent years. This annual fee is apportioned among the participating companies based on each company's sales of qualifying products to or utilization by certain U.S. government programs during the preceding calendar year. The fee is not deductible for U.S. federal income tax purposes. Utilization of generic drugs, generally drugs approved under ANDAs, is not included in a manufacturer's sales used to calculate its portion of the fee.

The ACA

Effective in 2010, the Affordable Care Act ("ACA") made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits. CMS will expand Medicaid rebate liability to the territories of the U.S. as well, beginning in 2023, if the territories elect to enroll in the Medicaid Drug Rebate Program. In addition, the ACA provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by CMS may also provide for the public availability of pharmacy acquisition cost data, which could influence our decisions related to setting product prices and offering related discounts.

With regard to the 340B program, effective in 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing; although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication.

The adoption of government controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures, could also limit payments for pharmaceuticals.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Generic Drugs

Given that we manufacture and market generic drug products, our business may be impacted by laws and policies governing the coverage, pricing and reimbursement of generic drugs. Generic drugs are the same API as initial innovator medicines and are typically more affordable in comparison to the innovator's products. Sales of generic medicines have benefitted from policies encouraging generic substitution and a general increasing acceptance of generic drugs on the part of healthcare insurers, consumers, physicians and pharmacists. However, while the U.S. generics market is one of the largest in the world, the recent trend of rising generic drug prices has drawn scrutiny from the U.S. government. Specifically, generic drug pricing is the subject of Congressional inquiries and media attention, and many generic drug manufacturers are the targets of government investigations.

In addition, like branded drug manufacturers, generic drug manufacturers are now required to pay an inflation penalty if price increases on generic drugs exceed the rate of inflation.

Also, the ACA revised the methodology for setting Medicaid generic drug reimbursement in order to further limit the reimbursement of generic drugs under the Medicaid program. Specifically, the Federal Upper Limit ("FUL"), which establishes the government's maximum payment amount for certain generic drugs, is no less than 175% of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. Similarly, reimbursement for generic drugs is also limited in Medicare Part B, as the Average Sales Price (the metric upon which reimbursement is based or ASP) for multiple-source drugs included within the same multiple-source drug billing and payment code is the volume-weighted average of the various manufacturers' ASPs for those drug products.

Reimbursement for Compounded Drugs

Given that we intend to compound and sell compounded products, some of which may include APIs that we manufacture, our business may be impacted by the downstream coverage and reimbursement of compounded products. Generally, federal reimbursement is available for compounded drugs but is typically dependent upon whether the individual ingredients or bulk drug substances that make up the compounded product are FDA-approved. Certain of our API products have not yet received FDA approval.

There is a national payment policy for compounded drugs under Medicare Part B, but the policy is unclear because it does not stipulate whether payment is available for ingredients that are bulk drug substances, which are generally not FDA-approved. Under Medicare Part B, claims for compounded drugs are typically submitted using a billing code for "not otherwise classified drugs," and CMS contractors who process Part B claims may conduct further reviews of outpatient claims to determine whether the drug billed under a nonspecific billing code is a compounded drug and to identify its ingredients in order to make payment decisions. However, CMS contractors who process Part B claims do not always collect information on the FDA-approval status of drug ingredients, and, therefore, payment may be made for ingredients that are not FDA-approved products. Therefore, there is uncertainty as to whether Medicare payments for compounded drugs are consistent with the Medicare Part B policy.

Under Medicare Part D, federal payments are not available for non-FDA-approved products—including bulk drug substances—and inactive ingredients used to make a compounded drug. Insurers that offer Medicare Part D benefits and Part D-only sponsors, generally, pay pharmacies for each ingredient in the compounded drug that is an FDA-approved product and is otherwise eligible for reimbursement under Part D. However, with respect to non-FDA approved bulk drug substances, insurers that offer Medicare Part D benefits and Part D-only sponsors may choose to pay for such bulk substances but may not submit these payments as part of the Part D transaction data CMS uses to determine federal payments to Part D plans.

Healthcare Fraud and Abuse Laws and Compliance Requirements

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales and marketing programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration (a term interpreted broadly to include anything of value, including, for example, gifts, discounts, chargebacks, and credits), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other third-party payors that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money owed to the federal government;
- provisions of the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes, referred to as the "HIPAA All-Payor Fraud Prohibition," that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal transparency laws, including the federal Physician Payment Sunshine Act, which was part of the ACA, that require manufacturers of certain drugs and biologics to track and annually report payments and other transfers of value they make to U.S. physicians, physician assistants, certain types of advance care nurses, and teaching hospitals, as well as physician ownership and investment interests in the manufacturer, and that such information is subsequently made publicly available in a searchable format on a CMS website;
- provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state transparency reporting and compliance laws; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and which may not have the same effect, thus complicating compliance efforts.

The ACA broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the product. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. In addition, private individuals have the ability to bring actions under the federal False Claims Act, and certain states have enacted laws modeled after the federal False Claims Act.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing, marketing, coverage and reimbursement of products regulated by the FDA or other government agencies. In addition to new legislation, FDA and healthcare fraud and abuse and coverage and reimbursement regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. Most recently, the Tax Cuts and Jobs Act (the "Tax Reform Act") was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. On June 17, 2021, the United States Supreme Court dismissed a challenge to the constitutionality of the ACA on procedural grounds because the individual mandate was repealed by Congress. It is possible that there will be changes to the ACA in the future. Additional reforms could have an adverse effect on anticipated revenues from therapeutic candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop therapeutic candidates. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

Furthermore, in the U.S., the health care industry is subject to political, economic and regulatory influences. Initiatives to reduce the federal budget and debt and to reform health care coverage are increasing cost-containment efforts. We anticipate that federal agencies, Congress, state legislatures and the private sector will continue to review and assess alternative health care benefits, controls on health care spending, and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit coverage or the amounts that federal and state governments will pay for health care products and services, which could also result in reduced demand for our products or additional pricing pressures and limit or eliminate our spending on development projects and affect our ultimate profitability. We are not able to predict whether further legislative changes will be enacted or whether FDA or healthcare fraud and abuse or coverage and reimbursement regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act of 1977 ("FCPA") prohibits any U.S. individual or business from corruptly offering, paying, promising or authorizing the provision of anything of value, directly or indirectly, to any foreign official, foreign political party or official thereof, or candidate for foreign political office to obtain or retain business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring the issuer to maintain books and records that accurately and fairly reflect all transactions of the issuer and its controlled subsidiaries and to devise and maintain an adequate system of internal accounting controls.

Environment

We are subject to inspections by the FDA for compliance with cGMP and other U.S. regulatory requirements, including U.S. federal, state and local regulations regarding environmental protection and hazardous and controlled substance controls, among others. Environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We have incurred, and may continue to incur, significant expenditures to ensure that we are in compliance with these laws and regulations. We would be subject to significant penalties for failure to comply with these laws and regulations.

China Government Regulation

In the People's Republic of China ("PRC" or "China," for the purposes of this document only, except where the context requires otherwise, references to China or the PRC exclude the special administrative regions of Hong Kong and Macau and Taiwan), we operate in an increasingly complex legal and regulatory environment. We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the principal PRC laws, rules and regulations relevant to our business and operations.

Foreign Investment in Pharmaceutical Industry

Foreign investment in China was previously subject to the Catalogue for the Guidance of Foreign Investment Industries (2017 Revision) issued and effective beginning July 28, 2017, and the Special Administrative Measures for the Access of Foreign Investment (2018 Revision) (the "Negative List") issued and effective beginning July 28, 2018, which together comprised the encouraged foreign-invested industries catalogue and the special administrative measures for the access of foreign investments to the restricted or the prohibited foreign-invested industries. The latter set out restrictions such as percentage of shareholding and qualifications of senior management. The Catalogue of Industries in which Foreign Investment is Encouraged and the Negative List have been revised several times. The most updated Catalogue of Industries in which Foreign Investment is Encouraged revision was issued on December 27, 2020 (the "2020 Catalogue") and came into effect on January 27, 2021. The most updated Negative List was issued on December 27, 2021 (the "2021 Negative List") and took effect on January 1, 2022, which further reduced restrictions on foreign investment. The manufacturing and production of new anti-cancer drugs, new cardiovascular medicine and new nervous system drugs all fall within the field of industries in which foreign investment is encouraged in the 2020 Catalogue.

General Regulations on China Drug Administration

The pharmaceuticals industry in China is mainly regulated and administrated by the National Medical Products Administration (the "NMPA"), under the administration of the State Administration for Market Regulation (the "SAMR"), the National Health Commission (the "NHC") and the National Health Care Security Administration (the "NHSA"). Pursuant to the Decision of the First Session of the Thirteenth National People's Congress on the State Council of the PRC (the "State Council") Institutional Reform Proposal promulgated by the National People's Congress of the PRC on March 17, 2018, (1) the SAMR was established; and the China Food and Drug Administration (the "CFDA") ceased to exist, while the NMPA was established under the administration of the SAMR; (2) the National Health and Family Planning Commission ceased to exist, while the NHC shall be established as a department under the State Council, incorporating duties of supervision and management which had been assigned to relevant departments and (3) the NHSA was established as a bureau directly subordinate to the State Council.

The NMPA, which inherited the drug supervision function from its predecessor the CFDA, is the primary drug regulator responsible for almost all of the key stages of the life-cycle of pharmaceutical products, including preclinical research, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution and pharmacovigilance.

The PRC Drug Administration Law (the "PRC Drug Administration Law") promulgated by the Standing Committee of the National People's Congress in 1984 and the Implementing Measures of the PRC Drug Administration Law promulgated by the Ministry of Health, or the MOH, in 1989 set forth the legal framework for the administration of pharmaceutical products, including the research, development and manufacturing of drugs.

The PRC Drug Administration Law was revised in February 2001, December 2013, April 2015, and again in August 2019. The purpose of the revisions was to strengthen the supervision and administration of pharmaceutical products and to ensure the quality and safety of those products for human use. The revised PRC Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products. It regulates and prescribes a framework for the administration of pharmaceutical preparations of medical institutions and for the development, research, manufacturing, distribution, packaging, pricing and advertisement of pharmaceutical products. New Implementing Measures of the PRC Drug Administration Law promulgated by the State Council took effect in September 2002 and was revised in February 2016, and again in March 2019, providing detailed implementing regulations for the revised PRC Drug Administration Law.

The PRC Drug Administration Law was newly revised on August 26, 2019 and came into effect on December 1, 2019. As compared to the old law, the current revised PRC Drug Administration Law mainly includes the following key highlights:

- The supervision and administration of pharmaceutical products will be improved by emphasizing the responsibility of the enterprise, strengthening the management of drug production process and clarifying the traceability requirements of drug quality and safety;
- The responsibility for drug supervision will be clarified, and the supervision measures will be improved;
- The punishment of illegal behaviors will be aggravated by increasing the fine limit, strengthening the punishment for the relevant personnel of pharmaceutical production enterprises and supplementing the responsibility of the drug marketing authorization holder (the "MAH");
- The MAH system will be implemented, which will cause the MAH holder to undertake the responsibility of the safety and effectiveness of drugs and to bear legal responsibility during the whole process of development, production, management and use of drugs; and
- The drug approval system will be reformed, including the abolishment of the separation of GMP and GSP certification.

Under these regulations, we need to follow related regulations for preclinical research, clinical trials and production of new drugs.

On April 27, 2021, the General Office of the State Council published the Opinions on Comprehensively Strengthening Regulatory Capacity for Drugs. The Opinions introduced the general requirements and several key tasks and safeguards to improve regulations on drugs, including enhancing drug inspection capability and establishing a national pharmacovigilance system.

Good Laboratories Practice Certification for Preclinical Research

To improve the quality of preclinical research, the CFDA promulgated the Administrative Measures for Good Laboratories Practice of Preclinical Laboratory in 2003, which was revised in 2017, and began to conduct the certification program of GLP. In addition, the CFDA promulgated the Administrative Measures for the Certification of Good Laboratory Practices of Preclinical Laboratory in April 2007 which determines whether an institution is qualified for undertaking pharmaceutical preclinical research upon the evaluation of the institution's organizational administration, its research personnel, its equipment and facilities and its operation and management of preclinical pharmaceutical projects. If all requirements are met, a GLP Certification will be issued by the CFDA, and the result will be published on the CFDA's website.

Approval for Clinical Trials and Production of New Drugs

According to the Provisions for Drug Registration promulgated by the SAMR in January 2020, which abolished the old Provisions for Drug Registration promulgated by the CFDA in 2007, the PRC Drug Administration Law, the Provisions on the Administration of Special Examination and Approval of Registration of New Drugs, or the Special Examination and Approval Provisions issued by the CFDA in 2009 and the Circular on Information Publish Platform for Pharmaceutical Clinical Trials issued by the NMPA in 2013, we must comply with the following procedures and obtain several approvals for clinical trials and production of new drugs.

Clinical Trial Application

Upon completion of its preclinical research, a research institution must apply for approval of a CTA before conducting clinical trials. According to the Decision of the CFDA on Adjusting the Approval Procedures of the Administrative Approval Items for Certain Drugs promulgated by the CFDA on March 17, 2017, the decision on the approval of clinical trials of drugs enacted by the CFDA can be made by the Center for Drug Evaluation of the CFDA, or the CDE in the name of the CFDA from May 1, 2017. In July 2018, the NMPA promulgated the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs, which further adjusted for those who apply for drug clinical trials in China, and stipulated that if an applicant does not receive any negative or questioning opinions from the CDE within sixty days after the date of accepting the application and the payment of the fee, drug clinical trials may be conducted in accordance with the plan being submitted.

According to the Provisions for Drug Registration (2020 Revision), a drug clinical trial consists of Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. Pursuant to the characteristics of a drug and the research purpose, the research contents shall include clinical pharmacological research, exploratory clinical trial, confirmatory clinical trial and post-marketing research. Clinical trials must be conducted in accordance with the new Administrative Measures for Good Clinical Practice, which was promulgated by NMPA and NHC on April 23, 2020 and took effect on July 1, 2020, which also sets forth the requirements for conducting the clinical trial, including preparation of clinical trials, clinical trial protocol, duties of the sponsor and investigators and protection of the trial subjects. According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs issued by the NMPA on July 24, 2018, where the application for clinical trial of new drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for Communication Session to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol.

New Drug Application

According to the Provisions for Drug Registration (2020 Revision), upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes, and preparation for acceptance of verification and inspection for drug registration, the applicant may apply to the NMPA for approval of a new drug application. The NMPA then determines whether to approve the application according to the comprehensive evaluation opinion provided by the CDE of the NMPA. We must obtain approval of a new drug application before our drugs can be manufactured and sold in the Chinese market.

Drug Manufacturing Permit and Good Manufacturing Practice

Pursuant to the PRC Drug Administration Law and its implementing measures, a drug manufacturer must obtain a Drug Manufacturing Permit from the local branch of the NMPA at provincial level before it starts to manufacture drug products. Prior to granting such permit, the relevant government authority will inspect the applicant's production facilities, and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards. Each Drug Manufacturing Permit is valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date and will be subject to reassessment by the authority in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal. All facilities and techniques used in the manufacture of

products for clinical use or for sale in China must be operated in conformity with GMP guidelines as established by the MOH and CFDA. GMP certification was no longer required from December 2019 and regular and random onsite checking and supervision will be implemented by the relevant authority. Failure to comply with applicable requirements could result in the termination of manufacturing and significant fines. The NMPA promulgated the Administration Measures for Drug Inspection (for Trial Implementation) in May 2021, which provides details of the onsite checking and inspection procedures and requirements after GMP certification was abolished.

Animal Test Permits

According to Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission in November 1988, as revised in January 2011, July 2013, and March 2017, and Administrative Measures on the Certificate for Animal Experimentation (for Trial Implementation) promulgated by the State Science and Technology Commission and other regulatory authorities in December 2001, performing experimentation on animals requires a Certificate for Use of Laboratory Animals. Applicants must satisfy the following conditions:

- Laboratory animals must be qualified and sourced from institutions that have Certificates for Production of Laboratory Animals;
- The environment and facilities for the animals' living and propagating must meet state requirements;
- The animals' feed and water must meet state requirements;
- The animals' feeding and experimentation must be conducted by professionals, specialized and skilled workers or other trained personnel;
- The management systems must be effective and efficient; and
- The applicable entity must follow other requirements as stipulated by the PRC laws and regulations.

Drug Registration Classification and Special Examination and Approval

According to the Provisions for Drug Registration (2007 Revision), drug registration applications are divided into three different types, namely Domestic New Drug Application, Domestic Generic Drug Application and Imported Drug Application. Drugs fall into one of three categories, namely chemical medicine, biological product or traditional Chinese or natural medicine. The registrations of chemical medicines are divided into six categories, among which, a Category 1 drug is a new drug that has never been marketed in any country. However, the Provisions for Drug Registration (2020 Revision) stipulated that drug registration shall be classified into several categories including traditional Chinese drugs, chemical drugs and biological drugs. Among them, the registration applications of chemical drugs shall be categorized by innovative chemical drugs, modified new chemical drugs, generic chemical drugs, etc.

In March 2016, the CFDA promulgated the Work Plan for Reforming the Chemical Medicines Registration Classification System, under which, the registrations of chemical medicines are divided into five categories as follows:

Category 1: Innovative drugs that are not marketed both domestically and abroad. These drugs contain new compounds with clear structures and pharmacological effects, and they have clinical value.

Category 2: Modified new drugs that are not marketed both domestically and abroad. With known active components, the drug's structure, phase, prescription manufacturing process, administration route and indication are optimized, and it has obvious clinical advantage.

Category 3: The drugs that are imitated by domestic applicants to original drugs that have been marketed abroad but not domestically. These kinds of drugs are supposed to have the same quality and effects with original drugs. Original drugs are the foremost drugs that are approved to be marketed domestically and /or abroad with complete and full safety and validity data as marketing evidence.

Category 4: The drugs that are imitated by domestic applicants to original drugs that have been marketed domestically. These kinds of drugs are supposed to have the same quality and effects with original drugs.

Category 5: The drugs that have been marketed abroad are applied to be marketed domestically.

As a support policy and implementing rule of the Provisions for Drug Registration (2020 Revision), the NMPA issued the Chemical Drug Registration Classification and Application Data Requirements in June 2020, effective in July 2020, which reaffirmed the principles of the classification of chemical drugs set forth by the Work Plan for Reforming the Chemical Medicines Registration Classification System, and made minor adjustments to the subclassifications of Category 5. According to such regulation, Category 5.1 are innovative chemical drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China.

According to the Special Examination and Approval Provisions for New Drugs, the CFDA conducts special examination and approval for new drugs registration application when:

(1) active ingredients and their preparations extracted from plants, animals and minerals, and newly discovered medical materials and their preparations have not been marketed in China;

(2) the chemical raw material medicines as well as the preparations and biological products thereof have not been approved for marketing home and abroad

(3) the new drugs are for treating AIDS, malignant tumors and rare diseases, etc., and have obvious advantages in clinic treatment; or

(4) the new drugs are for treating diseases with no effective methods of treatment.

The Special Examination and Approval Provisions for New Drugs provide that the applicant may file for special examination and approval at the stage of Clinical Trial Application if the drug candidate falls within items (1) or (2), and for drug candidates that fall within items (3) or (4), the application for special examination and approval must be made when filing for production.

Adjustment on the Administration of Imported Drug Registration

On October 10, 2017, the CFDA promulgated the Decision on Adjusting Relevant Matters Concerning the Administration of Imported Drug Registration, effective as of the date of its promulgation, which stipulates that, among others, (1) simultaneous research and application are allowed, meaning that, in the case of a clinical trial concerning a drug subject thereto to be conducted at an international multi-center clinical trial ("IMCCT") in China, Phase 1 clinical trials of the drug are allowed simultaneously, and the requirement that the drug subject to the clinical trial need to have been previously registered overseas or to have entered a Phase 2 or Phase 3 clinical trial shall not apply, except for preventative biological products; (2) the drug registration procedure is to be optimized, meaning that, upon the completion of a clinical trial at an IMCCT in China, an applicant may directly file a drug registration application and (3) for a new chemical drug or an innovative therapeutic biological drug for which a clinical trial or market registration is made, in each case as an imported drug, the requirement that such drug has received an overseas license issued by the country or region where the drug's overseas pharmaceutical manufacturer is located shall not apply.

Changes to the Review and Approval Process

In August 2015, the State Council issued a statement, Opinions on Reforming the Review and Approval Process for Pharmaceutical Products and Medical Devices, which contained several potential policy changes that could benefit the pharmaceutical industry:

- A plan to accelerate innovative drug approval with a special review and approval process, with a focus on areas of high unmet medical needs, including drugs for HIV, cancer, serious infectious diseases, orphan diseases and drugs on national priority lists.
- A plan to adopt a policy which would allow companies to act as the marketing authorization holder and to hire contract manufacturing organizations to produce drug products.
- A plan to improve the review and approval of clinical trials, and to allow companies to conduct clinical trials at the same time as they are in other countries and encourage local clinical trial organizations to participate in international multi-center clinical trials.

In November 2015, the CFDA released the Circular Concerning Several Policies on Drug Registration Review and Approval, which further clarified the following policies potentially simplifying and accelerating the approval process of clinical trials:

- A one-time umbrella approval procedure allowing approval of all phases of a new drug's clinical trials at once, rather than the current phase-by-phase approval procedure, will be adopted for new drugs' CTAs.
- A fast track drug registration or clinical trial approval pathway will be available for the following applications: (1) registration of innovative new drugs treating HIV, cancer, serious infectious diseases and orphan diseases; (2) registration of pediatric drugs; (3) registration of geriatric drugs and drugs treating China-prevalent diseases; (4) registration of drugs sponsored by national science and technology grants; (5) registration of innovative drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (6) registration of foreign innovative drugs to be manufactured locally in China; (7) concurrent applications for new drug clinical trials which are already approved in the U.S. or EU, or concurrent drug registration applications for drugs which have applied for marketing authorization and passed onsite inspections in the U.S. or EU and are manufactured using the same production line in China and (8) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and marketing authorization applications for drugs with urgent clinical need and patent expiry within one year.

In March 2016, the CFDA issued the Interim Provisions on the Procedures for Drug Clinical Trial Data Verification that provides procedural rules for CFDA's on-site verification of clinical data before drug approvals.

Also, in February 2016, the CFDA published the Opinions on Implementing a Prioritized Review System to Avoid Drug Review Backlogs, which introduces a prioritized review and approval pathway to clinical trial applications and registration applications of certain drugs as part of CFDA's ongoing reform of its current drug review and approval system.

The CFDA issued the Procedures for Priority Examination and Approval of Medical Devices (Procedures) on October 25, 2016, which came into effect on January 1, 2017. The Procedures, composed of seventeen articles, specify that the priority in examination and approval shall be given, in relation to the applications of registering Class-III domestic, or Class-II and Class-III imported medical devices, when those applications fall within such categories as diagnosis or treatment of rare disease or malignant tumor with significant clinical advantage. According to the Procedures, the medical device technical evaluation center of the CFDA will tentatively decide on the applicants applying for their project given priority examination and approval, names of their products and the reception numbers and disclose such information on its website for a period of no less than five working days. The Procedures provide that for projects given priority in examination and approval, the medical device technical evaluation center shall communicate with applicants in an active way, as required by applicable provisions, in the course of evaluating relevant technologies and may arrange for special talks when necessary; food and drug administrative departments at provincial levels shall take the review of the registered quality management system of medical devices as priority and the CFDA will prioritize their administrative examination and approval.

In December 2017, the CFDA innovations promulgated the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug, which abolished the Opinions on Implementing a Prioritized Review System to Avoid Drug Review Backlogs. The CFDA would prioritize the examination and approval on applications of new drugs in particular cases, including (1) applications of new drugs with significant clinical value satisfying particular conditions; (2) applications of new drugs with significant clinical advantages preventing or treating particular diseases and (3) other particular conditions.

According to the Announcement on Optimizing the Evaluation and Approval of Drug Registration promulgated by the NMPA and the NHC in May 2018, the Chinese government seeks to further simplify and accelerated the clinical trial approval process.

The Provisions for Drug Registration (2020 Revision) has incorporated the previous reform in respect of the accelerated approval for clinical trial and drug marketing registration and introduces four procedures for expedited marketing registration of drugs, which are procedures for groundbreaking therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval, and procedures for special examination and approval:

- Procedures for ground-breaking therapeutic drugs: during the drug clinical trials, for an innovative drug or improved new drug used for prevention and treatment of life-threatening illnesses or illnesses which have a serious impact on quality of life and for which there is no other effective prevention and treatment method or there is adequate evidence to prove that the said innovative drug or modified new drug has obvious clinical advantages over existing treatment approach, the applicant may request for application of procedures for ground-breaking therapeutic drugs.
- Procedures for conditional approval: during the drug clinical trials, for drugs which fall under the following circumstances, an application for conditional approval of marketing registration may be submitted (i) for drugs for treatment of life threatening illnesses for which there is no effective treatment approach, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; (ii) for drugs urgently needed for public health, the clinical trial of drugs already has data to prove efficacy and is able to forecast the clinical value; and (iii) for other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed, its benefits outweigh the risks according to the evaluation.
- Procedures for prioritized reviews and approval: at the time of the drug marketing registration, drugs have obvious clinical value may apply for application of procedures for prioritized review and approval, including (i) clinically and urgently needed but insufficient drug, innovative drugs and modified new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pharmaceutical product types, dosage form and specifications of pediatric drugs which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drug included in the procedures for ground-breaking therapeutic drug; (v) drug which comply with conditional approval criteria; and (vi) other circumstances of prioritized review stipulated by the NMPA.
- Procedures for special examination and approval: at the time of a threat or occurrence of public health emergency, the NMPA may, in accordance with law, decide to implement special examination and approval for urgently needed drug required for the prevention and treatment during the public health emergency. Drug included in the special examination and approval procedures may, based on special needs of disease prevention and control, be restricted for use within a certain period and scope.

On July 7, 2020, the NMPA promulgated the Announcement on Promulgating Three Documents Including the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (for Trial Implementation) and Priority Review and Approval Procedures for Drug Marketing Authorizations (for Trial Implementation), which abolished the Opinions on Encouraging

the Prioritized Evaluation and Approval for Drug. According to the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (for Trial Implementation), sponsors of innovative drug candidates which exhibit clinical benefits for the treatment of life-threatening or other serious conditions for which there is no existing effective prevention and treatment method, or compared with existing treatment methods that have sufficient evidence to show that they have obvious clinical advantages, can apply for breakthrough therapeutic drug programs during Phase I and II clinical trials for such drug candidates. According to the Priority Review and Approval Procedures for Drug Marketing Authorizations (for Trial Implementation), an applicant for drug marketing authorization may apply for priority review and approval procedures for the following drugs with obvious clinical value: (I) drugs in urgent clinical demand and in shortage, innovative drugs and modified new drugs for prevention and treatment of serious infectious diseases, rare diseases and other diseases; (II) new varieties, dosage forms and specifications of children's drugs that conform to children's physiological characteristics; (III) vaccines and innovative vaccines that are in urgent need for disease prevention and control; (IV) drugs that have been included in the procedures for breakthrough therapy designation; (V) drugs that are subject to conditional approval; and (VI) other circumstances under which priority review and approval shall be provided for by the NMPA.

On November 15, 2021, the CDE of the NMPA issued the Guiding Principles for Clinical Research and Development of Oncology Drugs Oriented by Clinical Value, which emphasized the clinical value-oriented and patient-centered concept during the whole research and development process of oncology drugs.

PRC Enterprise Income Tax Law and Its Implementation

According to the new PRC Enterprise Income Tax Law (the "EIT Law"), effective from January 1, 2008, and amended on February 24, 2017 and December 29, 2018, a uniform income tax rate of 25% is applied equally to domestic enterprises as well as foreign investment enterprises and permit certain High and New Technologies Enterprises ("HNTEs") to enjoy preferential enterprise income tax rates subject to these HNTEs meeting certain qualification criteria.

The EIT Law and its implementation rules provide that a withholding tax at the rate of 10% is applicable to dividends and other distributions payable by a PRC resident enterprise to investors who are "non-resident enterprises" (that do not have an establishment or place of business in China, or that have such establishment or place of business but the relevant dividend or other distribution is not effectively connected with the establishment or place of business). However, pursuant to the Arrangement between the Mainland and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income effective on December 8, 2006, the withholding tax rate for dividends paid by a Chinese resident enterprise is 5% if the Hong Kong enterprise owns at least 25% of the capital of the Chinese enterprise; otherwise, the dividend withholding tax rate is 10%. According to the Notice of the State Taxation Administration of the PRC (the "STA") on Issues relating to the Administration of the Dividend Provision in Tax Treaties promulgated on February 20, 2009 and effective on the same day, the corporate recipient of dividends distributed by Chinese enterprises must satisfy the direct ownership thresholds at all times during the twelve consecutive months preceding the receipt of the dividends. The STA promulgated the Notice on Certain Issues of the "Beneficial Owner" in Tax Treaties on February 2, 2018. Pursuant to these regulations and the Administrative Measures for Treaty Treatment for Non-Resident Taxpayers promulgated by the STA in October 2019 and effective from January 1, 2020, non-resident enterprises are required to file information sheets to the competent tax authorities in order to enjoy the favorable treatments under the treaties. However, the relevant tax authorities may check and verify at their discretion, and if a company is deemed to be a pass-through entity rather than a qualified owner of benefits, it cannot enjoy the favorable tax treatments provided in the tax arrangement. In addition, if transactions or arrangements are deemed by the relevant tax authorities to be entered into mainly for the purpose of enjoying favorable tax treatments under the tax arrangement, such favorable tax treatments may be subject to adjustment by the relevant tax authorities in the future.

Pursuant to the Announcement on Continuation of Enterprise Income Tax Policies for Extensive Development in the Western Region issued by the Ministry of Finance (the "MOF"), the STA and the National Development and Reform Commission (the "NDRC") and effective from January 1, 2021, which partially replaced the Notice on the Relevant Tax Policies for the Implementation of the Strategy of Extensive Development of the Western Regions, under which from January 1, 2021 to December 31, 2030, a reduced enterprise income tax rate of 15% is applicable to the enterprises set up in the western regions as designated by the relevant PRC regulations with their main business in the encouraged industries. The encouraged industries are those listed in the Catalog of Encouraged Industries in the Western Regions as promulgated by NDRC. To qualify for the reduced tax rate, an enterprise must derive 60% or more of its revenue from the business listed in the Catalog of Encouraged Industries in the Western Regions.

Regulations Relating to Business Tax and Value-added Tax

Pursuant to the Temporary Regulations on Business Tax, which were promulgated by the State Council on December 13, 1993 and effective on January 1, 1994, as amended on November 10, 2008 and effective January 1, 2009, any entity or individual conducting business in a service industry is generally required to pay business tax at the rate of 5% on the revenues generated from providing such services.

In November 2011, the MOF and the STA promulgated the Pilot Plan for Imposition of Value-Added Tax to Replace Business Tax ("Pilot Plan"). Since January 2012, the STA has been implementing the Pilot Plan, which imposes value-added tax ("VAT") in lieu of business tax for certain industries in Shanghai. The Pilot Plan was expanded to other regions, including Beijing, in September

2012 and was further expanded nationwide beginning August 1, 2013. VAT is applicable at a rate of 6% in lieu of business taxes for certain services, and 17% for the sale of goods and provision of tangible property lease services. VAT payable on goods sold or taxable services provided by a general VAT taxpayer for a taxable period is the net balance of the output VAT for the period after crediting the input VAT for the period. In March 2016, the MOF and STA jointly issued the Notice on Adjustment of Transfer Business Tax to Value Added Tax effective from May 2016, according to which PRC tax authorities have started imposing VAT on revenues from various service sectors, including real estate, construction, financial services and insurance as well as other lifestyle service sectors, replacing the business tax.

On November 19, 2017, the Temporary Regulations on Business Tax was abolished and the Interim Regulations of the People's Republic of China on Value Added Tax was revised by the State Council. According to the revised Interim Regulations of the People's Republic of China on Value Added Tax, selling goods, providing labor services of processing, repairs or maintenance, or selling services, intangible assets or real property in the PRC, or importing goods to the PRC, shall be subject to value added tax. According to a notice jointly issued by MOF and STA in April 2018, starting from May 1, 2018, the VAT rate will be lowered from 17% to 16% for manufacturing and certain other industries, and from 11% to 10% for transportation, construction, real estate leasing service, sale of real estate, basic telecommunication services and farm produce. According to a notice jointly issued by MOF, STA and the General Administration of Customs in March 2019, from April 1, 2019, the value-added tax rate of 16% will be further lowered to 13% and the value-added tax rate of 10% will be further lowered to 9%.

Regulations Relating to Environmental Protection

China has adopted extensive environmental laws and regulations with national and local standards for emissions control, discharge of wastewater and storage and transportation, treatment and disposal of waste materials. At the national level, the relevant environmental protection laws and regulations include the PRC Environmental Protection Law, the PRC Law on the Prevention and Control of Air Pollution, the PRC Law on the Prevention and Control of Water Pollution, the PRC Law on the Promotion of Clean Production, the PRC Law on the Prevention and Control of Noise Pollution, the PRC Law on the Prevention and Control of Solid Waste Pollution, the PRC Recycling Economy Promotion Law, the PRC Law on Environmental Impact Assessment, the Environmental Protection Tax Law and its implementation rules, and Regulations on the Administration of Pollutant Discharge Permits. In recent years, the PRC Government has introduced a series of new policies designed to generally promote the protection of the environment. For instance, on November 10, 2016, the General Office of the State Council has released the Implementing Plan for the Permit System for Controlling the Discharge of Pollutants (Plan). The Plan proposes the need of instituting a system for enterprises and public institutions to control their respective total amount of pollutants discharged, which shall be connected with the environmental impact assessment system organically. The Plan also stipulates that it is necessary to regulate the orderly issuance of pollutant discharge permits, to make a name list to manage the permission of pollutant discharge, to promote the administration of such permission system per industry and to impose severer administration and control over enterprises and public institutions located at such places where environment quality fails to reach relevant standards. Furthermore, the Plan requires that a national pollutant discharge permit management information platform shall be established by 2017 to strengthen the information disclosure and social supervision.

Regulations Relating to Foreign Exchange and Dividend Distribution

Foreign Exchange Regulation

The Foreign Exchange Administration Regulations, most recently amended in August 2008, are the principal regulations governing foreign currency exchange in China. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the State Administration of Foreign Exchange ("SAFE") by complying with certain procedural requirements. In contrast, approval from or registration with appropriate government authorities is required when RMB is converted into a foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

In November 2012, SAFE promulgated the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment ("SAFE Circular 59"), which has been partially repealed and revised. SAFE Circular 59 substantially amends and simplifies the foreign exchange procedure. Pursuant to SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds by foreign investors in China, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, and multiple capital accounts for the same entity may be opened in different provinces, which was not previously possible. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by the SAFE or its local branches over direct investment by foreign investors in China will be conducted by way of registration, and banks must process foreign exchange business relating to the direct investment in China based on the registration information provided by SAFE and its branches.

Under the Circular of the SAFE on Further Improving and Adjusting the Policies for Foreign Exchange Administration under Capital Accounts promulgated on January 10, 2014 and effective from February 10, 2014, administration over the outflow of the profits by domestic institutions has been further simplified. In principle, a bank is no longer required to examine transaction documents when handling the outflow of profits of no more than the equivalent of $50,000 by a domestic institution. When handling the outflow of profits exceeding the equivalent of $50,000, the bank, in principle, is no longer required to examine the financial audit report and capital verification report of the domestic institution, provided that it must examine, according to the principle of transaction authenticity, the profit distribution resolution of the board of directors (or the profit distribution resolution of the partners) relating to this profit outflow and the original copy of its tax record-filing form. After each profit outflow, the bank must affix its seal to and endorsements on the original copy of the relevant tax record-filing form to indicate the actual amount of the profit outflow and the date of the outflow.

On March 30, 2015, SAFE promulgated the Circular on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises ("SAFE Circular 19"), which became effective on June 1, 2015. According to SAFE Circular 19, the foreign exchange capital of foreign-invested enterprises may be settled on a discretionary basis, meaning that the foreign exchange capital in the capital account of a foreign-invested enterprise for which the rights and interests of monetary contribution has been confirmed by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operational needs of the foreign-invested enterprise. The proportion of such discretionary settlement is temporarily determined as 100%. The RMB converted from the foreign exchange capital will be kept in a designated account, and if a foreign-invested enterprise needs to make further payment from such account, it still must provide supporting documents and go through the review process with the banks.

Furthermore, SAFE Circular 19 stipulates that the use of capital by foreign-invested enterprises must adhere to the principles of authenticity and self-use within the business scope of enterprises. The capital of a foreign-invested enterprise and capital in RMB obtained by the foreign-invested enterprise from foreign exchange settlement must not be used for the following purposes:

(1) directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations;

(2) directly or indirectly used for investment in securities, unless otherwise provided by relevant laws and regulations;

(3) directly or indirectly used for granting the entrusted loans in RMB, unless permitted by the scope of business, repaying the inter-enterprise borrowing (including advances by the third party), or repaying the bank loans in RMB that have been sub-lent to the third party; and/or

(4) paying the expenses related to the purchase of real estate that is not for self-use, except for the foreign-invested real estate enterprises.

On June 9, 2016, SAFE issued the Notice to Reform and Regulate the Administration Policies of Foreign Exchange Capital Settlement to further reform foreign exchange capital settlement nationwide.

On October 23, 2019, SAFE issued Circular of the SAFE on Further Promoting the Facilitation of Cross-border Trade and Investment, or the Circular 28, which took effect on the same day. Circular 28 allows non-investment foreign-invested enterprises to use their capital funds to make equity investments in China, with genuine investment projects and in compliance with effective foreign investment restrictions and other applicable laws.

Our PRC subsidiaries' distributions to the offshore parent and carrying out cross-border foreign exchange activities shall comply with the various SAFE registration requirements described above.

Share Option Rules

Under the Administration Measures on Individual Foreign Exchange Control issued by the People's Bank of China on December 25, 2006, all foreign exchange matters involved in employee share ownership plans and share option plans in which Chinese citizens participate require approval from SAFE or its authorized branch. In addition, under the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly-Listed Companies, commonly known as SAFE Circular 7, or Share Option Rules, issued by the SAFE on February 15, 2012, Chinese residents who are granted shares or share options by companies listed on overseas stock exchanges under share incentive plans are required to (1) register with the SAFE or its local branches; (2) retain a qualified Chinese agent, which may be a PRC subsidiary of the overseas listed company or another qualified institution selected by the PRC subsidiary, to conduct the SAFE registration and other procedures with respect to the share incentive plans on behalf of the participants and (3) retain an overseas institution to handle matters in connection with their exercise of share options, purchase and sale of shares or interests and funds transfers.

In addition, the STA has issued certain circulars concerning employee share options or restricted shares, including the Circular of the STA on Issues Concerning Individual Income Tax in Relation to Share Options, promulgated in August 2009. Under these circulars, the employees working in China who exercise share options or are granted restricted shares will be subject to PRC individual income tax. The PRC subsidiaries of such overseas listed companies have obligations to file documents related to employee

share options or restricted shares with relevant tax authorities and to withhold individual income taxes of those employees who exercise their share options. If the employees fail to pay or the PRC subsidiaries fail to withhold their income taxes in accordance with relevant laws and regulations, the PRC subsidiaries may face fines or sanctions imposed by tax authorities or other PRC government authorities.

Regulation of Dividend Distribution

The principal laws, rules and regulations governing dividend distribution by foreign-invested enterprises in China are the Company Law of China, as amended, and the Foreign Investment Law, which took effect on January 1, 2020 and replaced the Wholly Foreign-owned Enterprise Law, the Cooperative Joint Venture Law, and the Equity Joint Venture Law. Under these laws, rules and regulations, foreign-invested enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. Both PRC domestic companies and wholly-foreign owned PRC enterprises are required to allocate at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of the registered capital of the enterprises. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

Labor Laws and Social Insurance

Pursuant to the PRC Labor Law and the PRC Labor Contract Law, employers must execute written labor contracts with full-time employees. All employers must comply with local minimum wage standards. Violations of the PRC Labor Contract Law and the PRC Labor Law may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

In addition, according to the PRC Social Insurance Law, employers like our PRC subsidiaries in China must provide employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, and medical insurance and housing funds.

Rest of the World Regulation

For other countries outside of the U.S. and China, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles having their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Human Capital

As of December 31, 2021, we had 652 full-time employees and 14 part-time employees. Of these, 242 are engaged in full-time research and development and laboratory operations, 268 are engaged in manufacturing activities and 142 are engaged in full-time selling, general and administrative functions.

As of December 31, 2021, 55% of our personnel were located in the U.S., 37% were located in Asia, 7% were located in Latin America, and 1% in Europe. We have also engaged and may continue to engage independent consultants and contractors to assist us with our operations. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any employment related work stoppages, and we consider our relations with our employees to be good.

Supporting our people is a fundamental value for Athenex. We believe the Company’s success depends on its ability to attract, develop and retain key personnel. We monitor our compensation and total reward programs closely and provide a competitive mix of compensation and benefits for all employees. This includes competitive salaries, bonus opportunities for approximately one-third of our employees, and long-term incentives in the form of stock options and other equity awards for nearly one-half of our employees. Benefits include opportunities for 401(k) matches, insurance covering health, dental and life, and HSA contributions.

Because of our global presence with locations and employees around the world, Athenex maintains a rich diverse culture. We believe this diversity is an asset and with the skills, experience and industry knowledge of our employees significantly benefit our operations and performance. We believe in a culture of equity, diversity and inclusion. We are also committed to advancing safe and respectful work environments. We recognize and value that our employees can make important contributions to our business based on their individual talents, backgrounds, and expertise, allowing everyone to thrive personally and professionally. We strive for a diverse workforce at every level of the company and its board of directors.

Health and safety in the workplace for our employees and personnel has been of primary importance, particularly with the many issues surrounding COVID-19. The COVID-19 pandemic has underscored the importance of keeping our employees safe and healthy. In response to the pandemic, the Company has taken actions aligned with the Centers for Disease Control and Prevention to protect its

workforce so that its workforce can more safely and effectively perform their work. We have invested in systems and technology to allow many employees the ability to work remotely. We have implemented wellness checks for employees including officers and board members. We did not lay off or furlough our work force in response to the COVID-19 pandemic.

Financial Information

We manage our operations and allocate resources in line with our three distinct reportable segments. Financial information regarding our operations, assets and liabilities, including our net loss for the years ended December 31, 2021, 2020, and 2019 and our total assets as of December 31, 2021 and 2020, is included in our Consolidated Financial Statements in Item 8 of this Annual Report.

Corporate Information

We were originally formed under the laws of the state of Delaware in November 2003 under the name Kinex Pharmaceuticals, LLC. In December 2012, we converted from a limited liability company to a Delaware corporation, Kinex Pharmaceuticals, Inc. In August 2015, we changed our name to Athenex, Inc. Our principal executive offices are located at 1001 Main Street, Suite 600, Buffalo, New York 14203, and our telephone number is (716) 427-2950. Our website address is www.athenex.com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report, and you should not consider information on our website to be part of this Annual Report.

Available Information

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other information with the Securities and Exchange Commission ("SEC"). Our filings with the SEC are available on the SEC's website at www.sec.gov. You may also access our press releases, financial information and reports filed with the SEC (for example, our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and any amendments to those Forms) on our website under the "Investor Relations" tab. Copies of any documents on our website are available without charge, and reports filed with or furnished to the SEC will be available as soon as reasonably practicable after such materials are electronically filed with or furnished to the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should consider carefully the following risk factors, as well as the other information in this report, including our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations", before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition and results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to the COVID-19 Pandemic and Macroeconomic Factors

The COVID-19 pandemic and other macroeconomic factors could continue to adversely impact our business, including our commercial operations, clinical development activities and clinical trials.

As a result of the COVID-19 pandemic, we experienced supply chain disruptions and, in line with the industry overall, slowed enrollment or suspensions of ongoing clinical trials for our earlier stage product candidates as healthcare resources are diverted to address the COVID-19 pandemic and the emergence and spread of COVID-19 variants. The surge of COVID-19 cases in India during the first half of 2021, a country where we source supplies and maintain partnerships that are key to our specialty drug business, including API, presented business and supply chain disruption risks for us. For example, we were unable to receive inventory from our partners in India for a certain period of time. We could face similar risks in other regions, or a resurgence in India, to the extent the virus is not able to be contained or there is widespread sickness and disruption of operations.

The future extent of the impact of the COVID-19 pandemic on our business and operations will depend on a number of factors, including (i) the ultimate spread and continued severity of the outbreaks in the U.S. and globally, including additional waves of outbreak as containment measures are lifted, (ii) the long-term scope, duration and impact of containment measures on individuals and businesses, and (iii) the timing to market and relative availability of testing, vaccination and treatment options for COVID-19. If the pandemic worsens, we experience additional waves of outbreak on a local, national or global scale, or the war in Ukraine causes a significant macroeconomic downturn, we may experience a multitude of additional disruptions that could severely impact our business, operations, clinical development activities and planned clinical trials, including without limitation, the following:

- a spread of COVID-19 among our workforce and/or management team, which would result in our reduced capacity to manage our business to the extent key personnel are impacted or our personnel are impacted in significant numbers;
- continued delays or difficulties in clinical trials, which could include extended periods of time in which early stage trials are suspended, sustained difficulties enrolling patients in clinical trials and/or disruptions to ongoing trials based on the attrition of patients as a result of contracting or being exposed to COVID-19, facility closures or limitations on the use of hospitals as clinical trial sites and governmental restrictions on "non-essential" procedures and activities, any of which may further delay our clinical development plans and timelines and also may impact the integrity of our clinical trial data for ongoing trials;
- temporary or long-term disruptions in our supply chains and resulting delays in the delivery of products, services or other materials necessary for our operations;
- interruptions in FDA operations or the operations of comparable foreign regulatory agencies, which may in turn impact our timelines for receiving regulatory approvals and feedback;
- complete or partial shutdowns of the buildout efforts at our New API Facility or production slowdowns or stoppages at the New API Facility;
- disruptions, including data breaches and data loss, due to the increased cybersecurity vulnerabilities caused by remote work and a distributed workforce on the one hand, and potential cyberattacks from state actors on the other hand;
- government regulations that may be imposed in response to the COVID-19 pandemic and the war in Ukraine may restrict the movement of our global supply chain and divert hospital resources that are necessary to administer our future product candidates or delay the review of future product candidates; and
- interruption or delays in our and our partners' ability to meet expected clinical development deadlines or to comply with contractual commitments with respect to the same, including timelines around preclinical studies and planned clinical trials which could in turn delay overall developmental and commercialization timelines.

If our partners experience significant or extended disruptions to their business due to COVID-19 and other macroeconomic factors, including the war in Ukraine, it could result in substantial supply shortages and harm our generics or specialty drug business, as well as our overall financial condition and results of operations. Each of these disruptions as well as others arising from the COVID-19 pandemic and other macroeconomic factors could adversely impact our ability to conduct clinical development activities,

planned clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

The economic disruption from the COVID-19 pandemic and the war in Ukraine may result in material adverse consequences for general economic, financial and business conditions, and could result in increased credit and counterparty risks.

Through our normal business activities, we are subject to significant credit and counterparty risks that arise in the ordinary course of business. These risks have been heightened due to the COVID-19 pandemic and resulting economic turbulence, giving rise to substantial macroeconomic uncertainty. Furthermore, following the Russian invasion of Ukraine, macroeconomic uncertainty has increased. In the event of a sustained economic downturn, our customers, lenders, licensing partners, service providers, and other counterparties may be unable to fully fulfil their respective obligations to us in a timely manner, or at all. In addition, governments that we have partnered with and received grants from in connection with the construction of certain production facilities may be unable to timely fulfil their obligations under such agreements due to the impact of these macroeconomic forces on their financial conditions.

In particular, we are a party to various strategic collaboration and license agreements that are important to our business and to our current and future product candidates. Unfavorable macroeconomic conditions caused by COVID-19 or the war in Ukraine may lead our business partners to delay or curtail planned expenditures under our licensing arrangements, which could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

As a result of COVID-19, we have experienced difficulties in collecting certain license agreement receivables. For instance, we have experienced significant delays in the receipt of payments due from Xiangxue and recorded a provision for credit loss of $8.9 million for the outstanding balance due under a license agreement and related currency conversion during the year ended December 31, 2020. In November 2021, we regained the exclusive rights to develop and commercialize Oral Paclitaxel, Oral Irinotecan, and tirbanibulin ointment for Hong Kong and Macau for $1.5 million, but the $8.5 million balance remains outstanding. We may be unable to collect the outstanding balance from this license partner. If any of these difficulties persist for one or more of our partnerships, we may need to declare a default and terminate a license arrangement, which could delay or impair our ability to develop and commercialize the product candidates in the territories covered by the license agreement. In addition, we may seek replacement partnerships to develop and commercialize these product candidates in the territories covered by the terminated arrangement, the negotiation and entry into which may be costly, impact our development timelines, and otherwise be on terms less favorable compared to existing contractual terms. This could in turn have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, a prolonged downturn in macroeconomic conditions or negative trends in the global credit markets could further negatively impact our ability to collect on receivables, including milestone payments, due to us which may increase our concessions and discount rates as well as the length of time until these receivables are collected. An inability to timely collect may lead to an increase in our borrowing requirements, our accounts receivable and potentially lead to increased write-offs, with possible adverse effects on our business, financial condition, results of operations and cash flows.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred net losses every year since our inception and anticipate that we will continue to incur net losses for the foreseeable future, and as a result, our management has identified and our auditors agreed that there is a substantial doubt about our ability to continue as a going concern.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront costs and expenses and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. Since our formation, we have relied on a combination of public and private securities offerings, public-private partnerships, the issuance of convertible notes and public grants to fund our operations. We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. We have not generated substantial revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we incurred losses in 2021, 2020 and 2019. For the years ended December 31, 2021, 2020 and 2019, we reported net losses of $202.0 million, $148.4 million and $125.5 million, respectively, and had an accumulated deficit of $913.4 million as of December 31, 2021. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative expenses associated with our operations.

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our drug candidates. Due to our receipt of the CRL for Oral Paclitaxel, which was our lead product candidate, and following two Type A meetings with the FDA, we determined to no longer pursue regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S. Given that our other drug development programs were not as

advanced as Oral Paclitaxel for mBC, we expect to incur losses for longer than initially anticipated. Typically, it takes many years to develop a new drug before it is available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses, our ability to generate revenue and the timing and amount of milestones, payments due pursuant to our financing arrangements, and other required payments to third parties in connection with our potential future arrangements with third parties. If any of our drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We expect our research and development expenses to continue to be significant in connection with our continued investment in our drug candidates and our ongoing and planned clinical trials for our drug candidates. In addition, as a public company, we incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant operating losses and negative cash flows from operations for the foreseeable future. These losses have had and will continue to have a material adverse effect on our stockholders' equity, financial position, cash flows and working capital.

The report of our independent registered public accounting firm that accompanies our audited consolidated financial statements contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern. If we are unable to continue as a going concern, holders of our securities might lose their entire investment. These factors, among others, may make it difficult to raise any additional capital and may cause us to be unable to continue to operate our business.

Our strategic pivot to focus on our cell therapy platform and our plan to dispose of non-core assets may not result in anticipated savings, could result in total costs and expenses that are greater than expected, could make it more difficult to retain qualified personnel and may significantly disrupt our operations, each of which could have a material adverse effect on our business.

We are undertaking a strategic pivot from our focus on the Orascovery platform to our cell therapy platform. As part of this pivot, we are planning to divest non-core assets to raise capital and extend our cash runway. There can be no assurance that our divestiture of these assets will be successful, or that the sale of any non-core assets will raise sufficient funds for us to continue our business. We may not realize in full the anticipated benefits, savings and improvements in our strategic pivot efforts due to unforeseen difficulties, delays, disruptions or unexpected costs. Even if we are able to sell non-core assets, the disposal may not result in the savings we anticipate. The costs of disposing of the assets may exceed the cost savings we generate.

The process of disposing of non-core assets may be disruptive to our daily operating activities and our execution of short- and long-term strategies. Any cost-saving measures we implement, including any workforce reduction, may distract remaining employees from our business, cause unplanned employee attrition, reduce employee morale and productivity, disrupt our disclosure controls and procedures and internal control over financial reporting, yield other unanticipated consequences and damage our reputation.

There can be no assurance that our focus on our cell therapy platform will be successful, result in the advancement of a proprietary drug product, or yield any revenue in the future. The drug development process is expensive, can take many years to complete, and its outcome is inherently uncertain. We may suffer significant additional setbacks in focusing on our cell therapy platform and may never become profitable. Any of these factors could have a material adverse effect on our business.

Our financial results are subject to volatility related to our revenue and expenses, and despite beginning to generate revenue from product sales, we have not yet been profitable and may never become profitable.

Our financial results are subject to volatility based on a number of factors, including the timing of milestone licensing fees that we receive or are required to pay, the amount and timing of our debt repayment obligations, the change in product types sold by APD and APS and whether those products are in high demand, our ability to predict the products in high demand in the market, competition in the market for generic drugs. As we currently only have commercialized our API products and recently commercialized Klisyri, our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, our proprietary drug candidates, and specialty products, such as medical testing kits. Our product sales of API totaled $4.0 million, $3.6 million and $12.7 million in the years ended December 31, 2021, 2020 and 2019, respectively. Our specialty products sales totaled $67.0 million, $89.6 million, and $50.4 million for the years ended December 31, 2021, 2020, and 2019, respectively. Our revenue and gross margins are also subject to fluctuation due to changes in product mix and the expenses we incur to continue our research and development and commercialization efforts.

We expect to continue to incur substantial losses through the projected development and commercialization of our drug candidates. Other than Klisyri, none of our proprietary drug candidates have been approved for marketing in the U.S., China or any other jurisdiction, and they may never receive such approval. Our ability to achieve revenue and profitability is dependent on our

ability to complete the development of our proprietary drug candidates, obtain necessary regulatory approvals, and have our proprietary drugs manufactured and successfully marketed.

Even as we receive regulatory approval of our proprietary drug candidates for commercial sale, we do not know when they will generate revenue, if at all. Our ability to generate revenue from product sales of our drug candidates depends on a number of factors, including our ability to:

- complete research regarding, and non-clinical and clinical development of, our proprietary drug candidates;
- formulate appropriate dosing protocols, drug preparations and capsule encapsulation methods;
- obtain regulatory approvals and marketing authorizations for drug candidates for which we complete clinical trials;
- develop a sustainable and scalable manufacturing processes, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- compliantly launch and commercialize proprietary drug candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtain market acceptance of our proprietary drug candidates and their routes of administration as viable treatment options;
- obtain optimal pricing for products in key global markets;
- obtain adequate coverage and reimbursement for our proprietary drug candidates from government (including U.S. federal healthcare programs) and private payors;
- identify, assess, acquire and/or develop new proprietary drug candidates;
- address any competing technological and market developments;
- negotiate and maintain favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintain, protect and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- successfully commercialize our 503B outsourcing facility products and U.S. specialty pharmaceutical products;
- further develop our API business; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the FDA, NMPA, or regulatory authorities in other jurisdictions to perform studies in addition to those that we currently anticipate.

If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce our operations. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development and commercialization of our drug candidates or continue to operate our business.

To date, we have financed our operations with the proceeds from debt financings, public and private securities offerings, public-private partnerships, the issuance of convertible notes and public grants, and as of the date of this report, we project insufficient liquidity to fund our operations through the next twelve months. Our drug candidates will require the completion of clinical studies and regulatory review, substantial investment before they can provide us with any product sales revenue. Our operations have consumed substantial amounts of cash since inception. The net cash used for our operating activities from continuing operations was $138.3 million, $127.8 million, and $97.0 million for the years ended December 31, 2021, 2020, and 2019 respectively. We expect to continue to spend substantial amounts on advancing the clinical development of our proprietary drug candidates. Moreover, our research and development expenses and other contractual commitments are substantial and may increase in the future. In addition, we may require additional financial resources and personnel to build out operations at the New API Facility.

We have also incurred debt service obligations under a senior secured loan agreement and related security agreements (the “Senior Credit Agreement”) with Oaktree Fund Administration, LLC as administrative agent, and the lenders party thereto (collectively “Oaktree”) and have minimum payment obligations to Oaktree under the Senior Credit Agreement, which could make it more difficult for us to fund our operations. Under the Senior Credit Agreement, we are required to make quarterly interest-only

payments until June 19, 2022, after which we are required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. Beginning on September 17, 2020, we were required to pay a commitment fee on any undrawn commitments equal to 0.6% per annum, payable on each subsequent funding date or the commitment termination date. Furthermore, under an amended to the Senior Credit Agreement we entered into in January 2022 (the "January Credit Agreement Amendment"), we paid Oaktree 62.5% of the proceeds of the sale of the Dunkirk Facility, or $25 million, as a mandatory prepayment of loans under the Senior Credit Agreement, along with accrued and unpaid interest and certain fees and expenses. Under the January Credit Agreement Amendment, we are obligated to make an additional mandatory prepayment of $12.5 million in principal plus costs and fees by June 14, 2022.

If we are unable to make these payments as they come due, we would trigger an event of default under the Senior Credit Agreement. If an event of default were to occur, Oaktree will have the right to accelerate all amounts outstanding under the Senior Credit Agreement, in addition to other remedies available to it as a secured creditor of ours. If we are unable to raise additional capital or monetize assets, we may breach financial covenants under the Senior Credit Agreement. The credit facility carried an outstanding balance of $150.0 million as of December 31, 2021. If we are unable to raise additional capital, we would not have sufficient cash on hand or available liquidity that can be utilized to repay the outstanding debt in the event of default. We do not expect to have further access to additional capital under the Senior Credit Facility. We could spend our available financial resources much faster than expected and may need to raise additional funds sooner than anticipated. If we are unable to raise capital when needed or on attractive terms, we will be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our inability to obtain additional funding when needed could seriously harm our business or make it impossible for us to continue to operate our business.

We may not be able to refinance, extend, or repay our substantial indebtedness owed to our senior secured lender, which would have a material adverse effect on our financial condition.

We anticipate that we will need to raise a significant amount of debt or equity capital in the future in order to repay our outstanding debt obligations owed to under the Senior Credit Agreement when a mandatory prepayment is due in June 2022, when the remaining amounts due under the Senior Credit Agreement mature on July 3, 2023, and to continue to fund our operations. We are obligated to make a mandatory prepayment of $12.5 million in principal plus costs and fees by June 14, 2022. In addition, we are required to make quarterly interest-only payments until June 19, 2022, after which we are required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. If we are unable to raise sufficient capital to repay these obligations and we are otherwise unable to extend the maturity dates or refinance these obligations, we would be in default. We cannot provide any assurances that we will be able to raise the necessary amount of capital to repay these obligations or that we will be able to extend the maturity dates or otherwise refinance these obligations. If we are unable to raise additional capital or monetize assets, we may breach financial covenants under the Senior Credit Agreement. The credit facility carried an outstanding balance of $150.0 million as of December 31, 2021. If we are unable to raise additional capital or monetize assets, we would not have sufficient cash on hand or available liquidity that can be utilized to repay the outstanding debt in the event of default. Upon a default on the senior debt, our senior secured lender would have the right to exercise its rights and remedies to collect, which would include foreclosing on our assets. Accordingly, a default would have a material adverse effect on our business and, if our senior secured lender exercises its rights and remedies, we would likely be forced to seek bankruptcy protection.

Covenants in the agreements governing our existing debt agreements restrict the manner in which we conduct our business.

The Senior Credit Agreement contains various covenants that limit, subject to certain exemptions, our ability and/or our certain of our subsidiaries' ability to, among other things, incur additional indebtedness or liens; make investments; consummate business combinations such as mergers and dispositions; prepay other indebtedness; and to declare dividends and other distributions, subject to certain exceptions, including specific exceptions with respect to product commercialization and development activities. In addition, the Senior Credit Agreement contains certain financial covenants, including, among other things, maintenance of minimum liquidity and a minimum revenue test, measured quarterly until the last day of the second consecutive fiscal quarter where the consolidated leverage ratio does not exceed 4.5 to 1, provided that thereafter we cannot allow our consolidated leverage ratio to exceed 4.5 to 1, measured quarterly.

The Senior Credit Agreement requires that we maintain a minimum liquidity amount in cash or permitted cash equivalent investments of $20.0 million. Our obligations under the Senior Credit Agreement are guaranteed by certain of our existing domestic subsidiaries and subsequently acquired or organized subsidiaries subject to certain exceptions. Our obligations under the Senior Credit Agreement and the related guarantees thereunder are secured, subject to customary permitted liens and other agreed upon exceptions, by (i) a pledge of all of the equity interests of our direct subsidiaries, and (ii) a perfected security interest in all of our tangible and intangible assets.

The restrictions contained in our Senior Credit Agreement governing our debt could adversely affect our ability to:

- finance our operations;

- make needed capital expenditures;
- make strategic acquisitions or investments or enter into alliances;
- withstand a future downturn in our business or the economy in general;
- engage in business activities, including future opportunities, that may be in our interest; and
- plan for or react to market conditions or otherwise execute our business strategies.

A breach of any of these covenants, subject to certain cure rights of the Company, could result in a default under the agreements governing our debt. Further, additional indebtedness that we incur in the future may subject us to further covenants. If a default under any such debt agreement is not cured or waived, the default could result in the acceleration of debt, which could require us to repay debt prior to the date it is otherwise due and that could adversely affect our financial condition. If we default under the Senior Credit Agreement, the lenders may seek repayment through our subsidiary guarantors or by executing on the security interest granted pursuant to the Senior Credit Agreement and related security agreements. If we are unable to raise additional capital or monetize assets, we may breach financial covenants under the Senior Credit Agreement. The credit facility carried an outstanding balance of $150.0 million as of December 31, 2021. If we are unable to raise additional capital or monetize assets, we would not have sufficient cash on hand or available liquidity that can be utilized to repay the outstanding debt in the event of default.

Our ability to comply with the covenants, restrictions and specified financial ratios contained in our senior secured loan agreement may be affected by events beyond our control, including prevailing economic, financial, and industry conditions. Even if we are able to comply with all of the applicable covenants, the restrictions on our ability to manage our business in our sole discretion could adversely affect our business by, among other things, limiting our ability to take advantage of financings, mergers, acquisitions, and other corporate opportunities that we believe would be beneficial to us. In addition, our obligations under the loan agreement are secured, on a first-priority basis, and such security interests could be enforced in the event of default by the collateral agent for the loan agreement.

An impairment of goodwill and long-lived assets have had and other impairment in the future could have a material adverse effect on our results of operations.

Our acquisitions of APS, Polymed, CDE and Kuur resulted in the recording of goodwill and other intangible assets. Goodwill is not amortized and is subject to impairment testing at least annually using a fair value-based approach. The identification and measurement of goodwill impairment involves the estimation of the fair value of our reporting units. The estimates of fair value of reporting units are based on the best information available as of the date of the assessment and incorporate management assumptions about expected future cash flows and other valuation techniques. Future cash flows can be affected by changes in industry or market conditions, among other factors. The recoverability of goodwill is evaluated at least annually or more frequently when events or changes in circumstances indicate that the fair value of a reporting unit has more likely than not declined below its carrying value. As a result of the significant decrease in our market capitalization and in accordance with our policy to perform a goodwill impairment test during the fourth quarter, we performed a goodwill impairment test for our reporting units, updating with information regarding conditions that existed as of December 31, 2021. We compared the fair value of our Global Supply Chain Platform and Oncology Innovation Platform reporting units to carrying value. Based on the results from the test on December 31, 2021, the carrying value of the Global Supply Chain Platform and Oncology Innovation Platform reporting units exceeded their fair value, and therefore, goodwill was determined to be fully impaired. Accordingly, the Company recorded goodwill impairment of $67.7 million during the year ended December 31, 2021 (see Part II, Item 8. Note 8—Intangible Assets, Net). We may never be able to recover the value of our investment in these acquisitions. A lack of sustained recovery or further deterioration in market conditions related to the general economy and the industries in which we operate, a sustained trend of weaker than anticipated financial performance, further decline in our share price for a sustained period of time, or an increase in the market-based weighted average cost of capital, among other factors, could significantly impact the impairment analysis and may result in future impairment charges that, if incurred, could have a material adverse effect on our financial condition and results of operations.

In addition, we review the recoverability of our long-lived assets, excluding goodwill, when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. On December 31, 2021, we reviewed the recoverability of the carrying value of the Polymed technology and customer list and the intangible assets related to the Taihao API facility and determined that their carrying value was greater than their fair value. We accordingly wrote off their corresponding values of $1.7 million and less than $0.1 million, respectively, as impaired.

We cannot accurately predict the amount and timing of any future impairment of assets, and, going forward, we may be required to take additional charges relating to certain of our reporting units. Any such charges would have an adverse effect on our financial results.

We are a party to ongoing legal proceedings and, while we cannot predict the outcome of those proceedings and other contingencies with certainty, if we settle these claims or the proceedings are not decided in our favor, our business and financial condition could be materially adversely affected.

We have been, and may in the future be, subject to various legal and regulatory proceedings, including class action litigation. It is inherently difficult to assess the outcome of these matters, and there can be no assurance that we will prevail in any proceeding or litigation. Legal and regulatory matters of any degree of significance could result in substantial cost and diversion of our efforts, which by itself could have a material adverse effect on our financial condition and operating results.

As disclosed in Part I, Item 3, "Legal Proceedings," following our receipt of the CRL in February 2021 and the subsequent decline of the market price of our common stock, two purported class action lawsuits were filed against the Company and certain members of its management team, along with a related shareholder derivative lawsuit. If we settle these claims or the litigation is not resolved in our favor, we may suffer reputational damage and incur legal costs, settlements or judgments that exceed the amounts covered by our existing insurance policies. We can provide no assurances that our insurer will insure the legal costs, settlements or judgements we incur in excess of our deductible. If we are not successful in defending ourselves from these claims, or if our insurer does not insure us against legal costs we incur in excess of our deductible, the result may materially adversely affect our business, results of operations and financial condition. Defending against these and any future lawsuits and legal proceedings, regardless of their merit, may involve significant expense, be disruptive to our business operations and divert our management's attention and resources. Negative publicity surrounding these legal proceedings may also harm our reputation, our stock price, and adversely impact our business and financial condition.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or proprietary drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Risks Related to Clinical Development of Our Proprietary Drug Candidates

The majority of our primary clinical candidates are still in the development stage and have not yet received regulatory approval, which may make it difficult to evaluate our current business and predict our future performance.

We are a globally-focused biopharmaceutical company formed in November 2003. Our operations to date have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials of our drug candidates. We have not yet successfully completed large-scale, pivotal clinical trials or obtained regulatory approvals for all of our drug candidates and have not yet established sales and marketing activities necessary for successful commercialization of the drug candidates we plan to commercialize. We are also dependent on the marketing and sales efforts of our partners for the successful commercialization of our approved drug, Klisyri. Consequently, any predictions you make about our future success or viability may not be accurate. In addition, as a developing business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges.

We are focused on the discovery and development of innovative drugs for the treatment of cancers. The fact that we have not yet, among other things, demonstrated our ability to initiate or complete large-scale clinical trials or manufacture drugs at commercial scale, particularly in light of the rapidly evolving cancer treatment field, may make it difficult to evaluate our current business and predict our future performance. These constraints make any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business will suffer. We depend substantially on the success of our proprietary drug candidates, which are in pre-clinical and clinical development.

As of March 1, 2022, we had a total of 7 planned or ongoing clinical trials for our drug candidates. We have one FDA approved drug product, Klisyri, and have completed two Phase 3 clinical trials for tirbanibulin ointment 1% for AK, and one Phase 3 clinical trial for Oral Paclitaxel for the treatment of patients with mBC. However, after careful consideration we determined to not pursue regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S. Our business and the ability to generate revenue related to product sales from our proprietary drug candidates will depend on the successful development, regulatory approval and commercialization for the treatment of patients with our drug candidates, which are still in development, and other drugs we may develop. Clinical development is a lengthy and expensive process with an uncertain outcome. The results of pre-clinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. In the case of any trials we conduct, results have in the past, and may in the future, fail to meet the desired safety and efficacy endpoints, or differ from earlier trials due to the larger number of clinical trial sites and additional countries and populations involved in such trials. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates. The success of our proprietary drug candidates will depend on several factors, including:

- successful enrollment in, and completion of, clinical studies;
- receipt of regulatory approvals from the FDA, NMPA and other regulatory authorities for our drug candidates;
- establishing commercial manufacturing capabilities, either by using our own facilities or making arrangements with third-party manufacturers;
- conducting our clinical trials compliantly and efficiently, and in many cases, relying on third parties to do so;
- obtaining, maintaining and protecting our intellectual property rights, including patent, trade secrets, know-how and regulatory exclusivity;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- competition with other drug candidates and drugs; and
- continued acceptable safety profile for our drug candidates following regulatory approval, if received.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from early trials due to the larger number of patients, clinical trial sites and additional countries and populations involved in such trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be favorable as previous trials with the same compound, even with the same indication.

Because most of our clinical candidates are in the development stage and have not yet received regulatory approval, we may never be able to generate sufficient revenues and cash flows to continue our operations.

We may not be successful in our efforts to identify or discover additional drug candidates. Due to our limited resources and access to capital, we must and have in the past decided to prioritize development of certain product candidates; these decisions may prove to have been wrong and may adversely affect our business.

Historically, we have focused our drug discovery efforts on developing our cancer platform, particularly our Orascovery and Src Kinase inhibition product candidates. However, following the receipt of the CRL for Oral Paclitaxel, which was our lead product candidate, and following two Type A meetings with the FDA, we determined to no longer pursue regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S., and have determined to redeploy our resources to other ongoing studies of Oral Paclitaxel and our Cell Therapy platform. If our platform fails to identify potential drug candidates, our business could be materially harmed. Additionally, our management, at the direction of our board of directors, has discretion in prioritizing which product candidates to develop.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or drug candidates;
- potential drug candidates may, after further study, be shown to lack efficacy, have harmful adverse effects, pose a safety risk to patients as compared to existing drugs, or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we possess, thereby limiting our ability to diversify and expand our drug portfolio.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We and our research partners have from time to time and may in the future experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the prioritization of the treatment of COVID-19 patients;
- patients declining to enroll in trials because of the COVID-19 pandemic;
- the availability of a sizeable population of eligible patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies,
- our ability to obtain and maintain patient consents;
- the failure of patients to complete a clinical trial; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

In addition, our clinical trials will compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we have conducted and expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

Some of our drug candidates represent a novel approach to cancer treatment, which could result in delays in clinical development, heightened regulatory scrutiny, and delays in our ability to achieve regulatory approval or commercialization, or market acceptance by physicians and patients of our drug candidates.

Some of our drug candidates, particularly those developed through our Cell Therapy platform, represent a departure from more commonly used methods for cancer treatment, and therefore represent a novel approach that carries inherent development risks. Although there is some previous clinical experience with nonengineered NKT cells, given that this is a novel approach, it is possible

that we may encounter unexpected clinical trial results, which may delay our development programs. In addition, our Orascovery platform intends to facilitate the delivery of chemotherapy agents orally, as opposed to IV, while our Src Kinase inhibitor candidates operate by a new mechanism of action. Because of this, unexpected safety and tolerability concerns may arise during the development process. The need to further develop or modify in any way the protocols related to our drug candidates to demonstrate safety or efficacy may delay the clinical program, regulatory approval or commercialization, if approved.

In addition, potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than enroll patients in any future clinical trial or to use our product candidates commercially once approved. This may have a material impact on our ability to generate revenues from our drug candidates. Further, given the novelty of the administration of our drug candidates, hospitals and physicians may prefer traditional treatment methods, may be reluctant to adopt the use of our products or may require a substantial amount of education and training, any of which could delay or prevent acceptance of our products by physicians and patients and materially hinder successful commercialization of our drug candidates.

Our products and product candidates may cause undesirable, or an increase in the frequency of, side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, NMPA or other regulatory authorities, as indicated by the FDA in its CRL with respect to our NDA for Oral Paclitaxel, that indicated a need for an additional study to examine safety and dosing. Further, once a product candidate receives marketing approval and we or others identify undesirable side effects caused by the product after the approval, or if drug abuse is determined to be a significant problem with an approved product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as a “Black Box warning” or a contraindication;
- we may be required to change the way the product is distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may decide to remove the product from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing an affected product or product candidate and significantly impact our ability to successfully commercialize or maintain sales of our product or product candidates and generate revenues.

If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, NMPA or other regulatory authorities, as the FDA indicated in its CRL with respect to our NDA for Oral Paclitaxel, or do not otherwise produce positive results, we will incur costs and experience delays in completing, and may ultimately be unable to complete, the development and commercialization of our drug candidates.

We may experience various unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including:

- regulators, IRBs or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or a finding that participants are being exposed to unacceptable health risks;

- regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates;
- not obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

Delays in testing or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Significant clinical trial delays also could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drug candidates and may harm our business and results of operations.

Manufacturing risks, including our inability to manufacture API and clinical products used in the clinical trials of our proprietary product candidates could adversely affect our ability to commercialize our product candidates.

Our business strategy depends on our ability to manufacture API in sufficient quantities and on a timely basis so as to meet our needs to manufacture our product candidates for our clinical trials and to meet consumer demand for our future products, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- our inability to manufacture API and clinical products in sufficient quantities to meet the needs of our clinical trials or to commercialize our products;
- our inability to manufacture API and clinical products in the event our manufacturing facilities' operations are suspended indefinitely or terminated due to events beyond our control;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our failure to increase production of products to meet demand;
- our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facility.

In addition, we conduct manufacturing operations at our facility in Chongqing, China to manufacture API and our proprietary product candidates. As a result, our business is subject to risks associated with that facility in particular and doing business in China generally, including:

- the possibility of our operations at the Chongqing facility being suspended indefinitely or terminated by an order of the local government due to events beyond our control;

- the impact of the ongoing COVID-19 pandemic on our operations in China;
- the possibility that the costs of building and maintaining the New API Facility exceed the revenue we are able to generate from manufacturing API at the facility;
- adverse political and economic conditions, particularly those negatively affecting the trade relationship between the U.S. and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- potentially lower protection of intellectual property rights;
- unexpected or unfavorable changes in regulatory requirements;
- possible patient or physician preferences for more established pharmaceutical products and medical devices manufactured in the U.S.; and
- difficulties in managing foreign relationships and operations generally.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. If our need for API increases, or demand for our products increase, we will have to invest additional resources to purchase components, hire and train employees and enhance our manufacturing processes and may have to use alternate suppliers of API to meet our needs. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. Any of these factors may affect our ability to manufacture our product and could reduce our revenues and profitability.

Risks Related to Development, Regulatory Approval and Commercialization

The regulatory approval processes of the FDA, NMPA and other regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, NMPA and other regulatory authorities in jurisdictions where we seek such approval is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. We cannot provide any assurances with respect to the timing for any regulatory approval or if our studies will be considered to be sufficient by regulators, as we experienced with our NDA for Oral Paclitaxel. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. It is possible that none of our other existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future will ever obtain regulatory approval.

Our drug candidates could fail to receive regulatory approval from the FDA, NMPA or another regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our drug candidates to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- the FDA, NMPA or another regulatory authority's finding of deficiencies related to the product, manufacturing processes or facilities of ours or of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA, NMPA or a regulatory authority in another jurisdiction may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval in those territories and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that is not desirable for the successful commercialization of that drug candidate. In addition, if our drug candidate produces undesirable side effects or safety issues, the FDA may require additional clinical or preclinical studies or the establishment of REMS, or the NMPA or a regulatory authority may require the establishment of a similar strategy, that may, for instance, significantly restrict distribution of our drug candidates and impose burdensome implementation requirements on us. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

The approval process for pharmaceutical products outside the U.S. varies among countries and may limit our ability to develop, manufacture and sell our products internationally. Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products internationally, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional testing. We may conduct clinical trials for, and seek regulatory approval to market, our product candidates in countries other than the U.S. and China. Depending on the results of clinical trials and the process for obtaining regulatory approvals in other countries, we may decide to first seek regulatory approvals of a product candidate in the U.S. or in countries other than the U.S., or we may simultaneously seek regulatory approvals in the U.S. and other countries. If we seek marketing approval for a product candidate outside the U.S., we will be subject to the regulatory requirements of health authorities in each country in which we seek approval. With respect to marketing authorizations in China, we will be required to seek regulatory approval from the NMPA. For marketing approval in Europe, we will seek to obtain marketing approval from the EMA. The approval procedure varies among regions and countries and may involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval.

Obtaining regulatory approvals from health authorities in countries outside the U.S. is likely to subject us to all of the risks associated with obtaining FDA approval described above. In addition, marketing approval by the FDA does not ensure approval by the health authorities of any other country, and marketing approvals by foreign health authorities do not ensure a similar approval by the FDA.

We are conducting, and may in the future conduct, clinical trials for our product candidates in sites outside the U.S. and the FDA may not accept data from trials conducted in such locations.

We have conducted, and may in the future conduct, certain of our clinical trials outside of the U.S., including in the U.K., China, Taiwan and Latin America. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of this data is subject to certain conditions imposed by the FDA. There can be no assurance the FDA will accept data from any clinical trials we conduct outside of the U.S. For example, in the CRL we received regarding the NDA for Oral Paclitaxel, the FDA indicated that the participants in a new clinical trial they are recommending should be reflective of the U.S. population. If the FDA does not accept the data from any of our other clinical trials conducted outside the U.S., it would likely result in the need for additional clinical trials, which would be costly and time-consuming and could delay or prevent the commercialization of any of our product candidates.

Regulatory approval may be substantially delayed or may not be obtained for one or all of our drug candidates for a variety of reasons.

We may be unable to complete development of our drug candidates on schedule, if at all. The completion of the studies for our drug candidates will require funding beyond our current resources. In addition, if regulatory authorities require additional time or studies to assess the safety or efficacy of our drug candidates, we may not have or be able to obtain adequate funding to complete the necessary steps for approval for any or all of our drug candidates. Preclinical studies and clinical trials required to demonstrate the safety and efficacy of our drug candidates are time consuming and expensive and together take several years or more to complete. For example, one of our product candidates, Oral Paclitaxel, for which we received a CRL in February 2021, has been in development since 2011. Delays in clinical trials, regulatory approvals or rejections of applications for regulatory approval in the U.S., United Kingdom, Taiwan, New Zealand, China, Latin America, or other jurisdictions may result from many factors, including:

- our inability to obtain sufficient funds required for a clinical trial;
- regulatory requests for, or the requirement of, additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;
- regulatory questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;

- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- failure to reach agreement with the FDA, NMPA or other regulators regarding the scope or design of our clinical trials;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- our inability to enroll and retain a sufficient number of patients who meet the inclusion and exclusion criteria in a clinical trial;
- our inability to conduct a clinical trial in accordance with regulatory requirements or our clinical protocols;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third-party clinical trial managers to satisfy their contractual duties or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results, or results that are inconsistent with earlier results;
- unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding safety or effectiveness of drug candidates during clinical trials;
- feedback from the FDA, NMPA, IRB, the Data and Safety Monitoring Board ("DSMB") or comparable entities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol;
- unacceptable risk-benefit profile or unforeseen safety issues or adverse side effects;
- decision by the FDA, NMPA, IRB, comparable entities or the Company, or recommendation by a DSMB or comparable entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- failure to demonstrate a benefit from using a drug candidate;
- lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions;
- our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain approval from IRBs or ethics committees to conduct clinical trials at their respective sites;
- manufacturing issues, including problems with manufacturing or timely obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; and
- difficulty in maintaining contact with patients during the study or after treatment, resulting in incomplete data.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

According to the Special Examination and Approval Provisions for New Drugs issued by the CFDA in 2009, the CFDA may conduct special examinations and approve new drug registration applications for drugs which (i) have active ingredients extracted from plants, animals and minerals, etc. and their preparations are not yet marketed in China, and newly discovered Chinese crude drugs and their preparations, (ii) contain chemical drug substances and their preparations and biological products not yet approved for marketing in China or abroad, (iii) are new drugs for the treatment of diseases, including, among others, AIDS, malignant tumors and rare diseases, with significant clinical advantage, and (iv) are new drugs for the treatment of diseases, for which effective therapeutic methods are not available. On May 17, 2018, the NMPA and NHC issued the Announcement on Optimizing the Review and Approval of Drug Registration, which clarifies that a priority review and approval mechanism will be available. The current PRC Drug Administration Law, which was promulgated on August 26, 2019 and came into effect on December 1, 2019, also stipulates that the government encourages research and development of innovative drugs for serious diseases such as cancer.

The Provisions for Drug Registration as revised in 2020 has incorporated the previous reform in respect of the accelerated approval for clinical trial and drug registration and introduces four procedures for expedited marketing registration of drugs, which are procedures for groundbreaking therapeutic drugs, procedures for conditional approval, procedures for prioritized reviews and approval, and procedures for special examination and approval.

On July 7, 2020, the NMPA promulgated the Announcement on Promulgating Three Documents Including the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (for Trial Implementation) and Priority Review and Approval Procedures for Drug Marketing Authorizations (for Trial Implementation), which abolished the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug. According to the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (for Trial Implementation), sponsors of innovative drug candidates which exhibit clinical benefits for the treatment of life-threatening or other serious conditions for which there is no existing effective prevention and treatment method, or compared with existing treatment methods that have sufficient evidence to show that they have obvious clinical advantages, may apply for breakthrough therapeutic drug programs during Phase I and II clinical trials for such drug candidates. According to the Priority Review and Approval Procedures for Drug Marketing Authorizations (for Trial Implementation), an applicant for drug marketing authorization may apply for priority review and approval procedures for the following drugs with obvious clinical value: (I) drugs in urgent clinical demand and in shortage, innovative drugs and modified new drugs for prevention and treatment of serious infectious diseases, rare diseases and other diseases; (II) new varieties, dosage forms and specifications of children's drugs that conform to children's physiological characteristics; (III) vaccines and innovative vaccines that are in urgent need for disease prevention and control; (IV) drugs that have been included in the procedures for breakthrough therapy designation; (V) drugs that are subject to conditional approval; and (VI) other circumstances under which priority review and approval shall be provided for by the NMPA. We cannot be sure that the NMPA will grant such priority treatment to any of our drug candidates.

If we experience delays in the completion of, or the termination of, a clinical trial, of any of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to generate revenues from the sale of any of those drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

Our approved drugs and drug candidates have caused and may cause undesirable adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events related to our approved drugs or drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials that would preclude approval of our drug candidates by the FDA, NMPA, or another regulatory authority or, if approved, could result in a more restrictive label. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our trials could be suspended or terminated and the FDA, NMPA or other regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. For example, in the CRL we received from the FDA, the FDA indicated that it had determined that our Oral Paclitaxel Phase III study demonstrated an unacceptable increase in neutropenia-related sequelae and has determined that additional risk mitigation strategies to improve toxicity, which may involve dose optimization and / or exclusion of the patients deemed to be at a higher risk of toxicity, are required to support potential approval of the NDA. Drug-related adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

For Klisyri® (tirbanibulin), adverse events reported during clinical trials and identified in the approved prescribing information included erythema, flaking/ scaling, crusting, swelling, vesiculation/pustulation, erosion/ ulceration, application site pruritus, and application site pain, which included pain, tenderness, stinging, and burning sensation at the application site.

In our clinical studies to date, we have observed the following SAEs that were deemed at least possibly related to each of our product candidates:

- Oral Paclitaxel - neutropenia, febrile neutropenia, pneumonia, septic shock, sepsis and other infections, dehydration gastroenteritis, anemia, pneumonitis, diarrhea, mucositis, gastrointestinal bleeding, vomiting and nausea, rectal bleeding, altered state of consciousness, hypokalemia, cardiac arrest, tachycardia, atrial fibrillation, cardiogenic shock, hypotension, pancytopenia, multiorgan failure, renal failure, atrial fibrillation, pleural effusion, supraventricular tachycardia, respiratory failure, malnutrition, dyspnea, cardiac failure, pulmonary tuberculosis, fatigue, upper abdominal pain, decreased appetite, and peripheral sensory neuropathy;
- Oral Docetaxel – vomiting, nausea, diarrhea and gastrointestinal toxicity;

- Oral Irinotecan - diarrhea, rash, gastrointestinal hemorrhage, vomiting, nausea, asthenia, neutropenia, anorexia, increased alanine aminotransferase, increased aspartate aminotransferase, enteritis, decreased neutrophil count and clostridium difficile infection;
- Tirbanibulin oral - allergic reaction, bacteremia, rash, syncope, perivascular dermatitis, neutropenic fever, hyponatremia, failure to thrive, hypersensitivity, lower extremity edema, mucositis, neutropenia, pancytopenia, thrombocytopenia, seizure and motor vehicle accident, embolic stroke, pneumonitis, fever, acute kidney injury, increased bilirubin and albumin levels, decreased blood platelet count, abdominal pain, arm pain, pain at the base of the neck, pyrexia, chills, rigors, tachypenea, oxygen desaturation, pneumonia, anemia, elevated ALT and AST, dehydration, leukopenia and tremor; and
- KX2-361 - pulmonary embolism; thromboembolic event, hyperuricemia and nausea.

Additionally, if we or others later identify undesirable side effects caused by Klisyri® or one or more of our drug candidates, if approved, a number of potentially significant negative consequences could result, including:

- we may suspend marketing of the drug;
- regulatory authorities may withdraw approvals of the drug;
- regulatory authorities may require additional warnings in the labeling;
- we may be required to develop a REMS for the drug or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a regulatory authority;
- we may be required to conduct post-marketing studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug or drug candidate, if approved, and could significantly harm our business, results of operations and prospects.

The commercialization of Klisyri® and of any of our drug candidates, if approved, subjects us to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

Klisyri® and our drug candidates, if any are approved, are subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-marketing information, including both federal and state requirements in the U.S. and requirements of foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements of the FDA, NMPA and regulatory authorities, including, in the U.S., ensuring that quality control and manufacturing procedures conform to current cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA or other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our drug candidates may be subject to conditions of approval or limitations on the approved indicated uses for which the drug may be marketed, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the drug candidate. The FDA may also require a REMS program as a condition of approval of one or more of our drug candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, NMPA or a regulatory authority approves our drug candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with our drugs, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information;

imposition of post-marketing studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our drugs, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our drug candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and in a manner consistent with the provisions of the approved prescribing information. The FDA, NMPA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA, NMPA and of other regulatory authorities may change. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, and we may not achieve or sustain profitability.

Risks Related to Commercialization of Klisyri® and Our Drug Candidates

If we and our partners are unable to successfully commercialize Klisyri® or experience significant delays in doing so for our other drug candidates, our business will be materially harmed.

Our business and the ability to generate revenue related to product sales depend in part on the successful commercialization of our approved product Klisyri® and the successful development, regulatory approval and commercialization of any current or future product candidates. Klisyri® has been approved by the FDA in the U.S. and the E.U., but Klisyri® has not received regulatory approval in any other jurisdiction and no sales can be made in any such jurisdiction unless such approval occurs. We have invested a significant portion of our efforts and financial resources to date in the development of Klisyri®, and our prospects are dependent on, and a portion of the value of our company relates to, our ability to successfully commercialize these products. The success of Klisyri® and any current or future product candidates depends on several factors, including:

- successfully completing clinical trials;
- receiving and maintaining regulatory approvals from applicable regulatory authorities;
- developing and maintaining effective sales, marketing and distribution capabilities or partnerships to commercialize our products;
- establishing adequate internal manufacturing capacity or arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- establishing commercial markets;
- obtaining coverage and reimbursement from third-party payers; and
- successfully competing with other products;

If we and our partners do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize Klisyri® or any current or future product candidates, which could materially harm our business, and we may not be able to earn sufficient revenues and cash flows to continue our operations.

We are dependent on the efforts of Almirall for the commercialization of Klisyri in the U.S. and Europe.

We have entered into collaborations with Almirall and are dependent on the efforts of Almirall for the commercialization of Klisyri in the U.S. and in Europe. The success of this arrangement will depend heavily on the efforts and activities of Almirall. In some situations, we may not be able to influence Almirall’s decisions regarding the commercialization of Klisyri or Almirall’s level of effort in marketing and selling Klisyri. Our ability to realize revenue from royalties or milestone payments depends significantly upon

Almirall's ability to commercialize, market and sell Klisyri. If they are unsuccessful, we may not receive some of the royalties or milestone payments provided for in the license agreement with Almirall.

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals for our drug candidates, we will not be able to commercialize these drug candidates, and our ability to generate revenue will be materially impaired.

Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize drug candidates in a timely manner. We cannot commercialize drug candidates without first obtaining regulatory approval to market each drug from the FDA, NMPA or regulatory authorities in the relevant jurisdictions. Some of our proprietary drug candidates are currently undergoing various phases of FDA clinical trials. We cannot predict whether these trials and future trials will be successful or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date. We have experienced this uncertainty with the receipt of a CRL for our NDA for Oral Paclitaxel, and the FDA recommended an additional clinical trial be completed and additional risk mitigation strategies to improve toxicity, which may involve dose optimization and/or exclusion of the patients deemed to be at a higher risk of toxicity, to support potential approval of the NDA. Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in the U.S., to the satisfaction of the FDA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. An NDA must include extensive preclinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA.

Regulatory authorities outside of the U.S., such as the regulatory authorities in emerging markets, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking non-U.S. regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time-consuming. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval and other risks specific to the relevant jurisdiction. For all of these reasons, we may not obtain non-U.S. regulatory approvals on a timely basis, if at all.

If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, if we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates.

We previously received priority review for Oral Paclitaxel in the U.S. and may seek fast track designation or priority review of applications for approval of our product candidate for future indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. A priority review designation means that the FDA's goal to review an application is six months, rather than the standard review period of ten months. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or thereafter.

Klisyri® and any of our drug candidates, if approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Klisyri® and any of our drug candidates, if approved, may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our drug candidates. In addition, physicians, patients and third-party payors may prefer other novel products to ours, and we may experience difficulties gaining acceptance for our orally administered drug candidates. We are also subject to regulatory restrictions on

how we market our drug candidates. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues, and we may not become profitable. The degree of market acceptance of Klisyri® and our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drugs are approved;
- physicians, hospitals, cancer treatment centers and patients considering our drugs as a safe and effective treatment;
- the potential and perceived advantages of our drugs over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, NMPA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, NMPA or other regulatory authorities;
- the timing of market introduction of our drugs as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our drugs;
- obtaining optimal pricing for products in key global markets;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities (including U.S. federal healthcare programs);
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- the emergence of new biomarker-driven therapies as alternatives to chemotherapy; and
- the effectiveness of our sales and marketing efforts.

If Klisyri® and any of our drug candidates, if approved, fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our drugs achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, are more cost effective or render our drugs obsolete.

Our partner Almirall is commercializing Klisyri® in the U.S. The commercial success of our products in the U.S. will depend on the degree of such market acceptance. Insurers and other third-party payers may also encourage the use of generic products, either in preference to or prior to the use of brand therapies. The degree of market acceptance of Klisyri® and any current or future product candidates, if approved, will depend on a number of factors, including:

- the market price, affordability and patient out-of-pocket costs, relative to other available products, which are predominantly generics;
- the possibility that third-party payers will not give favorable positions on their formularies or will place restrictions on their use, including through use of step therapy or prior authorization programs;
- the timing of market introduction;
- their effectiveness as compared with currently available products;
- physician willingness to prescribe and patient willingness to adopt them in place of current therapies;
- varying patient characteristics including demographic factors such as age, health, race and economic status;
- changes in the standard of care for the targeted indications;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in labeling;
- limitations in the approved clinical indications;
- our success in demonstrating their benefits including relative convenience and ease of initiation, prescription and administration;

- the strength of our selling, marketing and distribution capabilities;
- the quality of our relationships with physicians, patient advocacy groups, third-party payers and others in the medical community;
- the continuous availability of quality manufactured products;
- sufficient third-party coverage or reimbursement; and
- the degree to which the products are subject to material product liability claims

It is possible that we or our partners may find it necessary or desirable to provide rebates on Klisyri® or future product candidates, if approved, to customers or third-party payers or to implement patient assistance programs, including co-pay assistance programs, which could affect our profitability. In addition, we do not know how physicians, patients and third-party payers will respond to the pricing of Klisyri® in the U.S. or the pricing of any current or future product candidates in any jurisdiction, if approved.

The market opportunities for our currently marketed or potential products, if approved, are difficult to precisely estimate.

Even though we have obtained orphan drug designation for KX2-361 for the treatment of gliomas in the United States, we may not obtain or maintain orphan drug exclusivity for this product candidate, and we may not obtain orphan drug designation or exclusivity for any of our other product candidates or indications.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Similarly, the European Commission may designate a product as an orphan drug under certain circumstances.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same disease for that time period. The applicable period is seven years in the United States and ten years in the European Union. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In the United States, a second drug may be approved for the orphan indication despite a product's orphan drug exclusivity if the FDA determines that the later drug is safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

KX2-361 has obtained Orphan Drug Designation from the FDA for the treatment of gliomas . Even though we have received orphan drug designation for this product candidate for this indication, we may not be the first to obtain marketing approval for the orphan-designated indication in due to the uncertainties associated with developing pharmaceutical product candidates. We may also seek to obtain orphan drug designations in other international jurisdictions. However, there is no guarantee that we would be able to do so on a timely basis, or at all. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition or a drug with the same active moiety can be approved for a different indication. Orphan drug designation by FDA or EMA neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, even if we intend to seek orphan drug designation for other product candidates or indications, we may never receive such designations or obtain orphan drug exclusivity.

Moreover, there can be no assurance that the designation and/or exclusivity provisions currently in the law may not be changed in the future and the impact of any such changes, if made, on us. The orphan drug exclusivity provisions have been the subject of recent scrutiny from the press, from some members of Congress and from some in the medical community. Furthermore, the FDA's interpretations of the Orphan Drug Act have been successfully challenged in court and future court decisions could continue that trend. There can be no assurance that the exclusivity granted to orphan drugs approved by the FDA will not be modified in the future, and how any such change might affect our products, if approved.

Orphan drugs target rare diseases and must therefore capture significant market share at high per-patient cost to generate reasonable returns.

KX2-361 has obtained Orphan Drug Designation from the FDA and Oral Paclitaxel has obtained Orphan Drug Designations from both the FDA and EC, respectively. As orphan drug candidates target rare diseases with small patient populations, we believe that we would need to capture significant market share to achieve meaningful returns on these product candidates. Further, as is

typical of drugs for rare conditions, we would need to establish relatively higher prices in order to generate a return on investment and achieve meaningful gross margins. There can be no assurance that we will be successful in commercializing our orphan drug product candidates, if at all, or that we will be able to generate sufficient revenues from their sales to produce a meaningful return due to the limited market size.

Our manufacturing experience is limited and any failure by us to manufacture our products for commercial sale after receiving FDA approval would materially impact our revenue and financial condition.

The manufacture of drugs for commercial sale is subject to regulation by the FDA under cGMP regulations and by other regulators under other laws and regulations. We cannot assure you that we will continue to manufacture our products under cGMP regulations or other laws and regulations in sufficient quantities for commercial sale, or in a timely or economical manner.

Our manufacturing facilities require specialized personnel and are expensive to operate and maintain. Any delay in the regulatory approval or market launch of product candidates to be manufactured in these facilities will require us to continue to operate these expensive facilities and retain specialized personnel, which may increase our expected losses.

Through our public-private partnership, the New API Facility is complete in Chongqing, China. Our New API Facility in Chongqing was constructed in accordance with an agreement with CQ. Under the current agreement, CQ is responsible for construction of the facility but we are responsible for the costs of all equipment for the facilities. CQ will own the land and buildings, and we will lease the facilities, rent-free, for the first 10-year term, with an option to extend the lease for an additional 10-year term, during which, if we are profitable, we will pay a monthly rent of 5 RMB per square meter of space occupied. We have committed to achieving certain operational, revenue and tax generation milestones within certain time periods once we commence operation. If we are not able to achieve such milestones, CQ will have the opportunity to terminate the agreement and dispose of the plants in its discretion.

Additionally, the New API Facility will need to be cGMP validated. The New API Facility commenced operations in January of 2021, and the facility continues to conduct and complete product qualification activities. Validation is a lengthy process that must be completed before we can manufacture under cGMP requirements. We cannot guarantee that the FDA or foreign regulatory agencies will approve the manufacture of any products at these or other facilities, that such facilities will remain in compliance with cGMP regulations, or that such facilities will maintain a compliance status acceptable to the FDA or other regulatory agencies.

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time. We may not be able to resolve any such difficulties in a timely fashion, if at all. If anything were to interfere with the continuing manufacturing operations in our facilities, it could materially adversely affect our business and financial condition.

Currently, many of our product candidates are manufactured in small quantities for use in clinical trials. We cannot assure you that we will be able to successfully scale up the manufacture of Klisyri or any of our other product candidates in a timely or economical manner. As with Klisyri or other product candidates approved by the FDA or other drug regulatory authorities for commercial sale, we will need to manufacture them in larger quantities. If we are unable to successfully scale up our manufacturing capacity, the regulatory approval or commercial launch of such product candidate may be delayed or there may be a shortage in supply of such product candidate.

If we fail to develop manufacturing capacity and experience, fail to continue to contract for manufacturing on acceptable terms, or fail to manufacture our product candidates economically on a commercial scale or in accordance with cGMP regulations, our development programs and prospects for commercialization will be materially adversely affected. This may result in delays in receiving FDA or foreign regulatory approval for one or more of our product candidates or delays in the commercial production of a product that has already been approved. Any such delays could materially adversely affect our business and financial condition.

The manufacture of API is highly regulated by FDA, NMPA and other regulatory bodies and is subject to current good manufacturing practice requirements and to inspection by such regulators, which may result in adverse findings and actions against certain API manufacturing facilities.

API manufacturing facilities are subject to regulation by the applicable regulatory bodies in the place of manufacture as well as the regulatory agency in the country to which the product is exported. For instance, FDA's cGMP regulations apply to these facilities and violation of these, or other, regulations may result in adverse action against the facility, including cessation of manufacturing activities. Our API manufacturing facility in Chongqing is also subject to regulation by the NMPA. If the FDA, NMPA, DEMC or other regulators discover a problem at one facility, we may be subject to increased scrutiny and/or adverse actions across our operations, including fines or orders to cease manufacturing, which could have a material impact on our operations, clinical development, regulatory approval process, business strategy or results of operations.

We have limited experience in marketing proprietary drug products. If we are unable to establish such marketing and sales capabilities or enter into agreements with third parties to market and sell our proprietary drug candidates, we may not be able to generate sales revenue from such products.

We have limited sales, marketing and commercial product experience. For the product candidates and/or territories where we do not have existing partnerships pursuant to which our partners will be responsible for the marketing and sales of such products, we intend to continue to develop our in-house commercial organization and sales force for such products, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to establish sufficient internal sales, marketing and commercial distribution capabilities for these proprietary drug candidates, we will need to pursue additional collaborative arrangements for the sales and marketing of our proprietary drugs. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have less control over the marketing and sales efforts of such third parties which may present fraud and abuse and other regulatory considerations, and our revenue from product sales may be lower than if we had commercialized our proprietary drug candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our proprietary drug candidates.

There can be no assurance that we will be able to develop our in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any proprietary product, and as a result, we may not be able to generate sales revenue from such products.

Factors that may inhibit our efforts to successfully establish a sales force include:

- an inability to compete with other pharmaceutical companies to recruit, hire, train and retain adequate numbers of effective sales and marketing personnel with requisite knowledge of our target market;
- an inability to effectively manage a geographically dispersed sales and marketing organization in such jurisdictions;
- the inability of sales personnel to obtain access to adequate numbers of physicians to prescribe any future approved products;
- failure to adhere to regulatory requirements governing the sale of products in any jurisdiction;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- a delay in bringing products to market after efforts to hire and train our sales force have already commenced.

In the event we are unable to successfully market and promote our products, our business may be harmed.

We face substantial competition, and our competitors may discover, develop or commercialize competing drugs before or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of the types of cancer for which we are developing and commercializing our drug candidates and drugs. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain approval from the FDA, NMPA or other regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and/or slow our regulatory approval.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with

large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If our competitors market products that are more effective, safer, have fewer side effects or are less expensive than our products or that reach the market sooner than any of our current or future product candidates, if approved, we may not achieve commercial success.

Klisyri® and any of our drug candidates, if approved, may become subject to unfavorable pricing regulations, third party reimbursement practices or healthcare reform initiatives, which could harm our business.

Successful sales of Klisyri® and any of our drug candidates, if approved, depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and commercial payors are critical to new drug acceptance.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country but be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. For example, according to the guidance issued in March 2015 by the central government of China, each province will decide which drugs to include in its provincial major illness reimbursement lists and the percentage of reimbursement, based on local funding. Adverse pricing limitations may hinder our ability to recover our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval. For example, in China, according to a statement entitled Opinions on Reforming the Review and Approval Process for Pharmaceutical Products and Medical Devices, issued by the State Council in August 2015, the enterprises applying for new drug approval will be required to undertake that the selling price of new drug on Chinese mainland market shall not be higher than the comparable market prices of the product in its country of origin or Chinese neighboring markets, as applicable.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which coverage and reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a drug is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for our drugs, if and once approved, and, if coverage and reimbursement are available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. Obtaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any drug candidate that we successfully develop. If we or our partners fail to obtain and sustain an adequate level of coverage and reimbursement for Klisyri® or any current or future product candidates, if approved, by third-party payers, potential future sales would be materially adversely affected. There will be no commercially viable market for Klisyri® or any current or future product candidates, if approved, without adequate coverage and reimbursement from third-party payers, and any reimbursement policy may be affected by future healthcare reform measures. Further, we cannot be certain that adequate coverage and reimbursement will be available for either of our products in jurisdictions outside the U.S. or for any current or future product candidates, if approved. Additionally, even if there is a commercially viable market, if the level of coverage or reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payers, such as government or private healthcare insurers and pharmacy benefit managers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. A current trend in the U.S. healthcare industry is toward cost containment. Large public and private payers, managed care organizations, group

purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payers, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payers limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payers may limit the covered indications. Cost-control initiatives in the U.S. healthcare industry could put downward pressure on the price established for Klisyri® or any current or future product candidates, if approved, which could result in product revenues being lower than anticipated. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payers may not be willing to reimburse for Klisyri® or any current or future product candidates, if approved, which would significantly reduce the likelihood of them gaining market acceptance. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted.

We believe that U.S. third-party payers consider the efficacy, cost effectiveness, safety and tolerability of Klisyri® and will consider such factors of any current or future product candidates, if approved, and whether use of any such products should be a covered benefit under its health plan in determining whether to approve coverage and reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we do not obtain or maintain approval for reimbursement of Klisyri® or any current or future product candidates, if approved, from third-party payers on a timely or satisfactory basis or if pricing is set at unsatisfactory levels. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business could be materially adversely affected if Part D prescription drug plans were to limit access to or deny or limit reimbursement of any of our approved products.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our drugs on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our drugs. However, under Medicare Part D—Medicare's outpatient prescription drug benefit—there are protections in place to ensure coverage and reimbursement for oncology products and all Part D prescription drug plans are required to cover substantially all anti-cancer agents.

The State Council requires central and provincial authorities across China to promote a medical insurance program for major illnesses, which targets covering at least 50% of the medical cost as incurred by treating major illnesses but falls out of the coverage of the basic insurance programs. The Ministry of Human Resources and Social Security of the PRC (the "MHRSS"), together with other government authorities, has the power to determine the medicines included in the National Reimbursement Drug List (the "NRDL"). In February 2017, the MHRSS released the 2017 NRDL, which was amended in 2019, 2020, and 2021. Medicines included in the NRDL are divided into two parts, Part A and Part B. Patients purchasing medicines included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price. Patients purchasing medicines included in Part B of the NRDL are required to pay a certain percentage of the purchase price and obtain reimbursement for the rest of the purchase price. The percentage of reimbursement for Part B medicines differs from region to region in the PRC. The National Healthcare Security Administration requires provincial authorities to increase reimbursement rates step by step.

In some non-U.S. countries, the pricing of drugs and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining regulatory approval of a drug candidate. In addition, market acceptance and sales of our drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our drug candidates and may be affected by existing and future health care reform measures.

If our drug candidates are approved, we intend to test and market our approved drugs in a variety of international markets and we are exploring the licensing of commercialization rights or other forms of collaboration worldwide, which exposes us to additional risks of conducting business in additional international markets.

We conduct business operations in regions including the U.S., China, Taiwan, New Zealand and the United Kingdom, and other non-U.S. markets, including certain countries in Latin America, are an important component of our growth strategy. If we fail to obtain licenses or enter into collaboration arrangements with third parties in these markets, or if these parties are not successful, our revenue-generating growth potential will be adversely affected.

Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- initiatives to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- changes in a specific country's or region's laws, regulations or political and cultural climate or economic condition;
- differing regulatory requirements for drug approvals and marketing internationally;
- difficulty of effective enforcement of contractual provisions and intellectual property rights in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- potential conflicting third-party patent or other intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements, such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties or suspension or revocation of export privileges;
- economic weakness, including inflation or political instability, particularly in non-U.S. economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty and labor unrest, particularly in non-U.S. countries where labor unrest is more common than in the U.S.;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a non-U.S. market with low or lower prices rather than buying them locally;
- failure of our employees and contracted third parties to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to obtain or sustain revenue from international markets.

The use of legal, regulatory, and legislative strategies by both brand and generic competitors, including but not limited to "authorized generics" and regulatory petitions, may increase costs associated with the introduction or marketing of our generic products, could delay or prevent such introduction, and could adversely affect our results of operations.

Our competitors, both branded and generic, often pursue strategies to prevent, delay, or eliminate competition from generic alternatives to branded products. These strategies include, but are not limited to:

- entering into agreements whereby other generic companies will begin to market an authorized generic, a generic equivalent of a branded product, at the same time or after generic competition initially enters the market;
- launching a generic version of their own branded product prior to or at the same time or after generic competition initially enters the market;
- filing petitions with the FDA or other regulatory bodies seeking to prevent or delay approvals, including timing the filings so as to thwart generic competition by causing delays of our product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or to meet other requirements for approval, and/or to prevent regulatory agency review of applications, such as through the establishment of patent linkage (laws and regulations barring the issuance of regulatory approvals prior to patent expiration);
- initiating legislative or other efforts to limit the substitution of generic versions of brand pharmaceuticals;

- filing suits for patent infringement and other claims that may delay or prevent regulatory approval, manufacture, and/or scale of generic products;
- introducing “next-generation” products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the generic or the reference product for which we seek regulatory approval;
- persuading regulatory bodies to withdraw the approval of brand name drugs for which the patents are about to expire and converting the market to another product of the brand company on which longer patent protection exists;
- obtaining extensions of market exclusivity by conducting clinical trials of brand drugs in pediatric populations or by other methods; and
- seeking to obtain new patents on particular formulations of drugs or methods of administering drugs for which patent protection on the drug itself is about to expire.

If any other actions by our competitors and other third parties to prevent or delay activities necessary to the approval, manufacture, or distribution of our products are successful, our entry into the market and our ability to generate revenues associated with new products may be delayed, reduced, or eliminated, which could have a material adverse effect on our business, financial condition, results of operations, cash flows and/or share price.

Risks Related to Compounding

Our compounded preparations and the compounding industry are subject to regulatory and customer scrutiny, which may impair our growth and sales.

Formulations prepared and distributed by outsourcing facilities may contain ingredients found in FDA-approved drugs (i.e., “sterile-to-sterile” compounding) or ingredients that are on FDA’s interim or final list of bulk substances that may be used in compounding. Compounded formulations are subject to various statutory and FDA regulatory requirements. Outsourcing facilities are regulated under FDCA Section 503B. Certain compounding pharmacies and outsourcing facilities have experienced both facility and product quality issues and been the subject of negative media coverage in recent years. Such product quality and facility issues have resulted in increased scrutiny of compounding activities from the FDA and state governmental agencies. For example, the FDA has in the past requested that a number of compounding pharmacies and outsourcing facilities recall unexpired drug products and cease sterile compounding operations due to, among other reasons, lack of assurance of sterility. Pharmacies and outsourcing facilities have also, at the request of FDA, suspended sterile production or voluntarily recalled certain sterile compounded products after an FDA inspection of those facilities. As a result, some prescribers and hospital/clinic purchasing agents may be hesitant to prescribe or procure compounded formulations, and some patients may be hesitant to purchase the same.

In addition, an outsourcing facility must meet certain conditions under Section 503B of the FDCA in order for its compounded products to be exempt from the FDCA’s premarket approval requirements, from the FDCA requirement that products be labeled with adequate directions for use, and serialization and product tracing requirements. For example, the facility must register with FDA and produce at least one sterile drug product, and the drugs must be compounded by or under the direct supervision of a licensed pharmacist. The facility must also operate in compliance with FDA’s cGMP regulations and FDA’s guidance for outsourcing facilities addressing cGMP. If our outsourcing facility or any of our compounded products are found not to satisfy the criteria set forth in Section 503B, the marketing of our products absent Section 503B’s exemptions from FDA's new drug approval requirements, adequate directions for use on the product labeling, or without compliance with certain serialization and product tracing requirements could render our products adulterated or misbranded under the FDCA, which could have an adverse effect on our business.

The source of any bulk substance active ingredient used in compounding must be a Section 510 registered manufacturer, and the bulk substance must be accompanied by a Certificate of Analysis. If the outsourcing facility compounds using bulk drug substances, the bulk drug substances must either appear on FDA’s “interim” list of bulk substances that may be used in compounding under Section 503B which are those bulk drug substances for which FDA has determined there is a clinical need. Drugs may also be compounded if the FDA-approved drug appear on FDA’s published drug shortage list. Provided certain conditions are met, FDA will exercise enforcement discretion concerning use of “interim” Category 1 substances pending evaluation of the substances for inclusion on FDA’s final list of bulk drug substances for which there is a clinical need.

FDA has also finalized guidance on determining whether a product is an “essential copy” of a commercially available product, which the FDA has announced it intends to revisit in 2021. If our products were ever determined to be an essential copy of a commercially available product, FDA could engage in enforcement action. We use bulk drug substances in the preparation of certain of our compounded products. In the event the FDA’s evaluation of these bulk drug substances results in a determination not to include such substances on the FDA’s list of bulk drug substances for which there is a clinical need, or if FDA were to change its interim policy such that compounding with such bulk drug substances could not proceed while the FDA’s evaluation of the substances is pending or until the FDA has issued its final list of bulk drug substances for which there is a clinical need, our ability to continue marketing compounded products subject to Section 503B would be impaired, and our business could be harmed.

If a compounded drug formulation provided by our FDA-registered outsourcing facility leads to patient injury or death, results in a product recall, or causes FDA to request the company shut down its sterile compounding operations, we may be exposed to significant liability and reputational harm.

The production, labeling and packaging of compounded drugs is inherently risky. The success of our compounded formulations and facility operations depends to a significant extent upon perceptions of the safety and quality of our products. We could be adversely affected if our formulations are subject to negative publicity. We could also be adversely affected if any of our formulations or other products, any similar products sold by other companies, or any products sold by other outsourcing facilities, prove to be, or are alleged or asserted to be, harmful to patients. There are a number of factors that could result in the injury or death of a patient who receives one of our compounded formulations, including quality issues, manufacturing or labeling flaws, improper packaging or unanticipated or improper distribution or other uses of the products, any of which could result from human or other error. Any of these situations could lead to a recall of, or safety alert relating to, one or more of our products. Similarly, to the extent any of the ingredients used by us to produce compounded formulations have quality or other problems that adversely affect the finished compounded preparations, our sales could be adversely affected. In addition, in the ordinary course of business, we may voluntarily retrieve products from the field in response to a customer complaint. Because of our dependence upon medical and patient perceptions, any adverse publicity associated with illness or other adverse effects resulting from the use or misuse of our products, any similar products sold by other companies, or related to compounded formulations generally, could have a material adverse impact on our business, results of operations and financial condition.

Risks Related to Our Intellectual Property

A significant portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents, and if our pending patent applications fail to issue our business will be adversely affected. If we are unable to obtain and maintain patent protection for our technology and drugs, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S., China and other countries with respect to our proprietary technology and drug candidates. We have sought to protect our proprietary position by filing patent applications in the U.S., Europe, China and other countries related to novel technologies and drug candidates that we consider important to our business. The process of obtaining patent protection is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There can be no assurance that our pending patent applications will result in issued patents. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our platforms' product candidates. Third parties may have blocking patents that could be used to prevent us from commercializing our patented technologies, platforms and product candidates and practicing our proprietary technology. There can also be no assurance that a third party will not challenge the validity of our patents or that we will obtain sufficient claim scope in those patents, in view of prior art, to prevent a third party from competing successfully with our drug candidates. We may become involved in interference, inter partes review, post grant review, ex parte reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours.

The patent position of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Changes in patent laws or the interpretation of patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until eighteen months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

We may not be able to protect our intellectual property rights throughout the world.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions, due to inconsistent policies regarding the scope of claims allowable in patents. Changes in patent laws and rules, either by legislation, judicial

decisions, or regulatory interpretation in the U.S. and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property.

In addition, the laws of certain non-U.S. countries do not protect intellectual property rights to the same extent as U.S. federal and state laws do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing drugs made using our inventions in and into the U.S. or non-U.S. jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection but where enforcement rights are not as strong as those in the U.S. These drugs may compete with our drug candidates and our patent or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including Latin America and China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and our patent rights relating to our drug candidates could be found invalid or unenforceable if challenged in court or before the U.S. Patent and Trademark Office or comparable non-U.S. authority.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation can be expensive and time-consuming. Our current and potential competitors may have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that patent or other intellectual property rights owned by us are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent or other intellectual property rights do not cover the technology in question. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

If we initiate legal proceedings against a third party to enforce any patent, or any patents that may issue in the future from our patent applications, that relates to one of our drug candidates, the defendant could counterclaim that such patent rights are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include ex parte re-examination, inter partes review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Although any party alleging invalidity or unenforceability of our patents has a high burden of proof, nonetheless such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware of during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on certain drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may be subject to claims challenging the inventorship of our patents and ownership of other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as inventors or co-inventors. For example, we may have inventorship disputes arise

from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, we may lose rights such as exclusive ownership of, or right to use, our patent or other intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including litigation in the U.S. courts, inter partes review, post grant review, interference and ex parte reexamination proceedings before the USPTO or oppositions and other comparable proceedings in non-U.S. jurisdictions. Numerous issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing or commercializing drug candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates or manufacturing processes may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Because patent applications can take many years to issue, patent applications that are currently pending may later result in issued patents that our drug candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies that are first publicized or commercialized after the filing date of those patents infringes upon them. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our drug candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to prevent us from commercializing such drug candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent is held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable drug candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Third parties who bring successful claims against us for infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. In the event of a successful claim of infringement or misappropriation against us, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and monetary expenditure and undertaking additional preclinical studies, clinical trials or regulatory review. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. We cannot predict whether any required license would be available on commercially reasonable terms, or at all, and we may fail to obtain any of these licenses on commercially reasonable terms, if at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical personnel, management personnel, or both from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our products conflict with the intellectual property rights of third parties, we may incur substantial liabilities and we may be unable to commercialize products in a profitable manner or at all.

We seek to launch generic pharmaceutical products either where patent protection or other regulatory exclusivity of equivalent branded products has expired, where patents have been declared invalid or where products do not infringe the patents of others. However, at times, we may seek approval to market generic products before the expiration of patents relating to the branded versions of those products, based upon our belief that such patents are invalid or otherwise unenforceable or would not be infringed by our products. Our success depends in part on our ability to operate without infringing the patents and proprietary rights of third parties. The manufacture use and sale of generic versions of products has been subject to substantial litigation in the pharmaceutical industry. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. If our products were found to be infringing the intellectual property rights of a third-party, we could be required to cease selling the infringing products, causing us to lose future sales revenue from such products and face substantial liabilities for patent infringement, in the form of payment for the innovator's lost profits or a royalty on our sales of the infringing product. These damages may be significant and could materially adversely affect our business. Any litigation, regardless of the merits or eventual outcome, would be costly and time consuming and we could incur significant costs and/or a significant reduction in revenue in defending the action and from the resulting delays in manufacturing, marketing or selling any of our products subject to such claims.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other patent agencies in several stages over the lifetime of the patent. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment of a patent application or lapse of a patent include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The terms of our patents may not be sufficient to effectively protect our drug candidates and business.

In most countries in which we file patent applications, including the U.S., the term of an issued patent is twenty years from the earliest claimed filing date of a non-provisional patent application in the applicable country. With respect to any issued patents in the U.S., we may be entitled to obtain a patent term extension or extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. Although such extensions may be available, the life of a patent and the protection it affords is by definition limited. Even if patents covering our drug candidates are obtained, we may be open to competition from other companies as well as generic medications once the patent life has expired for a drug. If patents are issued on our currently pending patent applications, the resulting patents will be expected to expire on dates ranging approximately from 2024 to 2040, excluding any potential patent term extension or adjustment. Upon the expiration of our issued patents, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our technologies, platforms and product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that a related patent may expire before any particular product candidate can be commercialized or that such patent will remain in force for only a short period following commercialization, thereby reducing any significant advantage of the patent.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar legislation in other countries extending the terms of our patents, if issued, relating to our drug candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our U.S. patents, if issued, may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. Patent term extensions, however, cannot extend the remaining term of a patent beyond a total of fourteen years from the date of drug approval by the FDA, and only one patent can be extended for a particular drug.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension due to, for example, failure to apply within applicable deadlines, failure to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection

afforded could be less than we request. If we are unable to obtain a patent term extension for a given patent or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be shortened and our competitors may obtain earlier approval of competing drugs. As a result, our ability to generate revenues could be materially adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although we do not believe that our issued patents or any patents that may issue from our pending patent applications directed to our drug candidates if issued in their currently pending forms, as well as patent rights licensed by us, will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent or our other intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may also be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

In addition to our issued patents and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our confidentiality and other agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors require them to assign to us or grant us licenses to inventions they invent as a result of the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but litigation may be necessary in the future to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending

against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. Further, to the extent that our employees, contractors, consultants, collaborators and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in the security of our systems, security measures may be breached, and we may not have adequate remedies for any such breach.

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through acquisitions and in-licenses.

Because our programs may involve additional drug candidates that require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into license agreements with third parties providing us with rights under various third-party patents and patent applications, including the rights to prosecute patent applications and to enforce patents. Certain of these license agreements impose and, for a variety of purposes, we may enter into additional licensing and funding arrangements with third parties that also may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. Under our license agreements for the cell therapy platform, we are obligated to pay royalties on net sales of drug products, if commercialized, and milestone payments related to the development and commercialization of any drug candidates developed from the licensed platform. We may be obligated to make other specified payments relating to our drug candidates and/or pay license maintenance and other fees. In our agreements with BCM, we are also required to meet our co-development obligations with BCM, and if we fail to do so, BCM may terminate our agreements relating to the cell therapy platform. Certain of the license agreements relating to our Orascovery platform provide us with the exclusive right to practice technologies in major markets including North America, South America, the EU, Australia, New Zealand, Eastern Europe, China, Taiwan, Hong Kong, Macau and parts of Southeast Asia, although the right to practice the technologies and any inventions arising out of such technologies outside of these territories may be reserved to the licensing company. We also have clinical development obligations under certain of these agreements that we are required to satisfy. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided in these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

In particular, our ability to stop third parties from making, using, selling, offering to sell or importing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending, and enforcing patent claims that cover our technology, inventions and improvements. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our platforms and product candidates and the methods used to manufacture those platforms and product candidates. Our issued patents and those that may issue in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related platforms or product candidates or limit the length of the term of patent protection that we may have for our technologies, platforms and product candidates.

If our licensing and sublicensing activities result in non-compliance with our licensing agreements, our business relationships with our licensing partners may suffer and we may be required to pay monetary damages or rescind or amend existing agreements which are important to our business.

We have entered into agreements with third parties under which we have granted licenses to use certain of our patents and patent applications, including the rights to develop, seek regulatory approval for and sell products using our tirbanibulin 1% ointment, including to Almirall, which has rights to the U.S. and E.U. markets. We have also entered into similar agreements sublicensing the intellectual property for the Orascovery platform, which we have licensed from Hanmi. We have granted exclusive patent rights to certain of these partners and have granted them certain additional rights with respect to the intellectual property we have licensed to them. From time to time we may engage in other licensing transactions in which we acquire licenses to certain intellectual property or sublicense intellectual property rights. If we fail to comply with or are found to have violated the terms of any of our licenses, we may be required to rescind or amend our license agreements or pay damages to license counterparties or other rightsholders. This may also negatively impact our relationships with our licensing and sublicensing partners for our candidate platforms. For further information regarding the terms of our licenses, please see "*Business—License and Collaboration Agreements*".

We depend on our agreements with Hanmi to provide rights to the intellectual property relating to certain of our product candidates. Any termination or loss of significant rights under those agreements would adversely affect our development or commercialization of our lead product candidates.

We have licensed the intellectual property rights related to encequidar, an integral part of our current Orascovery product candidates, from Hanmi pursuant to two license agreements. If, for any reason, our license agreements are terminated or we otherwise lose those rights, it would adversely affect our business. Our license agreements with Hanmi impose on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages to Hanmi, and Hanmi may have the right to terminate our license, which could result in us being unable to develop, manufacture and sell our product candidates that incorporate encequidar.

In addition, under our 2013 license agreement with Hanmi, we have granted Hanmi a one-time right of first negotiation that, at Hanmi's discretion, requires us to negotiate in good faith the sale of our rights in Oral Paclitaxel and Oral Irinotecan under such agreement to Hanmi at a purchase price determined by an internationally-recognized investment banking firm with an office in Hong Kong at any time prior to the earlier of (1) our first commercial sale of products using such technology or (2) receipt by Hanmi of written notice from our company of the sublicense of the rights in an applicable product to a third party. If Hanmi exercises this right of first negotiation and we reach an agreement to sell our rights under that licensing agreement, our ability to continue to develop certain of our product candidates would be significantly impaired and would adversely affect our business and results of operations.

Each of our license agreements with Hanmi expires on the earlier of (1) expiration of the last of Hanmi's patent rights licensed under the agreement or (2) invalidation of Hanmi's patent rights which are the subject of the agreement, provided that the term will automatically be extended for consecutive one year periods unless either party gives notice to the other at least ninety days prior to expiration of the patent rights licensed under the agreement or before the then current annual expiration date of the agreement. The patent rights licensed to us under the agreements with Hanmi have expiry dates ranging from 2023 to 2033, unless the terms of such licensed patents are extended in accordance with applicable laws and regulations. Subject to certain conditions, Hanmi may also terminate the license agreements if we fail to comply with certain development milestones set out in each of the agreements. The agreements also contain customary termination rights for either party, such as in the event of a breach of the agreement or the initiation of bankruptcy proceedings by the other party or by mutual agreement. For further information regarding the license terms, right of first negotiation and termination provisions of the Hanmi in-license agreements, please see "*Business—License and Collaboration Agreements—In-Licenses —Hanmi Licensing Agreements*."

Risks Related to Our Reliance on Third Parties

We may rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, perform satisfactorily or operate in compliance with laws and regulations, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We have relied upon and may, in the future, rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, NMPA and other regulatory authorities for all of our drugs in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, NMPA or regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical and preclinical programs. In the event that any of our foreign CROs are impacted by political, social or financial instability, they may be unable to maintain production capacity or compliance with regulatory requirements. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, environmental, health and safety laws and regulations, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our total revenue is highly dependent on a limited number of pharmaceutical wholesalers, and the loss of, or any significant decrease in business from, any one or more of our major pharmaceutical wholesalers could adversely affect our financial condition and results of operations.

We have derived a significant portion of our revenue from a limited number of customers, as is typical in the pharmaceutical industry. During the years ended December 31, 2021, 2020 and 2019, we generated 49%, 38% and 45% of our total revenue, respectively, from the three largest wholesalers in the U.S. market. If we are unable to maintain our business relationships with these major pharmaceutical wholesalers on commercially acceptable terms, it could have a material adverse effect on our financial condition and results of operations. Even if we are able to maintain our relationships with customers, a change in the mix of products those customers purchase and which we are able to produce may affect our gross margin and results of operations.

If our Global Supply Chain Platform is insufficient, we will rely on third parties to manufacture our drug candidate supplies and our drug candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We rely on outside vendors to manufacture supplies and process our drug candidates. Our capacity to manufacture and process drugs on a commercial scale is limited and we may not be able to do so for all of our drug candidates. We have limited experience in managing the manufacturing process, and our process may be more difficult or expensive than the approaches currently in use. Accordingly, we may use third parties for our manufacturing process. Our reliance on third-party manufacturers may expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA, NMPA or other regulatory authorities must approve any manufacturers. This approval would require new testing and cGMP-compliance inspections by FDA, NMPA or other regulatory authorities. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drugs;
- our manufacturers may have little or no experience with manufacturing our drug candidates and, therefore, may experience quality issues or require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our drug candidates;
- our third-party manufacturers might be unable to timely manufacture our drug or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our drugs, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drugs;

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drugs;
- our third-party manufacturers could breach or terminate their agreement with us;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may experience supply chain difficulties or other business continuity issues related to events beyond their control such as fires, floods, earthquakes, hurricanes, epidemics, quarantines, wars, civil unrest, strikes or governmental action; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Each of these risks could delay or prevent the completion of our trials or the approval of any of our drug candidates by the FDA, NMPA or other regulatory authorities, result in higher costs or adversely impact commercialization of our drug candidates. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not conducted appropriately and test data are not reliable, patients could be put at risk of serious harm and the FDA, NMPA or other regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

The manufacture of drug and biological products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.

Currently, raw materials used in our drug products, including the pacific yew used in many of the API products we manufacture, are supplied by multiple suppliers. We have agreements for the supply of such raw materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. Furthermore, if contaminants are discovered in our supply of our drug candidates or in our or third parties' manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

If third-party manufacturers fail to comply with pharmaceutical manufacturing regulations, our financial results and financial condition will be adversely affected.

Before a third party can begin commercial manufacture of our drug candidates and potential drugs, contract manufacturers are subject to regulatory inspections of their manufacturing facilities, processes and quality systems. Due to the complexity of the processes used to manufacture drug and biological products and our drug candidates, any potential third-party manufacturer may be unable to initially pass federal, state or international regulatory inspections in a cost-effective manner in order for us to obtain regulatory approval of our drug candidates. If our contract manufacturers do not pass their inspections by the FDA, NMPA or other regulatory authorities, our commercial supply of drug product or substance will be significantly delayed and may result in significant additional costs, including the delay or denial of any marketing application for our drug candidates. In addition, drug and biological manufacturing facilities are continuously subject to inspection by the FDA, NMPA and other regulatory authorities, before and after drug approval, and must comply with cGMPs. Our contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business, reputation or corporate image. If a third-party manufacturer with whom we contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our drugs, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial results and financial condition.

Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, could require prior review by the FDA, NMPA or other regulatory authorities and/or approval of the manufacturing process and procedures in accordance with the FDA or NMPA's regulations, or comparable requirements. This review may be costly and time consuming and could delay or prevent the launch of a product. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that the FDA, NMPA or other regulatory authorities may require clinical testing as a way to prove equivalency, which would result in additional costs and delay.

We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We have partnered with companies such as BCM, Hanmi, Almirall, Xiangxue, XLifeSc and Gland and may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties, subject to any restrictions imposed by our financing arrangements, that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our early stage drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party.

Further, collaborations involving our drug candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or drug candidates;
- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator, including disputes over amounts payable under the agreements, that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates; and
- collaborators may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our drugs, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential

commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

We have engaged and will continue to rely on a single vendor to manage our order to cash cycle and our distribution activities in the U.S., and the loss or disruption of service from this vendor could adversely affect our operations and financial condition.

Our U.S. customer management, order processing, invoicing, cash application, chargeback and rebate processing and distribution and logistics activities are managed by Eversana Life Science Services ("Eversana"), a managed services provider with a focus on life sciences companies. If we were to lose the availability of Eversana's services due to a dispute, termination of or inability to renew the contract, or business continuity issues due to events beyond their control such as fires, floods, earthquakes, hurricanes, epidemics, quarantines, wars, civil unrest, strikes or governmental action, such loss could have a material adverse effect on our operations. Although multiple providers of such services exist, there can be no assurance that we could secure another source to handle these transactions on acceptable terms or otherwise to our specifications in the event of a disruption of services at operational centers.

Risks Related to Our Industry, Business and Operations

We are dependent on our key personnel, and if we are not successful in attracting and retaining qualified personnel, we may not be able to successfully implement our business strategy. Additionally, certain members of our leadership may engage in other business ventures that may have interests in conflict with ours.

We are highly dependent on Dr. Lau, our Chief Executive Officer, Dr. Kwan, our Chief Medical Officer, Dr. Lang, the president of Athenex Cell Therapy, and Mr. Yordon, our Chief Operating Officer, and the other principal members of our management and scientific teams. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants and restricted stock awards that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by changes in the price of our common stock that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel or consultants will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and preclinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

The loss of any member of the Company's senior management, either permanently or for an indeterminate period of time, and/or failure to successfully implement our succession plan to enable the effective transfer of knowledge or to facilitate smooth transitions in leadership could significantly disrupt the management of the Company's business and impair the Company's ability to execute its business strategies. We have experienced significant changes in senior management in recent years, including the departure of our Chief Financial Officer, General Counsel and President, China Division, and more changes could occur. Furthermore, replacing executive officers and key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Senior management transition periods, including adding new personnel, could be difficult as new employees gain an understanding of our business and strategy. If we are unable to successfully integrate new employees, we may have difficulty maintaining compliance with our internal control over financial reporting, disclosure controls and procedures, and executing our business strategy, which could have an adverse effect on our overall financial condition.

We may choose to hire part-time employees or use consultants. As a result, certain of our employees, officers, directors and consultants may not devote all of their time to our business, and may from time to time serve as officers, directors and consultants of other companies. These other companies may have interests in conflict with ours. For instance, Dr. Johnson Lau, who serves as our Chief Executive Officer and Chairman, and Dr. Manson Fok, who serves on our board of directors, are also directors of Avalon, a stockholder of ours. Dr. Lau also serves as the Chief Executive Officer of Axis, a joint venture that we majority own.

We also face competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We are substantially dependent on our public-private partnerships and if we or our counterparties fail to meet the obligations of those agreements and we lose the benefits of those partnerships, it would materially impact our development, operations and prospects.

We have entered into an arrangement with CQ relating to in the New API Facility in Chongqing, China, under which we have committed to achieving certain operating, revenue and tax generation milestones in exchange for CQ constructing the facility on our behalf. If we are unable to comply with our obligations under these arrangements, including the milestones we have committed to achieve, we may lose access to the properties covered by such arrangements which could disrupt our operations and manufacturing activities, cause us to divert resources to finding alternative facilities, which would not have any subsidies, and would have a significant impact on our operations and financial performance. We may also be subject to lawsuits or claims for damages against us if we are unable to comply with our obligations under these arrangements.

Furthermore, there is no guarantee that the counterparties to our public-private partnerships will comply with the terms of the agreements, including that their ability to fund their capital commitments under the agreements may be subject to their ability to raise additional capital and that construction timetables may not be met, nor is there guarantee that the successors to such counterparties will continue to comply with terms of the agreements, regardless of existence of such government stipulations as a guideline released on November 4, 2016 by the State Council of China, which provides that, among others governments and relevant departments at all levels shall strictly keep policy commitments lawfully made to society and administrative counterparties, shall carefully perform all the contracts lawfully entered into with investment subjects in activities like attraction of investment and public-private partnership, shall not breach contracts with such excuses as government transition and replacement of leaders, and shall bear legal and economic liability in event of their infringements and contract breaches. If our public-private partnership counterparties or their successors fail to comply with their obligations under these arrangements, our development programs and prospects will be materially adversely affected. Public-private partnerships are also subject to risks associated with government and government agency counterparties, including risks related to government relations compliance, sovereign immunity, shifts in the political environment, changing economic and legal conditions and social dynamics.

We may experience difficulties in managing our growth.

As our development and commercialization plans and strategies develop, and as we continue to operate as a public company, we may need to add a significant number of additional managerial, operational, sales, marketing, financial and other personnel to meet our operational needs. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees, particularly with respect to the build out of our marketing and sales team as we begin to commercialize approved products, including key leadership roles;
- managing our internal development and commercialization efforts effectively, including the clinical and FDA or other comparable authority review process for our drug candidates and developing and implementing marketing and sales plans, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. In addition, we expect to incur additional costs in hiring, training and retaining such additional personnel.

If we are not able to effectively expand our organization when necessary by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals.

We have a material weakness in our internal control over financial reporting, which if left unremediated could impact our ability to accurately report our consolidated financial results and may adversely affect the market price of our common stock.

As of December 31, 2021, we had a material weakness in our internal control over financial reporting related to our control over the review of the annual goodwill impairment analysis, and as a result, our internal control over financial reporting was not effective as of December 31, 2021. We cannot assure you that there will not be additional material weaknesses and significant deficiencies that our independent registered public accounting firm or we will identify in the future. Under standards established by the Public

Company Accounting Oversight Board, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected and corrected on a timely basis. As a public company, we also need to establish and maintain effective disclosure and financial controls and make changes in our corporate governance practices including our board and committee practices. Remediating this material weakness will require us to evaluate the assignment of internal and external responsibilities and we may have to hire or contract for additional resources, including potentially contracting with specialists to assist with technical aspects of management review, among other steps to strengthen the design of our internal control environment. Implementing any future changes to our internal controls may entail substantial costs, require additional training for our directors, officers and employees, and take a significant period of time to complete. If we are unable to remediate this material weakness, identify such additional issues or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected, and we may be unable to maintain compliance with applicable listing requirements.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected, which would cause us to be unable to produce accurate financial statements and may adversely affect our business.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our executive officers, employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the U.S., including regulations of the FDA and other similar non-U.S. regulatory authorities; provide true, complete and accurate information to the FDA and other similar non-U.S. regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse and privacy laws in the U.S. and similar non-U.S. fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. In addition to Klisyri, which was approved by the FDA in December 2020, if we obtain FDA approval of additional drug candidates and begin commercializing those drugs in the U.S., our potential exposure under U.S. laws will continue to increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We may have conflicts of interest with our affiliates and related parties, and in the past, we have engaged in transactions and entered into agreements with affiliates that were not negotiated at arms' length.

We have engaged, and may in the future engage, in transactions with affiliates and other related parties. These transactions may not have been, and may not be, on terms as favorable to us as they could have been if obtained from non-affiliated persons. While an

effort has been made and will continue to be made to obtain services from affiliated persons and other related parties at rates and on terms as favorable as would be charged by others, there will always be an inherent conflict of interest between our interests and those of our affiliates and related parties. Our affiliates may economically benefit from our arrangements with related parties. If we engage in related party transactions on unfavorable terms, our operating results will be negatively impacted.

We have engaged, and may engage in future, acquisitions or strategic partnerships that increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

Subject to any limitations imposed by our financing arrangements, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. For example, in May 2021, we acquired Kuur and its Cell Therapy technology. To realize the anticipated benefits of the Kuur acquisition, we must successfully integrate Kuur's business with ours. The integration of Kuur's business and any potential acquisition or strategic partnership entails numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- dilution of our stockholders due to the issuance of additional equity securities upon the achievement of milestones, including those provided for in the merger agreement with Kuur;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- conducting R&D activities in new therapeutic areas or treatment modalities in which we have little experience;
- integrating global operations and conducting our business in multiple geographic areas, each with its own legal system and regulations;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Our internal computer systems, or those used by our CROs, collaboration partners, third-party service providers or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of cybersecurity measures, our information technology and Internet based systems, including those of our current and future CROs, collaboration partners, third-party service providers and other contractors and consultants, are vulnerable to damage, interruption, or failure from computer viruses, unauthorized access, intrusion, and other cybersecurity incidents. As the majority of our workforce works remotely due to the ongoing COVID-19 pandemic, we face heightened risks related to remote work, including strain on our information technology systems, coordination issues and the threat of cyber-security incidents related to unauthorized system access, aggressive social engineering tactics, and attacks on our information technology systems used to conduct our business. This could result in the exposure of sensitive data including the loss of trade secrets, intellectual property, personal identifiable or sensitive information of employees, customers, partners, clinical trial patients and others, leading to a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we partially rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar cybersecurity incidents relating to their computer systems could also have a material adverse effect on our business. Certain data security breaches must be reported to affected individuals and the government, and in some cases to the media, under provisions of HIPAA, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, and financial penalties may also apply. To the

extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed.

We are aware of a security breach that occurred in March 2017. That incident occurred when the credentials of an approved consultant were compromised, and the consultant's credentials were used to access the remote desktop server and active directory server of our wholly owned subsidiary APS. Upon discovery of the breach, we immediately took steps to void the compromised credentials and reset all credentials having access to APS's systems. These particular APS information systems are independent of ours and did not contain any drug candidate, clinical trial or patient-specific data. However, information stored on APS' systems may have been vulnerable during the intrusion. To help mitigate future incidents, we have put in place enhanced security measures required for access by consultants. Notwithstanding such measures, we cannot be certain that no future security breaches will occur or that future breaches will not result in a material disruption of our development programs and our business operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, CROs, suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics or pandemics, acts of war or terrorism, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. In addition, we partially rely on our third-party research collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our drug candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates or our 503B products.

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk as we commercialize our clinical candidates, once approved. For example, we may be sued if our drugs that we manufacture, or our 503B products that we currently manufacture or plan to manufacture cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, as applicable, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drugs;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any drug candidate; and
- a decline in the price of our common stock.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with collaborators. Although we currently carry clinical trial insurance, which we believe to be adequate for our current operations, the amount of such insurance coverage may not be adequate now, or in the future, and we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Additionally, we may be sued if the products that we commercialize, market or distribute for our partners cause or are perceived to cause injury or are found to be otherwise unsuitable, and may result in:

- decreased demand for those products;
- damage to our reputation;
- costs incurred related to product recalls;
- limiting our opportunities to enter into future commercial partnership; and
- a decline in the price of our common stock.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources.

We maintain property insurance policies covering physical damage to, or loss of, our buildings and their improvements, equipment, office furniture and inventory as well as business interruption insurance covering loss of income & extra expenses associated with physical damage to our property. We maintain workers' compensation/employer's liability insurance covering death or work-related injury of employees. We purchase general liability insurance covering certain incidents involving third parties that occur on or in the premises of the company, and products liability insurance covering certain incidents involving third parties resulting from our products. We purchase directors' and officers' liability insurance and employment practices liability insurance. We do not maintain key-man life insurance on any of our senior management or key personnel. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We may increasingly become a target for public scrutiny, including complaints to regulatory agencies, negative media coverage, including social media and malicious reports, all of which could severely damage our reputation and materially and adversely affect our business and prospects.

We focus on the development of drugs used in the treatment of cancers, and such drugs may be the subject of regulatory, watchdog and media scrutiny and coverage, which also creates the possibility of heightened attention from the public, the media and our participants. In addition, members of our management and board include high-profile public figures who may be the subject of media and negative publicity and attention. From time to time, these objections or allegations, regardless of their veracity, may result in public protests or negative publicity, which could result in government inquiry or harm our reputation. Corporate transactions we or related parties undertake may also subject us to increased media exposure and public scrutiny. There is no assurance that we would not become a target for public scrutiny in the future or such scrutiny and public exposure would not severely damage our reputation as well as our business and prospects.

In addition, our directors and management have been in the past, and may continue to be, subject to scrutiny by the media and the public regarding their activities in and outside our company, which may result in unverified, inaccurate or misleading information about them being reported by the press. Negative publicity about our directors or management, even if untrue or inaccurate, may harm our reputation.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred net operating losses ("NOLs") for U.S. federal income tax purposes. Unused NOLs will carry forward to offset future taxable income, if any, until such unused NOLs expire (if ever). NOLs generated after December 31, 2017 are not subject to expiration, but the yearly utilization of such NOLs is limited to 80 percent of taxable income. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an ownership change (generally defined as a greater than 50 percentage points change (by value) in the equity ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock over any three-year period), the corporation's ability to use its pre-change NOLs and other

pre-change tax attributes to offset its post-change income may be limited. We believe that we have experienced such a change in 2021 and may experience more in the future, which may affect our ability to utilize our NOLs. As of December 31, 2021 and 2020, we had federal NOLs of approximately $93.7 million and $184.8 million, respectively, that could be limited by our past and any future ownership change, which could have an adverse effect on our future results of operations. The change in 2021 is a result in a reduction of $108.9 million from a Section 382 limitation that occurred in 2021, less an increase in potentially limited NOLs of $17.8 million as a result of the Kuur acquisition. Similar limitations will apply to our ability to carry forward any unused tax credits to offset future taxable income.

If our manufacturing facilities are damaged or destroyed or production at such facilities is otherwise interrupted, our business and prospects would be negatively affected.

If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA, NMPA or and other comparable regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales for any of our approved drugs.

Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. A number of factors could cause interruptions, including:

- the continued suspension or termination of operations at the New API Facility by the DEMC;
- plant shutdowns as a result of the ongoing COVID-19 pandemic;
- supply chain disruptions;
- regulatory holds on operations at the facilities or the loss of permits to operate facilities;
- equipment malfunctions or failures;
- malfunctions or compromise by third party actors of our technology systems;
- work stoppages;
- damage to or destruction of either facility due to natural disasters;
- regional power shortages;
- product tampering; or
- acts of war or terrorist activities.

Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition and operating results.

If we are unable to perform the clinical testing required to obtain regulatory approval, we will be unable to commercialize our product candidates.

Currently, we maintain insurance coverage against damage to our property and equipment. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our drug candidates if there were a catastrophic event or failure of our manufacturing facilities or processes.

Risks Related to Government Regulation

Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our drug candidates and affect the prices we may obtain.

In the U.S., China and certain other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any additional drug candidates for which we obtain regulatory approval.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this

legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The ACA included provisions to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among other things, the ACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program, imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole," which is now 70% of the negotiated price. There have been efforts to repeal or overturn the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, starting in 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. The Medicare reductions phase back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2% reduction. There may be additional reductions in Medicare and other healthcare funding as a result of future legislation.

We expect that the ACA, as well as other healthcare reform legislative measures that have been since adopted or may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

For example, on November 20, 2020, the United States Department of Health and Human Services ("HHS") finalized a regulation removing safe harbor protection under the Federal Anti-Kickback Statute for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law or unless it is passed through to the dispensing pharmacy and reflected in the price to the patient. The implementation of the rule has been delayed by the Biden administration to January 1, 2023 in response to ongoing litigation. In addition, effective January 1, 2024, a provision capping the rebate amount under the Medicaid Drug Rebate program at 100% of AMP will be eliminated, which means that a manufacturer could pay a rebate amount on a unit of the drug that is greater than the price the manufacturer receives for the drug. Further, effective January 1, 2023, a final rule issued by CMS will change the way copay assistance program prices are treated in best price for purposes of the Medicaid Drug Rebate Program. This change could result in manufacturers eliminating their patient assistance programs, which would make many innovator drugs more expensive for patients. This final rule is subject to ongoing litigation, but it is not clear when a decision will be made or how the court will rule.

In addition, on September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. Many similar proposals, including the plans to give Medicare Part D authority to negotiate drug prices, require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation, and cap out-of-pocket costs, have already been included in policy statements and legislation currently being considered by Congress. It is unclear to what extent these and other statutory, regulatory, and administrative initiatives will be enacted and implemented, and to what extent these or any future legislation or regulations by the Biden administration will have on our business, including market acceptance, and sales, of our products and product candidates.

Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict coverage and reimbursement and sales and promotional activities, for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether agencies such as the FDA or the Centers for Medicare & Medicaid Services will issue new regulations, guidance or interpretations that may impact our drug candidates. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We are subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and privacy and security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of our products and any of our product candidates for which we obtain regulatory approval. Our operations are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician payment transparency laws and regulations. These laws may impact, among other things, our proposed sales and marketing programs as well as any patient support programs we may consider offering. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act which imposes criminal and civil penalties, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent, including failure to timely return an overpayment received from the federal government or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- provisions of HIPAA, which created new federal criminal statutes referred to as the "HIPAA All-Payor Fraud Prohibition," prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to all payments or other transfers of value made to physicians, physician assistants, certain types of advance practice nurses, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members unless a specific exclusion applies; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the Federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that

the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring civil whistleblower or qui tam actions on behalf of the U.S. government under the Federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the U.S. will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Lastly, political, economic and regulatory influences are subjecting the health care industry in the U.S. to fundamental change. Initiatives to reduce the federal budget and debt and to reform health care coverage are increasing cost-containment efforts. We anticipate that federal agencies, Congress, state legislatures, and the private sector will continue to review and assess alternative health care benefits, controls on health care spending, and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit coverage for or the amounts that federal and state governments will pay for health care products and services, which could also result in reduced demand for our products or additional pricing pressures, and limit or eliminate our spending on development projects and affect our ultimate profitability.

Our business is subject to applicable laws and regulations relating to sanctions, anti-money laundering and anti-bribery practices, the violation of which could adversely affect our operations.

We must comply with all applicable economic sanctions, anti-money laundering and anti-bribery laws and regulations of the U.S. and other foreign jurisdictions where we operate, including China. U.S. laws and regulations applicable to us include the economic trade sanctions laws and regulations administered by the U.S. Department of the Treasury's Office of Foreign Assets Control, or OFAC, as well as certain laws administered by the U.S. Department of State. Our business is also subject to anti-money laundering laws and regulations, including the Proceeds of Crime Act 2002, the Terrorism Act 2000 and the Money Laundering Regulations 2007 in the U.K., the Bank Secrecy Act of 1970, the Money Laundering Control Act of 1986 and the USA PATRIOT Act of 2001 in the U.S. and equivalent or similar legislation in the other countries where we do business. In addition, we are subject to the FCPA and other anti-bribery laws such as the U.K. Bribery Act 2010 that generally prohibit the corrupt provision of anything of value to foreign governments and their officials and political parties for the purpose of influencing official conduct or obtaining or retaining an undue business advantage. Applicable anti-bribery laws also may prohibit commercial bribery.

We have operations, conduct clinical trials, deal with government entities, including hospitals and public health regulators, and have contracts in countries known to experience corruption and commercial bribery. Our activities in these countries, particularly China and countries in Latin America, create the risk of unauthorized payments or offers of payments by our employees, brokers or agents that could be in violation of various laws, including the FCPA, even though these parties are not always subject to our control and supervision. Corruption, extortion, bribery, pay-offs, theft and other fraudulent practices occur from time-to-time in China, where we conduct business. There is no assurance that our existing safeguards and procedures will be completely effective in ensuring compliance with such laws, and our employees, brokers or agents may engage in conduct for which we may be held responsible. Violations of the FCPA or other anti-bribery laws may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our reputation, business, operating results, and financial condition.

Regulations administered by OFAC govern transactions with countries and persons subject to U.S. trade sanctions. We are also subject to U.S. Government restrictions on transactions with specific entities and individuals, including, without limitation, those set forth on the Entity List, the Specially Designated Nationals List, the Denied Persons List, the Unverified List, and the U.S. State Department's lists of debarred parties and sanctioned entities, and we may also be subject to restrictions on transactions with specific entities and individuals subject to the sanctions administered by the United Nations Security Council, the EU, Her Majesty's Treasury, or other relevant sanctions authority. These regulations prohibit us from entering into or facilitating unlicensed transactions with, for

the benefit of, or in some cases involving the property and property interests of such persons, governments, or countries designated by the relevant sanctions authority under one or more sanctions regimes. Failure to comply with these sanctions and embargoes may result in material fines, sanctions or other penalties being imposed on us or other governmental investigations. In addition, various state and municipal governments, universities and other investors maintain prohibitions or restrictions on investments in companies that do business involving sanctioned countries or entities.

International economic and trade sanctions are complex and subject to frequent change, including jurisdictional reach and the lists of countries, entities, and individuals subject to the sanctions. Current or future economic and trade sanctions regulations or developments might have a negative impact on our business or reputation, and we may incur significant costs related to current, new, or changing sanctions programs, as well as investigations, fines, fees or settlements, which may be difficult to predict. In addition, companies subject to SEC reporting obligations are required under Section 13 of the Exchange Act to disclose in their periodic reports specified dealings or transactions involving Iran or other individuals and entities targeted by certain sanctions promulgated by OFAC that the reporting company or any of its affiliates engaged in during the period covered by the relevant periodic report. In some cases, Section 13 requires companies to disclose transactions even if they are permissible under U.S. law. The SEC is required to post this notice of disclosure pursuant to Section 13 on its website and report to the President and certain congressional committees regarding such filings.

Although we have policies and controls in place that are designed to ensure compliance with these laws and regulations, it is possible that an employee or intermediary could fail to comply with applicable laws and regulations. In such event, we could be exposed to civil penalties, criminal penalties and other sanctions, including fines or other punitive actions, and the government may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries, and modifications to compliance programs, which may increase compliance costs. In addition, such violations could damage our business and/or our reputation. Such criminal or civil sanctions, penalties, other sanctions, and damage to our business and/or reputation could have a material adverse effect on our financial condition and results of operations.

Any failure to comply with applicable regulations and industry standards or obtain various licenses and permits could harm our reputation and our business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the U.S., and in non-U.S. jurisdictions including China and countries in Latin America, impose strict rules, regulations and industry standards governing pharmaceutical and biotechnology research and development and manufacturing and marketing activities, which apply to us. Our failure to comply with such regulations could result in the termination of ongoing research or manufacturing and marketing, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our reputation, prospects for future work and operating results. For example, if we were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and our drugs could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our drugs. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from our product sales, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

Risks Related to Our Doing Business in China

Tensions between the U.S. and China over Hong Kong and any continued heightening of retaliatory policies may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

We have operations in Hong Kong and expect that a portion of our future revenue will be sourced from licensing partnerships and API sales in China. Accordingly, our operations, financial condition and results of operations are affected by economic, political and legal developments between the U.S. and China. The continued tensions between the U.S. and China over China's June 30, 2020 enactment of a new national security law in Hong Kong has resulted in heightened diplomatic tensions and a number of escalating retaliatory measures by the U.S. and China, including in an executive order signed by former President Trump on July 14, 2020, which ended the special economic status that was afforded to Hong Kong under the United States-Hong Kong Policy Act of 1992, a U.S. ban on investments in businesses linked to China's military, the U.S. announcement of the removal of restrictions on U.S. government official interactions with Taiwan and new rules issued by the Communist Party of China that would allow PRC courts to impose penalties on persons for complying with foreign sanctions that impose prohibitions or restrictions on Chinese economic or trade relationships.

These political tensions between the U.S. and China, together with the uncertainties around the Biden administration's stance with respect to China, create uncertainties for doing business in China, including compliance risks that may arise from retaliatory regulations, restrictions on technology transfers between the countries or measures enacted that further impede our ability to repatriate capital from our subsidiaries in China. The uncertainties caused by continued tensions, together with the risk of escalating retaliatory policies could increase our cost of doing business, adversely affect our business, financial condition and results of operations and may result in our inability to sustain our operations, and growth and expansion strategies with respect to China.

The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs.

Certain of our research operations and manufacturing facilities are in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. PRC authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach is aligned with the PRC government's policies, but we cannot ensure that our strategy and approach will continue to be aligned.

Fluctuations in exchange rates could result in foreign currency exchange losses, which may adversely affect our financial condition, results of operations and cash flows.

We incur portions of our expenses, and may in the future derive revenues, in currencies other than U.S. dollars, in particular, the RMB. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. For example, a portion of our clinical trial activities are conducted outside of the U.S., and associated costs may be incurred in the local currency of the country in which the trial is being conducted, which costs could be subject to fluctuations in currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in countries in which we conduct clinical trials could have a negative impact on our research and development costs.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy adopted by China and other non-U.S. governments. Specifically, in China, on July 21, 2005, the PRC government changed its policy of pegging the value of the RMB to the U.S. dollar. Following the

removal of the U.S. dollar peg, the value of the RMB has fluctuated as compared to the U.S. dollar. It remains unclear what further fluctuations may occur or what impact this will have on the currency and our results of operations.

It is difficult to predict how market forces or China, U.S. or other government policies may impact the exchange rate between the RMB, U.S. dollar and other currencies in the future. There remains significant international pressure on the PRC government to adopt a more flexible currency policy, which could result in greater fluctuation of the RMB against the U.S. dollar. Substantially all of our revenues are denominated in U.S. dollars and our costs are denominated in U.S. dollars and RMB, and a large portion of our financial assets is denominated in U.S. dollars. Generally, to the extent that we need to convert U.S. dollars into RMB for our operations, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive. Conversely, if we decide to convert our RMB into U.S. dollars for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount we would receive. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

A portion of our operations are in China. Accordingly, our financial condition and results of operations are affected to a large extent by economic, political and legal developments in China.

The Chinese economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, and control of foreign exchange and allocation of resources. Although the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the PRC government continues to play a significant role in regulating industry development by imposing industrial policies. The PRC government also exercises significant control over China's economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

While the Chinese economy has experienced significant growth in the past four decades, growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may also have a negative effect on us. Our financial condition and results of operation could be materially and adversely affected by government control over capital investments or changes in tax regulations that are applicable to us and consequently have a material adverse effect on our businesses, financial condition and results of operations.

Tariffs imposed by the U.S. and those imposed in response by other countries, as well as rapidly changing trade relations, could have a material adverse effect on our business and results of operations.

Changes in U.S. and foreign governments' trade policies have resulted in, and may continue to result in, tariffs on imports into and exports from the U.S. Throughout 2018, 2019 and 2020, the U.S. imposed tariffs on imports from several countries, including China. In response, China has proposed and implemented their own tariffs on certain products, which may impact our supply chain and our costs of doing business. If we are impacted by the changing trade relations between the U.S. and China, our business and results of operations may be negatively impacted. Continued diminished trade relations between the U.S. and other countries, including potential reductions in trade with China and others, as well as the continued escalation of tariffs, could have a material adverse effect on our financial performance and results of operations.

There are uncertainties regarding the interpretation and enforcement of laws, rules and regulations in China.

A portion of our operations are conducted in China through our PRC subsidiaries, and are governed by PRC laws, rules and regulations. Our PRC subsidiaries are subject to laws, rules and regulations applicable to foreign investment in China. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In 1979, the Chinese government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past few decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by Chinese regulatory agencies. In particular, because these laws, rules and regulations are relatively new, and because of the limited number of published decisions and the nonbinding nature of such decisions, and because the

laws, rules and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the Chinese legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

Substantial uncertainties exist with respect to the enactment, interpretation and implementation of Chinese Foreign Investment Law and Negative List and how they may impact the viability of our current corporate governance.

On March 15, 2019, the National People's Congress of the PRC promulgated the Foreign Investment Law of the People's Republic of China (the "FIL") which became effective on January 1, 2020. Simultaneously, the three foreign investment laws (i.e. the Wholly Foreign-Owned Enterprise Law, the Sino-Foreign Equity Joint Venture Enterprise Law, and the Sino-Foreign Cooperative Joint Venture Enterprise Law) were repealed on January 1, 2020. Pursuant to the FIL, foreign investors shall not invest in any field forbidden by the negative list for access of foreign investment. For any field on the negative list, foreign investors shall conform to the investment conditions provided in the negative list. Fields not included in the negative list shall be managed under the principle that domestic investment and foreign investment shall be treated uniformly. According to the FIL, the organization form and institutional framework shall be subject to the provisions of the Company Law of the People's Republic of China, the Partnership Enterprise Law of the PRC, and other PRC laws. Foreign invested enterprises, which were established in accordance with the aforesaid three foreign investment laws may retain their original organization forms and other aspects for five years after the implementation of the FIL. Specific implementation measures shall be formulated by the State Council.

In June 2017, the National Development and Reform Commission and the Ministry of Commerce jointly issued Catalogue of Industries for Guiding Foreign Investment (2017 Revision), which introduced Special Administrative Measures on Access of Foreign Investment (Negative List). Any industry not listed in the catalogue and Negative List is a permitted industry, and is generally open to foreign investment unless specifically prohibited or restricted by the Chinese laws and regulations. The FIL and Negative List may also materially impact our corporate governance practice and increase our compliance costs. For instance, the FIL imposes stringent ad hoc and periodic information reporting requirements on foreign investors and the applicable FIEs. Aside from investment implementation report and investment amendment report that are required at each investment and alteration of investment specifics, an annual report is mandatory, and large foreign investors meeting certain criteria are required to report on a quarterly basis. Any company found to be non-compliant with these information reporting obligations may potentially be subject to fines and/or administrative or criminal liabilities, and the persons directly responsible may be subject to criminal liabilities.

Chinese regulations relating to investments in offshore companies by Chinese residents may subject our future Chinese-resident beneficial owners or our Chinese subsidiaries to liability or penalties, limit our ability to inject capital into our Chinese subsidiaries or limit our Chinese subsidiaries' ability to increase their registered capital or distribute profits.

The SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, on July 4, 2014, which replaced the former circular, commonly known as SAFE Circular 75, promulgated by SAFE on October 21, 2005. According to Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment, the "Circular 13", which became effective on June 1, 2015, banks shall directly examine and handle foreign exchange registration under domestic direct investment and foreign exchange registration under overseas direct investment, and the SAFE and its branch offices shall indirectly regulate the foreign exchange registration of direct investment through banks. SAFE Circular 37, Circular 13 and other SAFE rules require Chinese residents to register with local branches of SAFE or delegated commercial banks in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such Chinese residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle". SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by Chinese individuals, share transfer or exchange, merger, division or other material events. In the event that a Chinese stockholder holding interests in a special purpose vehicle fails to fulfill the required registration, the Chinese subsidiaries of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its Chinese

subsidiary. Moreover, failure to comply with the various registration requirements described above could result in liability under Chinese law for evasion of foreign exchange controls.

We believe that certain of our stockholders are Chinese residents under SAFE Circular 37. These certain stockholders have undertaken to (1) apply to register with local SAFE branch or its delegated commercial bank as soon as possible after exercising their options and (2) indemnify and hold harmless us and our subsidiaries against any loss suffered arising from their failure to complete the registration. We do not have control over the stockholders and our other beneficial owners and cannot assure you that all of our Chinese-resident beneficial owners have complied with, and will in the future comply with, SAFE Circular 37 and subsequent implementation rules. The failure of Chinese-resident beneficial owners to register or amend their SAFE registrations in a timely manner pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future Chinese-resident beneficial owners of our company to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject such beneficial owners or our Chinese subsidiaries to fines and legal sanctions. Furthermore, SAFE Circular 37 is unclear how this regulation, and any future regulation concerning offshore or cross-border transactions, will be interpreted, amended and implemented by the relevant Chinese government authorities, and we cannot predict how these regulations will affect our business operations or future strategy. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our PRC subsidiaries and limit our PRC subsidiaries' ability to distribute dividends to us. These risks could in the future have a material adverse effect on our business, financial condition and results of operations.

Any failure to comply with Chinese regulations regarding the registration requirements for employee share option plans may subject the Chinese plan participants or us to fines and other legal or administrative sanctions.

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly Listed Companies, commonly known as SAFE Circular 7, or the Share Option Rules, replacing earlier rules promulgated in 2007. Pursuant to these rules, Chinese residents who are granted shares or share options by companies listed on overseas stock exchanges under share incentive plans are required to (1) register with the SAFE or its local branches; (2) retain a qualified Chinese agent, which may be a Chinese subsidiary of the overseas listed company or another qualified institution selected by the PRC subsidiary, to conduct the SAFE registration and other procedures with respect to the share incentive plans on behalf of the participants and (3) retain an overseas institution to handle matters in connection with their exercise of share options, purchase and sale of shares or interests and funds transfers. We and our executive officers and other employees who are Chinese residents and who have been granted options will be subject to these regulations. Failure to complete the SAFE registrations may subject them to fines, and legal sanctions, and may also limit our ability to contribute additional capital into our PRC subsidiary and limit our PRC subsidiary's ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors, executive officers and employees under Chinese law. See "*Regulation—Regulations Relating to Foreign Exchange and Dividend Distribution—Share Option Rules*."

We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law, and we may therefore be subject to PRC income tax on our global income.

Under the PRC Enterprise Income Tax Law and its implementing rules, both of which came into effect on January 1, 2008, as amended on February 24, 2017 and December 29, 2018, enterprises established under the laws of jurisdictions outside of China with "de facto management bodies" located in China may be considered Chinese tax resident enterprises for tax purposes and may be subject to the Chinese enterprise income tax at the rate of 25% on their global income. "De facto management body" refers to a managing body that exercises substantive and overall management and control over the production and business, personnel, accounting books and assets of an enterprise. The STA has issued guidance, known as Circular 82 that provides certain specific criteria for determining whether the "de facto management body" of a Chinese-controlled offshore-incorporated enterprise is located in China. Although Circular 82 only applies to offshore enterprises controlled by Chinese enterprises, not those, such as us, controlled by foreign enterprises or individuals, the determining criteria set forth in Circular 82 may reflect the STA's general position on how the "de facto management body" test should be applied in determining the tax resident status of offshore enterprises, regardless of whether they are controlled by Chinese enterprises. Although the reviewing procedure in Circular 82 was simplified on December 29, 2017, pursuant to Decision of the STA on Issuing the Catalogues of Tax Departmental Rules and Tax Regulatory Documents Which Are Invalidated, the "de facto management body" test is still valid. Currently, our management is located in the U.S., and we generate a portion of our revenues within China and a portion outside China. We believe that neither we nor any of our subsidiaries outside of China is a Chinese resident enterprise for Chinese tax purposes. However, the tax resident status of an enterprise is subject to determination by the Chinese tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body". If we were to be considered a Chinese resident enterprise, we would be subject to Chinese enterprise income tax at the rate of 25% on our global income. In such case, our profitability and cash flow may be materially reduced as a result of our global income being taxed under the Chinese Enterprise Income Tax Law.

Dividends payable to our foreign investors and gains on the sale of our common stock by our foreign investors may become subject to Chinese tax law.

Under the PRC Enterprise Income Tax Law and its implementing rules issued by the State Council, in general, a 10% Chinese withholding tax is applicable to dividends payable to investors that are non-resident enterprises that do not have an establishment or place of business in China or which have such establishment or place of business but the dividends are not effectively connected with such establishment or place of business, to the extent such dividends are derived from sources within China. Similarly, any gain realized on the transfer of shares of our common stock by such investors is also subject to Chinese tax at a current rate of 10%, subject to any reduction or exemption set forth in relevant tax treaties, if such gain is regarded as income derived from sources within China. If we are deemed a Chinese resident enterprise, dividends paid on our common stock, and any gain realized from the transfer of our common stock, would be treated as income derived from sources within China and would as a result be subject to Chinese taxation. Furthermore, if we are deemed a Chinese resident enterprise, dividends payable to individual investors who are non-Chinese residents and any gain realized on the transfer of common stock by such investors may be subject to Chinese tax at a current rate of 20%, subject to any reduction or exemption set forth in applicable tax treaties. It is unclear whether we or any of our subsidiaries established outside China are considered a Chinese resident enterprise, holders of our common stock would be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or areas. If dividends payable to our non-Chinese investors or gains from the transfer of our common stock by such investors are subject to Chinese tax, the value of your investment in our common stock may decline significantly.

We and our stockholders face uncertainties with respect to indirect transfers of equity interests in Chinese resident enterprises by their non-Chinese holding companies.

Pursuant to a notice, or Circular 698, issued by the STA, where a non-resident enterprise conducts an "indirect transfer" by transferring the equity interests of a Chinese resident enterprise indirectly via disposing of the equity interests of an overseas holding company, and such overseas holding company is located in a tax jurisdiction that: (1) has an effective tax rate less than 12.5% or (2) does not tax foreign income of its residents, the non-resident enterprise, being the transferor, shall report to the relevant tax authority of the Chinese resident enterprise such indirect transfer. Using a "substance over form" principle, the Chinese tax authority may disregard the existence of the overseas holding company if it lacks a reasonable commercial purpose and was established for the purpose of reducing, avoiding or deferring Chinese tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax, currently at a rate of 10%. In 2015, the STA issued a circular, known as Circular 7, which replaced or supplemented certain previous rules under Circular 698. Circular 7 sets out a wider scope of indirect transfer of Chinese assets that might be subject to PRC enterprise income tax, and more detailed guidelines on the circumstances when such indirect transfer is considered to lack a bona fide commercial purpose and thus regarded as avoiding Chinese tax. The conditional reporting obligation of the non-Chinese investor under Circular 698 is replaced by a voluntary reporting by the transferor, the transferee or the underlying Chinese resident enterprise being transferred. Furthermore, if the indirect transfer is subject to Chinese enterprise income tax, the transferee has an obligation to withhold tax from the sale proceeds, unless the transferor reports the transaction to the PRC tax authority under Circular 7. Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC enterprise income tax pursuant to Circular 7 where such shares were acquired in a transaction through a public stock exchange. Circular 698 was abolished by an announcement promulgated by the STA in October 2017 and effective from December 1, 2017, or STA Circular 37, which, among other things, provides specific provisions on matters concerning withholding of income tax of non-resident enterprises at the source.

As newly implemented, there is uncertainty as to the application of Circular 7 and STA Circular 37, both of which may be determined by the tax authorities to be applicable to our offshore restructuring transactions or sale of the shares of our offshore subsidiaries where non-resident enterprises, being the transferors, were involved. The PRC tax authorities may pursue such non-resident enterprises with respect to a filing regarding the transactions and request our PRC subsidiaries to assist in the filing. As a result, we and our non-resident enterprises in such transactions may become at risk of being subject to filing obligations or being taxed under Circular 7, and may be required to expend valuable resources to comply with Circular 7 or to establish that we and our non-resident enterprises should not be taxed under Circular 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial condition and results of operations.

Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

The Chinese government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. A portion of our revenue may in the future be denominated in RMB. Shortages in availability of foreign currency may then restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations. The RMB is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account", which includes foreign direct investment and loans, including loans we may secure from our onshore subsidiaries. Currently, our Chinese subsidiaries, which are wholly foreign owned enterprises, may purchase foreign

currency for settlement of "current account transactions," including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant Chinese governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our future revenue may be denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of China or pay dividends in foreign currencies to our stockholders, including holders of our common stock. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant Chinese governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Scrutiny companies based in or with operations in China may result in increased regulatory review of us and negatively impact the trading price of our common stock and could have a material adverse effect upon our business, including our results of operations, financial condition, cash flows and prospects.

We believe that the passage and implementation of the Holding Foreign Companies Accountable Act (the "HFCAA"), the delistings of China Mobile Ltd., China Telecom Corp., and China Unicom Hong Kong Ltd. by executive order from the Trump administration on December 31, 2020, and the general negative publicity surrounding companies with operations in China, including concerning the directors and officers of such companies, that are listed in the U.S. have negatively impacted stock prices for such companies and the HFCAA may result in additional delistings of companies with significant China operations from U.S. securities exchanges. Various equity-based research organizations have published reports on China-based companies after examining, among other things, their corporate governance practices, related party transactions, sales practices and financial statements that have led to special investigations and stock suspensions on national exchanges, including as a result of purported whistle-blowing or leaking by employees or former employees. Any similar scrutiny of us, regardless of its lack of merit, could result in a diversion of management resources and energy, potential costs to defend ourselves against rumors, decreases and volatility in the trading price of our common stock, and increased directors and officers insurance premiums and could have a material adverse effect upon our business, including our results of operations, financial condition, cash flows and prospects.

Risks Related to Our Common Stock

If we fail to comply with the continued listing standards of the Nasdaq Global Market, our common stock may be delisted from the exchange.

Our common stock is currently listed for trading on the Nasdaq Global Market under the symbol "ATNX". The continued listing of our common stock on Nasdaq is subject to our compliance with a number of listing standards. In particular, we are required to maintain a minimum bid price of $1.00 per share. In January 2022, our shares began trading below $1.00. There can be no assurance that we will be able to regain compliance with these requirements or that our common stock will continue to be listed on Nasdaq.

If we fail to satisfy the Nasdaq continued listing requirements, such as the corporate governance requirements, the stockholder's equity requirement or maintaining the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting or even notification of failure to comply with such requirements would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In addition, the delisting of our common stock could lead to a number of other negative implications such as a loss of media and analyst coverage, a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and likely result in a reduced level of trading activity in the secondary trading market for our securities, and materially adversely impact our ability to raise capital on acceptable terms or at all. Delisting from Nasdaq could also have other negative results, including the potential loss of confidence by our current or prospective third-party providers and collaboration partners, the loss of institutional investor interest, and fewer licensing and partnering opportunities. In the event of a delisting, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

If our common stock were no longer listed on Nasdaq, investors might only be able to trade on one of the over-the-counter markets. There is no assurance, however, that prices for our common stock would be quoted on one of these other trading systems or that an active trading market for our common stock would exist, which would materially and adversely impact the market value of our common stock and your ability to sell our common stock.

The trading price of our common stock has been and is likely to continue to be volatile, which could result in substantial losses to you.

The trading price of our common stock has been and is likely to continue to be volatile and could fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with a portion of their business operations located in China that have listed their securities in the U.S. may affect the volatility in the price of and trading volumes for our common stock. Some of these companies have experienced significant volatility, including significant price declines after their initial public offerings. The trading performances of these companies' securities at the time of or after their offerings may affect the overall investor sentiment towards other companies with significant China operations listed in the U.S. and consequently may impact the trading performance of our common stock.

In addition to market and industry factors, the price and trading volume for our common stock may be highly volatile for specific business reasons, including:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- any adverse changes to our relationship with manufacturers or suppliers;
- the results of our testing and clinical trials;
- the results of our efforts to acquire or license additional drug candidates;
- variations in the level of expenses related to our existing drug candidates or preclinical and clinical development programs;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- variations in our results of operations;
- announcements about our earnings that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on earnings;
- publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;
- changes in financial estimates by securities research analysts;
- announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures or capital commitments;
- press reports or other negative publicity, whether or not true, about our business;
- changes to our acting management team, including as a result of additions, departures and health-related leaves of absence;
- fluctuations of exchange rates between the RMB and the U.S. dollar;
- release or expiry of lock-up or other transfer restrictions on our outstanding common stock;
- sales or perceived potential sales of additional common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- general economic and market conditions and overall fluctuations in the U.S. equity markets, including due to the war in Ukraine;
- changes in accounting principles; and
- changes or developments in China or global regulatory environment.

Any of these factors may result in large and sudden changes in the volume and trading price of our common stock. We could be subject to additional securities class action litigation against us following a future period of volatility in the market price of our shares.

In addition, the stock market, in general, and small pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors, including the war in Ukraine, COVID-19 pandemic, supply chain disruptions, limited supply of natural resources, and acts of war, may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, the current decline in the financial markets and related factors beyond our control may cause our common stock price to decline rapidly and unexpectedly.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of our common stock for return on your investment, if any.

We intend to retain most, if not all, of our available funds and earnings to fund the development and growth of our business. In addition, our Senior Credit Agreement with Oaktree restricts our and our restricted subsidiaries' ability to pay dividends. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our common stock as a source for any future dividend income.

Our board of directors has significant discretion as to whether to distribute dividends, subject to the restrictions contained in our financing agreements. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, restrictions on the form and amount of such dividends in our debt agreements, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on an investment in our common stock will likely depend entirely upon any future price appreciation of our common stock. There is no guarantee that our common stock will appreciate in value or even maintain its current market price. You may not realize a return on your investment in our common stock and you may even lose your entire investment in our common stock.

There are limitations on the liability of our officers and directors, and we may have to indemnify our officers and directors in certain instances.

Our amended and restated certificate of incorporation limits, to the maximum extent permitted under Delaware law, the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors. The indemnification provisions may require us, among other things, to indemnify such officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers (other than liabilities arising from willful misconduct of a culpable nature), to advance their expenses incurred as a result of certain proceedings against them as to which they could be indemnified. Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify a director, officer, employee or agent made or threatened to be made a party to an action by reason of the fact that he or she was a director, officer, employee or agent of the corporation or was serving at the request of the corporation, against expenses actually and reasonably incurred in connection with such action if he or she acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Delaware law does not permit a corporation to eliminate a director's duty of care and the provisions of our certificate of incorporation have no effect on the availability of equitable remedies, such as injunction or rescission, for a director's breach of the duty of care.

We believe that our limitation of officer and director liability assists us to attract and retain qualified employees and directors. However, in the event an officer, a director or the board of directors commits an act that may legally be indemnified under Delaware law, we will be responsible to pay for such officer(s) or director(s) legal defense and potentially any damages resulting there from. Furthermore, the limitation on director liability may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders from instituting litigation against directors for breach of their fiduciary duties, even though such an action, if successful, might benefit our stockholders and us. Limitations of director liability may be viewed as limiting the rights of stockholders, and the broad scope of the indemnification provisions contained in our certificate of incorporation could result in increased expenses.

Our directors, executive officers and principal stockholders have substantial control over us, which could limit your ability to influence the outcome of key transactions, including a change of control.

Our directors, officers and stockholders who own greater than 5% of our outstanding common stock, together with their affiliates, beneficially owned, in the aggregate, approximately 45.4% of our outstanding common stock based on the number shares outstanding as of December 31, 2021. As a result, these stockholders, if acting together, will be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of

control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

In addition, our directors and officers as a group, beneficially own in the aggregate approximately 11.8% of our outstanding common stock based on the number shares outstanding as of December 31, 2021. As such, our directors and executive officers could have considerable influence over matters such as approving a potential acquisition of us. Our directors and executive officers' investment in and position in our company could also discourage others from pursuing any potential acquisition of us, which could have the effect of depriving the holders of our common stock of the opportunity to sell their shares at a premium over the prevailing market price.

Anti-takeover provisions in our charter documents may discourage our acquisition by a third party, which could limit our stockholders' opportunity to sell their shares at a premium.

Our amended and restated certificate of incorporation and bylaws include provisions that could limit the ability of others to acquire control of our company, modify our structure or cause us to engage in change-of-control transactions. These provisions could have the effect of depriving our stockholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control in a tender offer or similar transaction.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our Oncology Innovation Platform operates in several facilities globally: Our corporate headquarters is located in Buffalo, New York, where we occupy approximately 51,000 square feet of the Conventus Center for Collaborative Medicine, which includes approximately 16,000 square feet of a formulation testing and chemistry lab under a lease that expires in July 2025 and is renewable for an additional 10 years. We occupy approximately 1,300 square feet of office space in Cranford, New Jersey under a lease that expires in April 2024 that serves as our clinical research headquarters. We also occupy approximately 5,500 square feet of office and lab space which represents a portion of the IC Development Centre in Hong Kong under a lease that expires in November 2022 that serves as our Hong Kong headquarters and research and development center. We occupy approximately 6,200 square feet of office space in Taipei, Taiwan under a lease that expires in December 2022 which serves for clinical research and clinical data management. In addition, we occupy approximately 9,900 square feet of office space in multiple locations across Latin America under lease agreements which expire at various dates through October 2022, which serve as clinical research facilities.

Our Commercial Platform is headquartered and operates in approximately 15,000 square feet of office space in the Woodfield Preserve Office Center in Schaumberg, Illinois under a lease that expires in March 2027.

Our Global Supply Chain Platform utilizes several facilities globally: We occupy space in facilities in Clarence and Amherst, New York and Chongqing, China which provide our manufacturing and packaging capabilities for our proprietary and 503B products and our Active Pharmaceutical Ingredient operations. In addition, Chongqing Sintaho Pharmaceuticals Co., Ltd. (“CQ Sintaho”), a wholly owned subsidiary of the Company, entered into a lease agreement with Chongqing International Biological City Development & Investment Co., Ltd (“CQ D&I”), an affiliate of CQ. Pursuant to the lease agreement with CQ D&I, CQ Sintaho has leased the newly constructed API of 34,517 square meters rent-free, for the first 10-year term, with an option to extend the lease for an additional 10-year term, during which, if CQ Sintaho is profitable, it will pay a monthly rent of 5 Chinese Renminbi per square meter of space occupied. This lease agreement was executed in January 2021. See “*Business – Global Supply Chain Platform—Strategic Public-Private Partnerships—China Partnership*” for more information.

We believe that these facilities will be sufficient to meet our current needs.

Item 3. Legal Proceedings.

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. Regardless of the outcome, litigation can have an adverse impact on us because of prosecution, defense and settlement costs, unfavorable awards, diversion of management resources and other factors.

Securities Litigation

Following our receipt of the CRL in February 2021 and the subsequent decline of the market price of the Company’s common stock, two purported securities class action lawsuits were filed in the U.S. District Court for the Western District of New York on March 3, 2021 and March 22, 2021, respectively, against the Company and certain members of its management team seeking to recover damages for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

The complaints generally allege that between August 7, 2019 and February 26, 2021 (the purported class period), the Company and the individual defendants made materially false and misleading statements regarding the Company's business in connection with the Company’s development of Oral Paclitaxel for the treatment of metastatic breast cancer and the likelihood of FDA approval, and that the plaintiffs suffered losses when the Company’s stock price dropped after its announcement on February 26, 2021 regarding receipt of the CRL. The complaints seek class certification, damages, fees, costs, and expenses. On August 5, 2021, the Court consolidated the two actions and appointed a lead plaintiff and lead counsel. Pursuant to a stipulated scheduling order, the lead plaintiff filed an amended complaint on November 19, 2021. Defendants filed their motion to dismiss on January 25, 2022. Plaintiffs’ opposition to that motion is due by March 28, 2022 and the defendants’ reply is due by May 20, 2022. The Company and the individual defendants believe that the claims in the consolidated lawsuits are without merit, and the Company has not recorded a liability related to these shareholder class actions as the risk of loss is remote. The Company and the individual defendants intend to vigorously defend against these claims but there can be no assurances as to the outcome.

Shareholder Derivative Lawsuit

On June 3, 2021, a shareholder derivative lawsuit was filed in the United States District Court for the District of Delaware by Timothy J. Wonnell, allegedly on behalf of the Company, that piggy-backs on the securities class actions referenced above. The complaint names Johnson Lau, Rudolf Kwan, Timothy Cook, and members of the Board as defendants, and generally alleges that they

caused or failed to prevent the securities law violations asserted in the securities class actions. On September 13, 2021, the Court (i) granted the defendants' motion to stay the derivative action until after resolution of the motion to dismiss the consolidated securities class actions, and (ii) administratively closed the derivative litigation, directing the parties to promptly notify the Court when the related securities class action has been resolved so the derivative action can be reopened. The Company and the individual defendants believe the claims in the shareholder derivative action are without merit, and the Company has not recorded a liability related to this lawsuit as the risk of loss is remote. The Company and the individual defendants intend to vigorously defend against these claims should the case be reopened, but there can be no assurances as to the outcome.

From time to time, the Company may become subject to other legal proceedings, claims and litigation arising in the ordinary course of business. In addition, the Company may receive letters alleging infringement of patent or other intellectual property rights. The Company is not currently a party to any other material legal proceedings, nor is it aware of any pending or threatened litigation that, in the Company's opinion, would have a material adverse effect on the business, operating results, cash flows or financial condition should such litigation be resolved unfavorably.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

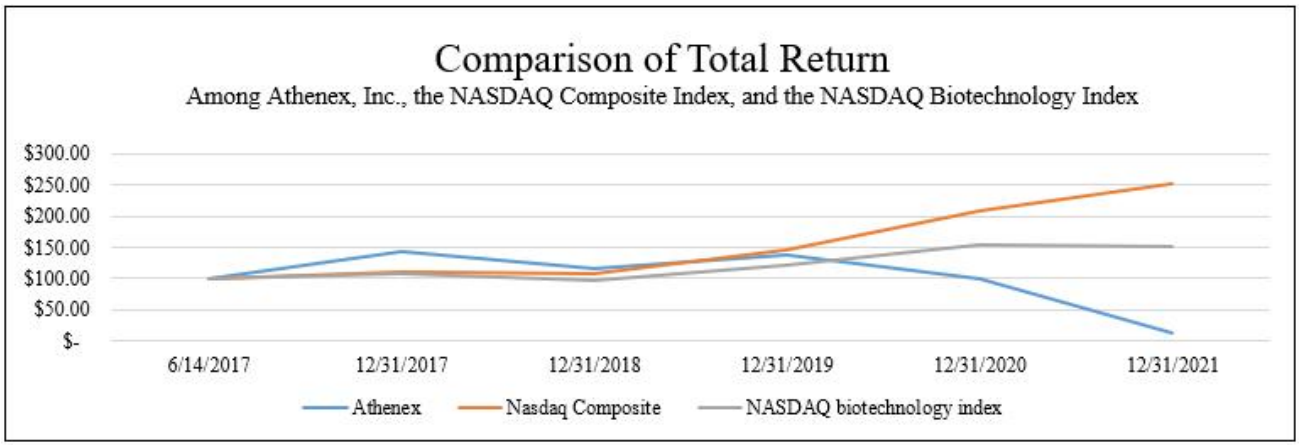
Market for our Common Stock

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "ATNX" since June 14, 2017. Prior to that date, there was no public trading market for our common stock.

As of January 31, 2022, there were 92 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street by brokers and other nominees.

Stock Price Performance Graph

The graph below shows a comparison from June 14, 2017, the date on which our common stock first began trading on the Nasdaq Global Select Market, of the cumulative total return on an assumed investment of $100.00 in cash in our common stock as compared to the same investment in the NASDAQ Composite Index and the NASDAQ Biotechnology Index, all through to December 31, 2021. Such returns are based on historical results and are not intended to suggest future performance.



Cumulative Total Return Comparison

	June 14, 2017	December 31, 2017	2018	2019	2020	2021
Athenex, Inc.	$ 100.00	$ 144.55	$ 115.36	$ 138.82	$ 100.55	$ 12.36
NASDAQ Composite	$ 100.00	$ 111.44	$ 107.11	$ 144.84	$ 208.05	$ 252.55
NASDAQ Biotechnology Index	$ 100.00	$ 108.33	$ 98.23	$ 122.20	$ 153.59	$ 152.62

This performance graph is not deemed to be "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Dividend Policy

We have never declared or paid cash or stock dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operations of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends on common stock will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, any contractual restrictions on dividends, and other factors that our board of directors may deem relevant.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with the historical consolidated financial statements and the notes thereto included in Part II, Item 8 "Financial Statements and Supplementary Data." This discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Annual Report. Actual results may differ materially from those contained in any forward-looking statements. You should carefully read "Special Note About Forward-Looking Statements" and Part I, Item 1A, "Risk Factors."

Overview and Recent Developments

We are a biopharmaceutical company dedicated to becoming a leader in the discovery, development and commercialization of next generation drugs for the treatment of cancer. Our mission is to improve the lives of cancer patients by creating more effective, safer and tolerable treatments. We have assembled a strong and experienced leadership team and have established operations across the pharmaceutical value chain to execute our goal of becoming a global leader in bringing innovative cancer treatments to the market and improving health outcomes.

We are organized around three operating segments: (1) our Oncology Innovation Platform, dedicated to the research and development of our proprietary drugs; (2) our Commercial Platform, focused on the sales and marketing of our specialty drugs and the market development of our proprietary drugs; and (3) our Global Supply Chain Platform, dedicated to providing a stable and efficient supply of active pharmaceutical ingredients ("API") for our clinical and commercial efforts. Our current clinical pipeline in the Oncology Innovation Platform is derived from the following core technologies: (1) Cell Therapy, (2) Orascovery, based on a P-glycoprotein ("P-gp") pump inhibitor, and (3) Src Kinase Inhibition.

Oncology Innovation Platform Developments

Through our acquisition of Kuur Therapeutics, Inc. (formerly known as Cell Medica, "Kuur") in 2021, we acquired rights to intellectual property to further the development of autologous and allogeneic, or "off-the-shelf", natural killer T ("NKT") cell immunotherapies for the treatment of solid and hematological malignancies. We are advancing the following product candidates: KUR-501, KUR-502, and KUR-503.

KUR-501 is an autologous product in which NKT cells are engineered with a chimeric antigen receptor ("CAR") targeting GD2 ("GINAKIT" cells). GD2 is expressed on almost all neuroblastoma tumors and certain other malignancies. KUR-501 is currently being evaluated in a phase 1 clinical trial (GINAKIT2) treating children with relapsed-refractory ("R/R") high risk neuroblastoma. In May 2021, we presented an interim data update from the first eleven evaluable patients at the American Society of Gene & Cell Therapy ("ASGCT"). During this initial evaluation, the safety profile of KUR-501 was manageable, and there was no dose limiting toxicity ("DLT"). No patients experienced grade 2 or higher toxicities related to KUR-501. There were no grades 3-5 cytokine release syndrome ("CRS") and no evidence of immune effector cell-associated neurotoxicity syndrome ("ICANS") in any of the patients. Grades 3-4 adverse events ("AEs"), reported regardless of relationship to KUR-501, have included anemia, leukopenia, lymphopenia, neutropenia, thrombocytopenia, abdominal distension, acute gastroenteritis, liver enzyme increase, vomiting, bone pain, headache, neck pain, fever, urinary tract infection, altered mental status, and hypoxia. As this clinical development program is still in the early stages, we do not yet have meaningful statistics on safety, including AEs, to report. Observed responses included one complete response ("CR") and one partial response ("PR"). Four additional patients have exhibited stable disease ("SD"). We also observed long-term persistence of NKT cells expressing CAR. Importantly, we observed NKT cell localization to the tumor site.

KUR-502 is an allogeneic ("off-the-shelf") product in which NKT cells are engineered with a CAR targeting CD19. KUR-502 is currently being evaluated in a phase 1 clinical trial (ANCHOR) treating adults with R/R CD19 positive malignancies, including B cell lymphoma, acute lymphoblastic leukemia ("ALL"), and chronic lymphocytic leukemia ("CLL"). In December 2021, we presented an interim data update on the first five evaluable patients at the American Society of Hematology ("ASH") annual meeting. Tumor biopsies showed presence of NKT cells expressing CARs in the disease sites, indicating that the KUR-502 cells are able to traffic to the tumor. The safety profile was manageable with no DLT. There was one case of grade 1 CRS, no ICANS, and no graft versus host disease ("GvHD") attributable to KUR-502. Grades 3-4 AEs, reported regardless of relationship to KUR-502, have included lymphopenia, leukopenia, neutropenia, thrombocytopenia, liver enzyme elevation, bilirubin elevation, anemia, diarrhea, hypoalbuminemia, and myositis. As this clinical development program is still in the early stages, we do not yet have meaningful statistics on safety, including AEs, to report. Of the first five evaluable patients, the overall response rate was 80%, and the complete response rate was 60%.

KUR-503 is an allogeneic ("off-the-shelf") product in which NKT cells are engineered with a CAR targeting glypican-3 ("GPC3"). GPC3 is a molecule that is highly expressed on most hepatocellular carcinomas ("HCC") but not normal liver or other non-neoplastic tissue. KUR-503 is currently in preclinical development, and we are planning to submit an IND by the first half of 2023.

Pursuant to the terms of the Merger Agreement, we paid $70.0 million upfront to Kuur shareholders and its former employees and directors, comprised primarily of shares of our common stock. Additionally, Kuur shareholders and its former employees and

directors are eligible to receive up to $115.0 million of milestone payments, which may be paid, at the Company's sole discretion, in either cash or additional common stock of the Company, or a combination of both. The Company identified the Merger as a business combination pursuant to ASC 805 and used the acquisition method of accounting to account for the transaction. The purchase price, after adjusted for closing conditions, consisted of 14,228,066 shares of the Company's common stock issued at $3.71 per share with a fair value of $52.8 million, plus the fair value of the future milestone payments amounting to $19.8 million, recorded as contingent consideration. For additional information, please see "Part II, Item 8, Note 3—Business Combination."

We continue to advance TCR affinity-enhancing specific T-cell ("TAEST") therapy with our drug candidate, TCRT-ESO-A2. TCRT-ESO-A2 is an autologous T cell receptor ("TCR")-T cell therapy targeting solid tumors that are NY-ESO-1 positive in HLA-A*02:01 positive patients. A phase 1 clinical trial treating adults with advanced solid tumors expressing NY-ESO-1 is currently open enrolling.

On February 26, 2021, we received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding our New Drug Application ("NDA") for oral paclitaxel and encequidar ("Oral Paclitaxel") for the treatment of metastatic breast cancer ("mBC"). Following the CRL, we held two Type A meetings with the FDA to discuss the deficiencies raised in the CRL, review a proposed design for a new clinical trial intended to address the deficiencies raised in the CRL, and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S. In October 2021, after careful consideration of the FDA feedback, we determined to redeploy our resources to focus on other ongoing studies of Oral Paclitaxel and our Cell Therapy platform. On November 29, 2021, we announced the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") validation of the Marketing Authorization Application ("MAA") for Oral Paclitaxel, for review. The Phase 3 study of Oral Paclitaxel in mBC (KX-ORAX-001) served as the basis of the MAA.

We are continuing to evaluate Oral Paclitaxel in combination with check point inhibitors. The development of our other Orascovery product candidates, including oral irinotecan and encequidar ("Oral Irinotecan"), oral docetaxel and encequidar ("Oral Docetaxel"), oral topotecan and encequidar ("Oral Topotecan"), and oral eribulin and encequidar ("Oral Eribulin") has been suspended at this time.

On February 18, 2021, our partner Almirall (Almirall, S.A., BME: ALM) launched Klisyri® (tirbanibulin ointment) for actinic keratosis (AK) in the US. On September 27, 2021, we announced Almirall launched Klisyri in Germany and the UK, as part of a phased European launch, after receiving approval from the European Commission in July 2021 and the UK MHRA in August 2021, for Klisyri indicated for the topical treatment of AK of the face or scalp in adults. The launch of Klisyri in the U.S. resulted in a milestone payment of $20.0 million pursuant to our 2017 out-license agreement with Almirall, recognized as revenue in the first quarter of 2021, and the launch in Europe resulted in a milestone payment of $5.0 million, recognized as revenue in the third quarter of 2021.

On February 15, 2021, we entered into the Second Amendment to the 2011 license agreement with PharmaEssentia Corp. ("PharmaEssentia") for tirbanibulin ointment. The Second Amendment expands the territory to include Japan and South Korea and includes a license to use the intellectual property for additional dermatology indications and skin cancer in the existing territories. On July 26, 2021, we announced that we entered into licensing agreements and strategic partnerships with Seqirus Pty Ltd ("Seqirus"), a subsidiary of CSL Limited, and AVIR Pharma Inc. ("AVIR") for tirbanibulin. Under the terms of the agreements, Seqirus will have an exclusive license to commercialize tirbanibulin in Australia and New Zealand, and AVIR will have an exclusive license to commercialize tirbanibulin in Canada.

With respect to Arginine Deprivation therapy, the enrollment of the Phase 1 trial of PT01 for the treatment of patients with advanced malignancies has been suspended, and no further studies are planned at this time.

Commercial and Global Supply Chain Platform Developments

We suspended production activities at our Taihao API facility in Chongqing, China, in May 2019, based on concerns raised by the Department of Emergency Management of Chongqing ("DEMC") related to the location of our plant. We subsequently resumed producing API at the Taihao API facility primarily for our ongoing clinical studies and commercial launches of proprietary drugs in accordance with local regulatory guidance, while we started building out Sintaho, a new API facility in Chongqing. In July 2021, we received verbal notice from the DEMC that we will be required to terminate the production activities at its Taihao API facility. We are continuing to engage in dialogue with the DEMC. While we are able to continue producing certain API at the Taihao API facility in limited quantities and a certain extent of our operations are now being conducted at Sintaho, we are in the process of moving the remainder of the operations and production activities to Sintaho and exploring other sources of API, in the event we are unable to reach an agreement with the DEMC for the continued production activities of the Taihao API facility.

On October 1, 2021, we entered into a lease agreement with Fort Schuyler Management Corporation ("FSMC"), a not-for-profit corporation affiliated with the State of New York, to lease the 409,000 square feet, newly constructed cGMP ISO Class 5 high potency pharmaceutical manufacturing facility located in Dunkirk, NY. This rights to lease this facility were transferred to ImmunityBio in February 2022. For additional information, please see "Part II, Item 8, Note 21—*Subsequent Events*."

COVID-19 related measures

Since early 2020, after monitoring developments related to the spread of COVID-19, we have undertaken a number of measures in response to the COVID-19 pandemic, with a goal to prioritize the health and safety of our employees and ensure continuity in our business. These measures included implementing a work-from-home policy at various times and other efforts in accordance with recommendations by local authorities for certain of our personnel across the globe as well as imposing restrictions on travel and in-person meetings to protect the health and safety of our workforce while we continue to advance our clinical programs and operations. We have continued to add additional safety procedures and tools in all our locations. We adhere to all state and federal requirements as the same may be in force from time to time.

We have been deemed an "essential business" by New York State and, as a result, we have experienced minimal disruptions at our New York-based operations in Clarence and Buffalo. Despite these efforts, we may from time to time experience additional disruptions related to the COVID-19 pandemic resulting from employees falling ill with COVID-19. We have supplied our employees with appropriate face coverings and other necessary personal protective equipment and have taken other measures to reduce the risk of the spread of COVID-19 at our work sites. We are actively monitoring our operations and supply chain across the globe and are making adjustments to respond to logistical challenges that arise due to the COVID-19 pandemic where appropriate, particularly due to the emergence and spread of the COVID-19 Omicron variant, which has impacted our operations and supply chain during 2021 as discussed further below. We have continued to produce some medicines that are used to treat COVID-19 as part of our commitment to contribute to the COVID-19 relief effort.

With respect to our clinical development program, for our earlier stage product candidates, we have experienced and expect to continue to experience slowed enrollment for our clinical trials as well as suspensions in our clinical trials as healthcare resources are diverted to address the COVID-19 pandemic. We remain committed to advancing our pipeline while ensuring the safety of all participants as well as the integrity of the data. We will continue to monitor developments with respect to the COVID-19 pandemic as well as industry and regulatory best practices for continuing clinical development programs during the pandemic, including, if and where appropriate, the use of virtual communications, interviews, and visits as well as self-administration and remote monitoring techniques to address health and safety concerns while minimizing disruptions and delays to our clinical development timelines.

We also put in place a number of measures intended to adjust or allocate resources towards prioritizing key business operations such as clinical and regulatory activities, and to delay or defray compensation costs in order to preserve our cash on hand and liquidity during a volatile period in the U.S. and global capital markets.

While the disruptions to our business caused by the pandemic are currently expected to be temporary, there is still uncertainty regarding the pandemic's overall duration and the severity of any future outbreaks. For example, the surge of COVID-19 cases in the first half of 2021 in India, a country where we source products and maintain partnerships that are key to our specialty drug business, including API, presented business and supply chain disruption risks for us. We could face similar risks in other regions, or a resurgence in India, to the extent the virus is not able to be contained, there is widespread sickness and disruptions on. The scope and impact of any such measures is not yet known and will depend on a number of factors, including but not limited to the ultimate spread and severity of the outbreaks and the scope, duration and impact of containment measures on individuals and businesses. If our partners experience significant or extended disruptions to their business due to COVID-19, it could result in supply shortages and harm our specialty drug business, as well as our overall financial condition.

Going Concern Considerations

We have three operating segments: our Oncology Innovation Platform, Global Supply Chain Platform and Commercial Platform. Since inception, we have devoted a substantial amount of our resources to research and development of our lead product candidates under our Orascovery and Src Kinase Inhibition technology platforms, as well as under the Cell Therapy platform and Arginine Deprivation Therapy technology, while building up our commercial infrastructure. We have incurred significant net losses since inception.

We have incurred operating losses since inception and, as a result, as of December 31, 2021 and 2020, we had an accumulated deficit of $913.4 million and $713.6 million, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. We project insufficient liquidity to fund our operations through the next twelve months beyond the date of this report. This condition raises substantial doubt about our ability to continue as a going concern. See Part II, Item 8. Note 1—Company and Nature of Business for further information regarding our ability to continue as a going concern.

As a result of the significant decrease in our market capitalization since we last performed a goodwill impairment test in the fourth quarter of 2020, we evaluated the impact on each of our reporting units to assess whether there was an impairment triggering event. The Company identified impairment triggering events during the first quarter of 2021 and, consistent with our annual policy, performed a test as of our annual goodwill impairment evaluation date, October 1, 2021, subsequently updating that analysis to December 31, 2021 using new information that became available regarding conditions that existed as of December 31, 2021. We compared the fair value of our Global Supply Chain Platform and Oncology Innovation Platform reporting units to carrying value. Based on the results from the test on March 31, 2021, the fair value of each of our reporting units exceeded their carrying value, and

the goodwill was not impaired. Based on the results from the test during the fourth quarter of 2021, the carrying value of the Global Supply Chain Platform and Oncology Innovation Platform reporting units exceeded their fair value, and therefore, goodwill was determined to be fully impaired. Accordingly, the Company recorded goodwill impairment of $67.7 million during the year ended December 31, 2021, of which, $26.6 million was related to the Global Supply Chain Platform reporting unit and $41.1 million was related to the Oncology Innovation Platform reporting unit (see Part II, Item 8. Note 8—*Intangible Assets, Net*). Estimating the fair value of goodwill requires the use of estimates and significant judgments that are based on a number of factors. These estimates and judgments may not be within our control and accordingly it is reasonably possible that the judgments and estimates could change in future periods.

However, a lack of sustained recovery or further deterioration in market conditions related to the general economy and the industries in which we operate, a sustained trend of weaker than anticipated financial performance, further decline in our share price for a sustained period of time, or an increase in the market-based weighted average cost of capital, among other factors, could significantly impact the impairment analysis and may result in future impairment charges that, if incurred, could have a material adverse effect on our financial condition and results of operations.

We have funded our operations to date primarily from the issuance and sale of our common stock through public offerings, senior secured loans, private placements, and to a lesser extent, from convertible bond financing, revenue, and grant funding. As of December 31, 2021, we had cash and cash equivalents of $35.2 million, restricted cash of $16.5 million, and short-term investments of $10.2 million.

On August 20, 2021, we entered into a sales agreement (the "Sales Agreement") with SVB Leerink LLC, in connection with the offer and sale of up to $100,000,000 of shares of our common stock, par value $0.001 per share ("ATM Shares"). The ATM Shares to be offered and sold under the Sales Agreement will be issued and sold pursuant to a registration statement on Form S-3 (File No. 333-258185) that became effective on August 12, 2021. During the year ended December 31, 2021, we sold 762,825 shares of our common stock for an average price of $1.49 per share under the Sales Agreement.

Outlook

Our company's mission is to become a leader in bringing innovative cancer treatments to the market and to improve patient health outcomes. Historically, we had focused development of our Orascovery platform which is based on a technology that converts IV chemotherapy to oral chemotherapy. We conducted a large phase 3 clinical trial in metastatic breast cancer comparing Oral Paclitaxel to IV paclitaxel, which was the basis of our NDA submission. Unfortunately, in February 2021, we received a CRL from the FDA which asked for an additional clinical study to support approval. After careful evaluation and prioritization of our R&D pipeline, we have decided to focus our R&D resources on our innovative cell therapy platform, which is based on NKT cells. NKT cells have unique biology that has potential advantages over current T cell and NK cell based technologies. We believe these advantages include the following:

(1) There is still a major unmet need in hematological and solid tumors in that even in those indications where autologous CAR-T cells have been previously approved, up to 60% of patients receiving CAR-T therapy do not achieve long term durable responses.

(2) Cellular therapies have generally not been effective in the treatment of solid tumors. NKT cells are an ideal platform for treatment of solid tumors because NKT cells home to tumors, and we have data demonstrating that CAR-NKT cells are superior in tumor homing compared to CAR-T cells.

(3) Our allogeneic ("off-the-shelf") CAR-NKT cell therapy products may be produced at larger scale than autologous products, potentially at lower cost.

(4) Our allogeneic CAR-NKT cells are manufactured starting with the lymphocytes of healthy donors. Use of healthy donors, rather than patients (who are the source of autologous cell therapy starting materials), results in a more robust and consistent product, because patient lymphocytes are usually dysfunctional due to previous cancer therapy.

NKT cells demonstrate anti-tumor activity, even without a CAR. This is because NKT cells can kill immune suppressive cells in the local tumor microenvironment. Thus, when we add a CAR to NKT cells they are now equipped with two different anti-tumor mechanisms, which may lead to more potent anti-tumor activity and reduce the potential for relapse.

Advancing KUR-501 CAR-NKT Targeting GD2 – KUR-501 is an autologous product in which NKT cells are engineered with a CAR targeting GD2 and is currently being evaluated in a phase 1 clinical trial (GINAKIT2) treating children with R/R high risk neuroblastoma. Neuroblastoma is a rare pediatric cancer and patients with R/R high risk neuroblastoma have very poor outcomes. Therefore, we believe there is a significant unmet need for better treatment options. Interim data presented at the American Society of Gene and Cell Therapy (ASGCT) 2021 Annual Meeting for the first eleven evaluable patients, showed long-term persistence of CAR-NKT cells and CAR-NKT cell localization at the tumor site. Responses were observed in two patients, including one CR, one PR, and four patients achieved SD. The safety profile of KUR-501 was manageable and the product is being administered in the outpatient

setting. GINATKIT2 will continue enrolling patients at higher dose level cohorts with a goal to identify an optimal dose that we may take into a pivotal study.

Advancing KUR-502 CAR-NKT Targeting CD19 – Early data, as presented at the ASH annual meeting in December of 2021, indicated that, of the first five evaluable patients, there was a promising overall response rate of 80% with a complete response rate of 60%. KUR-502 is an allogeneic, "off-the-shelf" product in which NKT cells are engineered with a CAR targeting CD19. Today, autologous CAR-T cell treatments are available to patients, but the patient-to-patient variability and long manufacturing lead times limit patient care options. As an allogeneic "off-the-shelf" product, KUR-502 leverages economies of scale and has the potential to significantly increase patient access to innovative CAR-NKT treatments. Our aim is to expand the phase 1 (ANCHOR) clinical trial treating adults with R/R CD19 positive malignancies currently being conducted at BCM to a phase 1 multicenter clinical trial (ANCHOR2).

Focusing on Specific Programs of Oral Paclitaxel – For Oral Paclitaxel, while our MAA submission is currently under review by the U.K. MHRA, we have focused our efforts on our ongoing combination clinical trials with checkpoint inhibitors where we believe there is an opportunity. Oral Paclitaxel is currently being evaluated in combination with pembrolizumab in NSCLC; and dostarlimab +/- carboplatin in neoadjuvant breast cancer, as part of I-SPY 2.

Licensing and Partnership Opportunities – We continue to increase the global reach of tirbanibulin 1% ointment by maintaining strong global partnerships with existing partners such as Almirall, Seqirus, and AVIR and by evaluating other strategic territories to launch the product. Our team will continue to work closely with our partners to explore additional treatment regimens and indications for tirbanibulin 1% ointment. We will pursue strategic licensing and partnership opportunities for our small molecule programs and target opportunities that will create potential value for stockholders and support our business strategy and mission.

As we pursue these strategic priorities, we expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase as we seek to:

- Advance the preclinical and clinical research program and development activities of our Cell Therapy technology platform;
- Continue our preclinical and clinical research program and development activities related to our Mission;
- Seek to identify additional research programs and product candidates within existing Cell Therapy platform; and
- Maintain, expand, and protect our IP portfolio.

Results of Operations

Except where otherwise noted, the following discussion compares fiscal years 2021 and 2020 results. For a discussion on the comparison between fiscal year 2020 and fiscal year 2019 results, see the Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the SEC and incorporated by reference herein.

Since inception, we have devoted a substantial amount of our resources to research and development of our lead product candidates under our Orascovery, Src Kinase inhibition, Cell Therapy and arginine deprivation therapy technologies, to sales and general administrative costs associated with our operations, and to the development of our specialty drug operations in our Commercial Platform and 503B operations. We have incurred significant net losses since inception. Our net losses were $202.0 million, $148.4 million, and $125.5 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021 and 2020, we had an accumulated deficit of approximately $913.4 million and $713.6 million, respectively.

We have funded our operations to date primarily from the issuance and sale of our common stock through public offerings, private placements, debt and convertible bonds, and to a lesser extent, through revenue generated from our Global Supply Chain Platform. Our operating activities from continuing operations used $138.3 million, $127.8 million and $97.0 million of cash during the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had cash and cash equivalents of $35.2 million, restricted cash of $16.5 million, and short-term investments of $10.2 million.

Key Components of Results of Operations

Revenue

We derive our consolidated revenue primarily from (i) the sales of generic injectable products by our Commercial Platform; (ii) licensing and collaboration projects conducted by our Oncology Innovation Platform, which generates revenue in the form of upfront payments, milestone payments, and payments received for providing research and development services for our collaboration projects and for other third parties; (iii) the sales of 503B and API products by our Global Supply Chain Platform; and (iv) grant awards from government agencies and universities for our continuing research and development efforts.

The following table sets forth the components of our consolidated revenue and the amount as a percentage of total revenue for the periods indicated.

	Year ended December 31,					
	2021		2020		2019	
	(in thousands)	%	(in thousands)	%	(in thousands)	%
Product sales, net	$ 92,264	77%	$ 105,274	73%	$ 80,535	80%
License and other revenue	27,917	23%	39,117	27%	20,694	20%
	$ 120,181		$ 144,391		$ 101,229	

Cost of Sales

Along with sourcing from third-party manufacturers, we manufacture clinical products in our U.S. current Good Manufacturing Practices (“cGMP”) facility in New York. Cost of sales primarily includes the cost of finished products, raw materials, labor costs, manufacturing overhead expenses and reserves for expected scrap, as well as transportation costs. Cost of sales also includes depreciation expense for production equipment, changes to our excess and obsolete inventory reserves, certain direct costs such as shipping costs, net of costs charged to customers, and sublicense fees related to in-license agreements.

Research and Development Expenses

Research and development (“R&D”) expenses primarily consist of the costs associated with in-licensing of product candidates, milestone payments, conducting preclinical studies and clinical trials, activities related to regulatory filings and other R&D activities. The following table sets forth the components of our R&D expenses and the amount as a percentage of total R&D expenses for the periods indicated.

	Year Ended December 31,					
	2021		2020		2019	
	(in thousands)	%	(in thousands)	%	(in thousands)	%
Wages, benefits, and related costs	$ 22,136	28%	$ 22,809	30%	$ 19,569	23%
Clinical trial costs	22,953	29%	36,245	48%	45,839	54%
Preclinical research costs	11,443	14%	8,411	11%	8,418	10%
Drug licensing costs	8,559	11%	2,437	3%	8,071	10%
Other research and development costs	15,106	19%	6,002	8%	2,496	3%
Total research and development costs	$ 80,197		$ 75,904		$ 84,393	

Our current R&D activities mainly relate to the clinical development of our Oncology Innovation Platform.

We expense R&D costs as incurred. We record costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment or clinical site activations. We do not allocate employee-related costs, depreciation, rental and other indirect costs to specific R&D programs because these costs are deployed across multiple product programs under R&D. For 2021, other research and development costs include the cost of manufacturing Oral Paclitaxel in advance of the potential product launch in 2021. These costs are not expected to continue.

We cannot determine with certainty the duration, costs and timing of the current or future preclinical or clinical studies of our drug candidates. The duration, costs, and timing of clinical studies and development of our drug candidates will depend on a variety of factors, including:

- The scope, rate of progress, and costs of our ongoing, as well as any additional, clinical studies and other R&D activities;
- Future clinical study results;
- Uncertainties in clinical study enrollment rates;
- Significant and changing government regulation; and
- The timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a drug candidate, including delays caused by the ongoing COVID-19 pandemic, could mean a significant change in the costs and timing associated with the development of that drug candidate.

R&D activities are central to our business model. We expect our R&D expenses to decrease overall, as the development of most non-Cell Therapy technologies has been suspended. R&D expenses related to our Cell Therapy platform are expected to increase as we prepare for additional clinical and preclinical studies for our Cell Therapy programs. There are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial, regulatory and public health, including the ongoing COVID-19 pandemic, factors beyond our control will likely impact our clinical development programs and plans.

Selling, General and Administrative Expenses

Selling, general and administrative, (“SG&A”), expenses primarily consist of compensation, including salary, employee benefits and stock-based compensation expenses for sales and marketing personnel, and for administrative personnel that support our general operations such as executive management, legal counsel, financial accounting, information technology, and human resources personnel. SG&A expenses also include professional fees for legal, patent, consulting, auditing and tax services, as well as other direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in the selling, marketing, general and administrative activities. SG&A expenses also include costs associated with our commercialization efforts for our proprietary drugs, such as market research, brand strategy and development work on market access, scientific publication, product distribution, and patient support.

We anticipate that our SG&A costs associated with the commercialization of the Orascovery platform and the development of the facility in Dunkirk, NY will decrease in future periods. We expect that certain costs, including share compensation costs, insurance costs, and other administrative costs, will decrease as a result of the sale of our interest in the pharmaceutical manufacturing facility located in Dunkirk, NY. Meanwhile, we anticipate that cost related to legal, compliance, accounting and investor and public relations expenses associated with being a public company will remain consistent.

Interest Expense and Interest Income

Interest expense consists primarily of interest on our long-term loans and the amortization of our debt discount. Interest income consists primarily of interest generated from our cash and short-term investments in U.S. Treasury securities, U.S. agency securities, high rated commercial papers and corporate bonds.

Loss on Extinguishment of Debt

The loss on extinguishment of debt is the result of refinancing the senior secured loan agreement with Perceptive Advisors LLC and its affiliates (“Perceptive”) with the Senior Credit Agreement with Oaktree, as well as the subsequent assignment of a portion of the Senior Credit Agreement to Sagard. The refinancing of the senior secured loan agreement with Perceptive resulted in an exit fee and the recognition of the unamortized debt discount as a loss on extinguishment of debt in the consolidated statements of operations and comprehensive loss. The assignment of a portion of the Senior Credit Agreement to Sagard qualified as a partial debt extinguishment and resulted in a proportional loss from the existing unamortized debt discount, inclusive of unamortized deferred financing fees.

Results of Operations

Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

The following table sets forth a summary of our consolidated results of operations for the years ended December 31, 2021 and 2020, together with the changes in those items in dollars and as a percentage. This information should be read together with our consolidated financial statements and related notes included elsewhere in this report. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Year ended December 31,			
	2021	2020	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue				
Product sales, net	$ 92,264	$ 105,274	$ (13,010)	-12%
License and other revenue	27,917	39,117	(11,200)	-29%
Total revenue	$ 120,181	$ 144,391	(24,210)	
Cost of sales	(82,406)	(95,355)	12,949	-14%
Gross profit	37,775	49,036	(11,261)	
Research and development expenses	(80,197)	(75,904)	(4,293)	6%
Selling, general, and administrative expenses	(72,553)	(92,859)	20,306	-22%
Impairments	(69,419)	—	(69,419)	100%
Interest income	227	874	(647)	-74%
Interest expense	(20,742)	(11,219)	(9,523)	85%
Loss on extinguishment of debt	—	(10,278)	10,278	-100%
Income tax benefit (expense)	10,604	(4,088)	14,692	NM
Net loss from continuing operations	(194,305)	(144,438)	(49,867)	
Loss from discontinued operations	(7,731)	(3,996)	(3,735)	93%
Net loss	(202,036)	(148,434)	(53,602)	
Less: net loss attributable to non-controlling interests	(2,268)	(2,255)	(13)	-1%
Net loss attributable to Athenex, Inc.	$ (199,768)	$ (146,179)	$ (53,589)	

Revenue

Product sales for the year ended December 31, 2021 was $92.6 million, a decrease of $13.0 million, or 12%, as compared to $105.3 million for the year ended December 31, 2020. This decrease was primarily attributable to a decrease in APD product sales of $22.6 million. The prior year had an increase in demand for COVID-19 related drugs and for FDA shortage products, including some significant non-recurring orders. In addition, in the first half of 2021, we experienced significant COVID-related challenges in our Indian supply chain and to a lesser extent in China. As a result, we did not receive some inventory from our partners located in these countries for a certain period of time. This decrease in APD product sales was partially offset by an increase in 503B sales of $7.8 million as the result of the increase in demand for certain drugs used to treat patients hospitalized with COVID-19. Contract manufacturing sale and API product sales experienced increases of $1.4 million and $0.4 million, respectively.

License fees and other revenue decreased to $27.9 million for the year ended December 31, 2021, from $39.1 million for the year ended December 31, 2020, a decrease of $11.2 million, or 29%. During the year ended December 31, 2021, we recorded $20.0 million and $5.0 million of license revenue pursuant to our license agreement with Almirall upon the launch of Klisyri in the U.S. in February 2021 and in Europe in September 2021, respectively, and $0.5 million related to the upfront fee pursuant to the Second Amendment to the PharmaEssentia Agreement, for the license of Tirbanibulin in Japan and South Korea. During the year ended December 31, 2020, we recognized $37.7 million in license revenue, net of $2.3 million VAT pursuant to the Xiangxue License to develop and commercialize Oral Paclitaxel, Oral Irinotecan, and tirbanibulin ointment in People's Republic of China ("PRC" or "China"), Hong Kong, and Macau, and $1.0 million in license revenue pursuant to the license agreement we entered into with PharmaEssentia to develop and commercialize Oral Paclitaxel, Oral Irinotecan, and Oral Docetaxel in Taiwan, Singapore, and Vietnam.

Cost of Sales

Cost of sales totaled $82.4 million for the year ended December 31, 2021, a decrease of $12.9 million, or 14%, as compared to $95.4 million for the year ended December 31, 2020. The decrease in our cost of APD product sales was in-line with the decrease in APD product revenue and was partially offset by increases in cost of sales related to the increases in 503B, Contract Manufacturing, and API product sales. In the year ended December 31, 2020, we incurred sublicense fees of $5.8 million on our license revenue, which did not occur in 2021.

Research and Development Expenses

R&D expenses totaled $80.2 million for the year ended December 31, 2021, an increase of $4.3 million, or 6%, as compared to $75.9 million for the year ended December 31, 2020. This was primarily due to an increase in costs related to Oral Paclitaxel, drug licensing costs, cell therapy costs, and compensation, and included the following:

- $9.5 million increase in Oral Paclitaxel product development, API, and medical affairs costs associated with the potential product launch in 2021;
- $6.2 million increase in drug licensing costs, due to license payments for specialty pharmaceutical products, a license milestone payment related to Arginine deprivation therapy, and the repurchase of Orascovery rights from Xiangxue; and
- $4.4 million increase in cell therapy development costs.

The increase in these R&D expenses was partially offset by a decrease of $8.8 million in costs of clinical operations after completion of the Phase 3 studies for tirbanibulin ointment and Oral Paclitaxel, a decrease of $4.4 million in regulatory costs in connection with our NDA preparations, a decrease of $1.4 million in preclinical operations, a decrease of $0.7 million in research and development related compensation and a decrease of $0.5 million in costs of other product development.

Selling, General and Administrative Expenses

Selling, general, and administrative expenses totaled $72.6 million for the year ended December 31, 2021, a decrease of $20.3 million, or 22%, as compared to $92.9 million for the year ended December 31, 2020. This was primarily due to a $24.8 million decrease of costs for preparing to commercialize Oral Paclitaxel as significant pre-launch activities occurred in 2020 and slowed upon receipt of the Complete Response Letter in February 2021. In addition, we did not record a provision for credit losses in 2021, compared to provision for credit losses of $8.9 million from 2020. Compensation related costs decreased by $0.2 million in 2021 compared to 2020. These decreases were partially offset by a $4.2 million increase from the change in fair value of contingent consideration, a $5.9 million increase in operating costs including insurance costs, IT costs, other professional fees, and the costs to operate our manufacturing facility in Chongqing, China, and a $3.5 million increase in professional fees and other expenses related to the acquisition of Kuur.

Impairments

During the year ended December 31, 2021, we recognized goodwill impairment expense of $67.7 million and impairment of other intangible assets of $1.7 million. Of the total goodwill impairment, $26.6 million was related to the Global Supply Chain Platform reporting unit, representing a full impairment of the goodwill allocated to that reporting unit, and $41.1 million was related to the Oncology Innovation Platform reporting unit, representing a full impairment of the goodwill allocated to that reporting unit. Goodwill impairment is the excess of a reporting unit's carrying amount over its fair value. The decrease in our estimation of the reporting units' fair value was related to the Company's decision to no longer pursue regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S. and the delays in the launch of products in our newly constructed manufacturing facilities. No such impairment was recorded during the year ended December 31, 2020.

Interest Income and Interest Expense

Interest income consisted of interest earned on our short-term investments and decreased by $0.6 million, or 74%, from 2020 to 2021 due a decrease in our short-term investment holdings during the year and a decrease in market rates for commercial paper, corporate bonds, and U.S. Treasury securities. Interest expense for the year ended December 31, 2021 totaled $20.7 million, an increase of $9.5 million, or 85%, as compared to $11.2 million for the year ended December 31, 2020, primarily due to increased borrowings. Interest expense in 2021 consisted of interest on borrowings under the Senior Credit Agreement with Oaktree while interest expense in 2020 included interest on borrowings under the credit agreement with Perceptive we entered into in June 2018, and the Senior Credit Agreement with Oaktree we entered into in June 2020 to repay in full the outstanding loan and fees under the credit agreement with Perceptive.

Loss on Extinguishment of Debt

We recognized a $7.2 million loss on the extinguishment of debt related to the termination of the senior secured loan agreement with Perceptive and a $3.0 million loss on the partial extinguishment of debt related to the assignment of a portion of the senior secured loan from Oaktree’s co-investors to Sagard during the year ended December 31, 2020. We did not incur loss on the extinguishment of debt during the year ended December 31, 2021.

Income Tax Expense

For the year ended December 31, 2021, income tax benefit amounted to $10.6 million, compared to income tax expense of $4.1 million for 2020. The income tax benefit in the current year is primarily the result of taxable temporary difference due to the deferred

tax liability recognized for the indefinite lived intangible assets acquired in connection with the acquisition of Kuur's in-process research and development ("IPR&D"). This taxable temporary difference is considered a source of taxable income to support the realization of deferred tax assets from the acquirer which resulted in a reversal of our valuation allowance. The income tax expense in the prior year was primarily attributable to foreign income tax withholdings on our revenue earned under our out-license arrangements.

Loss from discontinued operations

Loss from discontinued operations is comprised of operating results of the activities related to the build out of our manufacturing facility in Dunkirk, NY. This facility was sold in the first quarter of 2022. The increase in loss from discontinued operations was due to an increase in headcount and general costs necessary to prepare the Dunkirk facility for manufacturing operations. This increase was partially offset by income from a government grant in 2021, which consisted of a reimbursement of operating expenses received from New York State related to the preparation of the facility. Distributions by New York State under this arrangement in prior years were made for direct construction costs that were capital in nature and were not made to offset our operating expenses incurred in relation to such construction.

Liquidity and Capital Resources

Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Our cash requirement was primarily cash used for our R&D programs, SG&A costs associated with our operations, the development of our specialty drug operations in our Commercial Platform and 503B operations, and the investment we made in our pre-launch activities in anticipation of commercializing our proprietary drugs. We incurred net losses of $202.0 million, $148.4 million and $125.5 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $913.4 million. Our operating activities from continuing operations used $138.3 million, $127.8 million and $97.0 million of cash during the years ended December 31, 2021, 2020, and 2019, respectively. We intend to continue to advance our various clinical and pre-clinical programs which could lead to increased cash outflow of R&D costs. While we expect our R&D expenses to decrease overall, as the development of most non-Cell Therapy technologies has been suspended, R&D expenses related to our Cell Therapy platform are expected to increase as we prepare for additional clinical and preclinical studies for our Cell Therapy programs. We can provide no assurance that the funding requirements to diversify the product portfolio for specialty drug products in the Commercial Platform and 503B operations will decline in the future. Our principal sources of liquidity as of December 31, 2021 were cash and cash equivalents totaling $35.2 million, restricted cash of $16.5 million, held in a controlled bank account in connection with the Senior Credit Agreement with Oaktree, and short-term investments totaling $10.2 million, which are generally high-quality investment grade corporate debt securities.

Our obligations under the Senior Credit Agreement are guaranteed by us and certain of our existing domestic subsidiaries and subsequently acquired or organized subsidiaries subject to certain exceptions. Our obligations under the Senior Credit Agreement and the related guarantees thereunder are secured, subject to customary permitted liens and other agreed upon exceptions, by (i) a pledge of all of the equity interests of our direct subsidiaries, and (ii) a perfected security interest in all of our tangible and intangible assets.

The Senior Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions, including specific exceptions with respect to product commercialization and development activities. In addition, the Senior Credit Agreement contains certain financial covenants, including, among other things, maintenance of minimum liquidity and a minimum revenue test, measured quarterly until the last day of the second consecutive fiscal quarter where the consolidated leverage ratio does not exceed 4.5 to 1, provided that thereafter we cannot allow our consolidated leverage ratio to exceed 4.5 to 1, measured quarterly. Failure of the Company to comply with the financial covenants will result in an event of default, subject to certain cure rights of the Company. At December 31, 2021, we were in compliance with all applicable covenants.

Debt and Equity Financings

ATM Financing

On August 20, 2021, we entered into a sales agreement with SVB Leerink LLC, in connection with the offer and sale of up to $100,000,000 of shares of our common stock, par value $0.001 per share, in an at-the-market offering (the "ATM Offering"). During the year ended December 31, 2021, we sold 762,825 shares of our common stock for an average price of $1.49 per share under the Sales Agreement.

Public Offering of Stock

In September 2020, we completed an underwritten public offering of 10,000,000 shares of our common stock. We granted the underwriters a 30-day option to purchase up to an additional 1,500,000 shares of common stock, which was exercised in full in

September 2020. All shares were offered at a price of $11.00 per share. Net proceeds were $118.7 million, after deducting underwriting discounts and commissions and offering expenses of $7.9 million.

Oaktree Senior Credit Agreement

On June 19, 2020 (the "Closing Date"), we entered into the Senior Credit Agreement to borrow up to $225.0 million in five tranches with a maturity date of June 19, 2026, bearing interest at a fixed annual rate of 11.0%, payable quarterly. We are required to make quarterly interest-only payments until June 19, 2022, after which we are required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. Since September 17, 2020, we have been required to pay a commitment fee on any undrawn commitments equal to 0.6% per annum, payable on each subsequent funding date and the commitment termination date. We are also required to pay an exit fee at maturity equal to 2.0% of the aggregate principal amount of the loans funded under the Senior Credit Agreement.

The first tranche of $100.0 million was drawn prior to June 30, 2020, with $54.1 million of the proceeds used in part to repay in full the outstanding loan and fees under the credit agreement with Perceptive and an additional $11.0 million of the upfront loan proceeds held by us as restricted cash in a debt service reserve account, and $6.4 million in fees and expenses incurred in connection with the financing, leaving $28.5 million in available proceeds from the first tranche. The second tranche of $25.0 million was drawn prior to September 30, 2020 and the third tranche of $25.0 million was drawn prior to December 31, 2020. Our ability to draw Tranches C and E of the Senior Credit Agreement was associated with the marketing approval and future sales of Oral Paclitaxel. These tranches were reduced to zero in connection with the amendment described below and are not available for future borrowing.

We are required to make mandatory prepayments of the senior secured loans with net cash proceeds from certain asset sales or insurance proceeds or condemnation awards, in each case, subject to certain exceptions and reinvestment rights. In connection with the sale of the Dunkirk Facility in February 2022, we entered into an amendment to the Senior Credit Agreement (the "January Credit Agreement Amendment") whereby we were required to repay $25.0 million, or 62.5% of the proceeds from the sale, of the outstanding principal of the loan. In addition, on the date of closing the Dunkirk Transaction, we were required to pay (i) accrued and unpaid interest and (ii) a 7.0% fee, allocated as a 2.0% Exit Fee and a 5.0% Prepayment Fee (each as defined in the Senior Credit Agreement), on the principal amount being repaid. We were required to pay Oaktree an amendment fee of $0.3 million and certain related expenses. Further, the January Credit Agreement Amendment requires us to make an additional prepayment of $12.5 million in principal plus the costs and fees described above by June 14, 2022, within 120 days of the closing of the Dunkirk Transaction.

We may voluntarily prepay the Senior Credit Agreement at any time subject to a prepayment premium which up until June 19, 2022 is equal to the amount of interest that would have been paid up to, but not including, June 19, 2022 (excluding interest amounts already paid), plus 3.0% of the principal amount of the senior secured loans being repaid. Thereafter, the prepayment premium equals 3.0% of the principal amount of the senior secured loans being repaid and is reduced over time until June 19, 2024, after which no prepayment premium is required.

Our obligations under the Senior Credit Agreement are guaranteed by us and certain of our existing domestic subsidiaries and subsequently acquired or organized subsidiaries subject to certain exceptions. Our obligations under the Senior Credit Agreement and the related guarantees thereunder are secured, subject to customary permitted liens and other agreed upon exceptions, by (i) a pledge of all of the equity interests of our direct subsidiaries, and (ii) a perfected security interest in all of our tangible and intangible assets.

The Senior Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions, including specific exceptions with respect to product commercialization and development activities. In addition, the Senior Credit Agreement contains certain financial covenants, including, among other things, maintenance of minimum liquidity and a minimum revenue test, measured quarterly until the last day of the second consecutive fiscal quarter where the consolidated leverage ratio does not exceed 4.5 to 1, provided that thereafter we cannot allow our consolidated leverage ratio to exceed 4.5 to 1, measured quarterly. Failure of the Company to comply with the financial covenants will result in an event of default, subject to certain cure rights of the Company. At December 31, 2021, we were in compliance with all applicable covenants.

The Senior Credit Agreement contains events of default which are customary for financings of this type, in certain circumstances subject to customary cure periods. Following an event of default and any cure period, if applicable, Oaktree will have the right upon notice to terminate any undrawn commitments and may accelerate all amounts outstanding under the Senior Credit Agreement, in addition to other remedies available to it as a secured creditor of the Company.

In connection with our entry into the Senior Credit Agreement, we granted warrants to Oaktree to purchase up to an aggregate of 908,393 shares of our common stock at a purchase price of $12.63 per share. Under the January Credit Agreement Amendment, the warrants were amended to change the exercise price to be paid per share upon exercise of the warrants. The January Credit Agreement Amendment provides that the exercise price for 50% of the shares underlying the warrants will be $1.10 per share. The exercise price for the remaining 50% of the warrants was not changed by the January Credit Agreement Amendment.

Outlook

We have borrowed and, in the future, may borrow additional capital from institutional and commercial banking sources to fund future growth. We may borrow additional funds on terms that may include restrictive covenants, including covenants that further restrict the operation of our business, liens on assets, high effective interest rates, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements or by monetizing non-core assets, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As of December 31, 2021, we had cash and cash equivalents of $35.2 million, restricted cash of $16.5 million, and short-term investments of $10.2 million. We are implementing cost savings programs and plan to monetize non-core assets and raise capital in order to extend our cash runway in 2022. If we are unable to raise additional capital or monetize assets, we believe that the existing cash and cash equivalents, restricted cash, and short-term investments will not be sufficient to fund current operating plans through one year after the date that these audited consolidated financial statements are issued. We have concluded that this raises substantial doubt about our ability to continue as a going concern. See Part II, Item 8. Note 1—Company and Nature of Business for further information regarding our ability to continue as a going concern. We have based these estimates on assumptions that may prove to be wrong, and we could spend the available financial resources much faster than expected and need to raise additional funds sooner than anticipated. Although we plan to raise additional funds though the sale of non-core assets and selling equity securities, these plans are subject to market conditions which are outside of our control, and therefore cannot be deemed to be probable. There can be no assurance that additional financing, if available, can be obtained on terms acceptable to us. If we are unable to obtain such additional financing, we would need to reevaluate our future operating plans.

We anticipate that our expenses will cover the following activities as we:

- Advance the preclinical and clinical research program and development activities of our Cell Therapy technology platform;
- Continue our preclinical and clinical research program and development activities related to our Mission;
- Seek to identify additional research programs and product candidates within existing Cell Therapy platform; and
- Maintain, expand and protect our intellectual property (“IP”) portfolio.

We have made certain changes to our budgeted expenses in light of the CRL for Oral Paclitaxel we received in February 2021 and the Type A meetings with the FDA, including curtailing commercialization expenses and investing in additional products for our specialty drug product business. However, our expenses could increase as we continue to fund clinical and preclinical development of our research programs by advancing our Cell Therapy programs, certain candidates in our pipeline, our specialty drug products, working capital and other general corporate purposes. Capital expenditure at the Sintaho facility may continue to grow and be significant as we build out the plant to manufacture Tirbanibulin APIs. We have based our estimates on assumptions that might prove to be wrong and we might use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to accurately estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

Our future capital requirements will depend on many factors, some or all of which may be impacted by the COVID-19 pandemic, including:

- Our ability to generate revenue and profits from our Commercial Platform or otherwise;
- The costs, timing and outcome of regulatory reviews and approvals;
- Progress of our drug candidates to progress through clinical development successfully;
- The initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our other programs and potential drug candidates;
- The costs of construction and fit-out of planned drug manufacture at our API manufacturing facility;
- The number and characteristics of the drug candidates we pursue;

- The costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our IP rights and defending IP related claims;
- The extent to which we acquire or in-license other products and technologies; and
- Our ability to maintain and establish collaboration arrangements on favorable terms, if at all.

Until we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, and government grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of holders of common stock. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and might require the issuance of warrants, which could potentially dilute the ownership interest of holders of common stock. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we might have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that might not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we might be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

We believe that the existing cash and cash equivalents, restricted cash, and short-term investments will not be sufficient to fund current operating plans through one year after the date that these audited consolidated financial statements are issued. Our estimates are based on relevant conditions that are known and reasonably knowable at the date of these consolidated financial statements being available for issuance and are subject to change due to changes in business, industry or macroeconomic conditions. Further, we do not expect to have access to additional capital under the Senior Credit Agreement. We have based these estimates on assumptions that may prove to be wrong, and we could spend the available financial resources much faster than expected and need to raise additional funds sooner than anticipated. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

Cash Flows

The following table provides information regarding our cash flows from continuing and discontinued operations for the years ended December 31, 2021, 2020, and 2019:

	Year ended December 31,		
	2021	2020	2019
		(in thousands)	
Net cash used in operating activities from continuing operations	$ (138,271)	$ (127,758)	$ (96,981)
Net cash provided by (used in) investing activities from continuing operations	119,927	(114,338)	11,357
Net cash provided by financing activities from continuing operations	2,640	209,519	167,452
Net cash used in discontinued operations	(19,229)	(8,211)	(4,337)
Net effect of foreign exchange rate changes	548	(799)	389
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (34,385)	$ (41,587)	$ 77,880

Net Cash Used in Operating Activities

The use of cash in all periods presented resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The primary use of our cash in all periods presented was to fund our R&D, regulatory and other clinical trial costs, drug licensing costs, inventory purchases, pre-launch commercialization activities, build-out of our manufacturing facilities, and other expenditures related to sales, marketing and administration. Our prepaid expenses and other current assets, accounts payable and accrued expense balances in all periods presented were affected by the timing of vendor invoicing and payments.

During the year ended December 31, 2021, operating activities from continuing operations used $138.3 million of cash, which resulted principally from our net loss from continuing operations of $194.3 million, adjusted for non-cash charges of $90.7 million, non-cash income benefit of $10.8 million related to the reversal of our valuation allowance on our deferred tax assets to offset the deferred tax liability assumed in connection with the acquisition of Kuur's IPR&D, and cash used by our operating assets and liabilities of $23.8 million. Our net non-cash charges during the year ended December 31, 2021 consisted of $69.4 million of impairment of goodwill and intangible assets, $9.2 million of stock-based compensation expense, $4.7 million depreciation and amortization expense, $4.2 million change in fair value of contingent consideration, $2.9 million amortization of debt discount, and $0.6 million write-off of deferred debt issuance costs related to the Revenue Interest Financing. Our operating assets increased $2.7 million for accounts receivable mainly related to the timing of revenues, decreased $4.1 million in prepaid expenses and other assets, and increased $5.9 million for inventory of all drug products. Our operating liabilities decreased by $19.2 million mainly due to a decrease in accrued wages and benefits, accrued construction costs for the Dunkirk, NY facility, accrued costs for potential product launch, accrued selling fees and rebates, and accrued interest, partially offset by an increase in deferred revenue. Net cash used in operating activities from discontinued operations in 2021 was $4.1 million, primarily related to the operating expenses incurred by the activities at the Dunkirk facility.

During the year ended December 31, 2020, operating activities from continuing operations used $127.8 million of cash, which resulted principally from our net loss from continuing operations of $144.4 million, adjusted for non-cash charges of $37.2 million. Cash used by our operating assets and liabilities was $20.5 million primarily due to increases in accounts receivable and a decrease in accrued expenses. Our net non-cash charges during the year ended December 31, 2020 primarily consisted of $10.9 million of stock-based compensation, $10.3 million of loss on extinguishment of debt, $9.5 million provision for expected credit losses, $4.5 million of depreciation and amortization, and $1.8 million of amortization of debt discount. Net cash used in operating activities from discontinued operations in 2020 was $3.5 million, related to the operations at the Dunkirk facility.

During the year ended December 31, 2019, operating activities from continuing operations used $97.0 million of cash, which resulted principally from our net loss of $125.0 million, adjusted for non-cash charges of $15.4 million. Cash provided by our operating assets and liabilities was $12.6 million primarily due to increases in accounts payable and accrued expenses. Our net non-cash charges during the year ended December 31, 2019 primarily consisted of $3.8 million in depreciation and amortization expense, $9.9 million in stock-based compensation expense, and $1.0 million in amortization of debt discount. Net cash used in operating activities from discontinued operations in 2019 was $0.5 million, related to the operations at the Dunkirk facility.

Net Cash (Used in) Provided by Investing Activities

In 2021, cash provided by investing activities of continuing operations of $119.9 million was primarily attributable to $128.9 million in the sale and maturity of short-term investments, net of purchases, $8.4 million in purchasing property and equipment for continuing operations, primarily, our Sintaho facility, and $2.1 million in payments for licenses, partially offset by cash received from the acquisition of Kuur of $1.4 million. Net cash used in investing activities of discontinued operations in 2021 was $14.9 million, related to purchasing property and equipment at the Dunkirk facility.

In 2020, cash used in investing activities of continuing operations of $114.3 million was primarily attributable to $105.5 million in purchases of short-term investments, net of sales and maturities, $8.6 million in purchasing property and equipment for continuing operations $0.2 million in payment for licenses. Net cash used in investing activities of discontinued operations in 2020 was $4.6 million, related to purchasing property and equipment at the Dunkirk facility.

In 2019, cash provided by investing activities of continuing operations of $11.4 million was primarily attributable to $24.4 million in sale and maturity of short-term investments, net of purchases, and $0.9 million provided by the acquisition of CIDAL, offset by $9.7 million in purchasing property and equipment for continuing operations, and $4.2 million in payment for licenses. Net cash used in investing activities of discontinued operations in 2019 was $3.9 million, related to purchasing property and equipment at the Dunkirk facility.

Net Cash Provided by Financing Activities

In 2021, cash provided by financing activities of continuing operations was $2.6 million, which primarily consisted of the proceeds from the exercise of stock options of $1.6 million, proceeds from the sale of shares in the ATM Offering of $1.3 million in December, and proceeds from the issuance of debt of $0.8 million, partially offset by the repayment of long-term debt and finance lease obligations of $1.0 million. Net cash used in financing activities of discontinued operations in 2021 was $0.2 million, related to the repayment of finance lease obligations.

In 2020, cash provided by financing activities of continuing operations was $209.5 million, which primarily consisted of $127.0 million from the sale of common stock and $143.0 million from the draw downs of debt from our Senior Credit Agreement with Oaktree and $2.1 million to fund our new API plant in China, $7.0 million from the issuance of warrants to Oaktree and Sagard, and $1.7 million from the exercise of stock options, partially offset by $54.3 million repayment of the Perceptive loan and other long-term debt, and $7.9 million and $9.4 million issuance costs related to sale of our common stock in our underwritten follow-on public offering and the issuance of the new Oaktree debt and warrants to Oaktree and Sagard, respectively. Net cash used in financing activities of discontinued operations in 2020 was $0.1 million, related to the repayment of finance lease obligations.

In 2019, cash provided by financing activities of continuing operations was $167.5 million, which primarily consisted of net proceeds of $161.1 million from the issuance of our common stock mostly from private placements, net of offering expenses of approximately $1.1 million, and $6.5 million from the issuance of debt to fund our new API plant in China, offset by $1.0 million repayment of debt and finance lease obligations.

Indebtedness

We had $157.7 million and $157.8 million of debt as of December 31, 2021 and 2020, respectively. As of December 31, 2021 and 2020, this primarily consisted of the Senior Credit Agreement entered into with Oaktree during 2020, and a credit agreement with Chongqing Maliu Riverside Development and Investment Co., LTD, and finance and operating lease obligations.

In 2020, we entered into a Senior Credit Agreement with Oaktree to borrow up to $225.0 million in five tranches with a maturity date of June 19, 2026, bearing interest at a fixed annual rate of 11.0%, payable quarterly. We have drawn three tranches amounting to $150.0 million; the remaining two tranches totaling $75.0 million were reduced to zero in connection with the January Credit Agreement Amendment in February 2022. We are required to make quarterly interest-only payments until June 19, 2022, after which we are also required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. Since September 17, 2020, we have been required to pay a commitment fee on any undrawn commitments equal to 0.6% per annum, payable on each subsequent funding date and the commitment termination date. We are also required to pay an exit fee at maturity equal to 2.0% of the aggregate principal amount of the loans funded under the Senior Credit Agreement. Upon closing of the Dunkirk Transaction in February 2022, we repaid $25.0 million of the outstanding principal, plus any unpaid and accrued interest, plus the 2.0% exit fee and the 5.0% prepayment fee pursuant to the January Credit Agreement Amendment.

In 2019, we entered into a credit agreement which amended the existing partnership agreement with Chongqing Maliu Riverside Development and Investment Co., LTD (“CQ”), for a Renminbi ¥50.0 million (USD $7.2 million at December 31, 2019) line of credit to be used for the construction of the new API plant in China. We are required to repay the principal amount with accrued interest within three years after the plant receives the cGMP certification, with 20% of the total loan with accrued interest is due within the first twelve months following receiving the certification, 30% of the total loan with accrued interest due within twenty-four months, and the remaining balance with accrued interest due within thirty-six months. Interest accrues at the three-year loan interest rate by the People’s Bank of China for the same period on the date of the deposit of the full loan amount, which is expected to approximate 4.75% annually. If we fail to obtain the cGMP certification within three years upon the completion and acceptance of the plant, we shall return all renovation costs with the accrued interest to CQ, in a single transaction within the first ten business days of the next day. If we fail to obtain the cGMP certification within three years of the acceptance of the plant, we are required to return all renovation costs with accrued interest to CQ within ten business days. As of December 31, 2021, the balance due to CQ was $7.8 million.

Capital Expenditures

Our liquidity position and capital requirements are subject to a number of factors. For example, our cash inflow and outflow may be impacted by the following:

- Our ability to generate revenue;
- Our ability to improve margins on our commercial products;
- Fluctuations in working capital; and
- Our ability to raise additional funds.

Our primary short-term capital needs, which are subject to change, include expenditures related to:

- Continuous support of the development and research of our proprietary drug products;
- Build out of our new API plant in China and improvements in our existing manufacturing capacity and efficiency;
- New research and product development efforts; and
- Support of our commercialization efforts related to our current and future products.

Although we believe the foregoing items reflect our most likely uses of cash in the short term, we cannot predict with certainty all of our short-term cash uses or the timing or amounts of cash used. If cash generated from operations is insufficient to satisfy our working capital and capital expenditure requirements, we may be required to sell additional equity or debt securities or obtain credit financing. This capital may not be available on satisfactory terms, if at all. Furthermore, any additional equity financing may be dilutive to our stockholders, and debt financing, if available, may include restrictive covenants.

Contractual Obligations

A summary of our contractual obligations as of December 31, 2021 is as follows:

	Payments Due by Period				Total Amounts Committed
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	
			(in thousands)		
Operating leases	$ 3,020	$ 4,218	$ 1,819	$ 132	$ 9,189
Long-term debt	47,507	25,811	89,377	—	162,695
Finance lease obligations	159	207	—	—	366
License fees	916	400	—	—	1,316
	$ 51,602	$ 30,636	$ 91,196	$ 132	$ 173,566

Our operating and finance leases are principally for facilities and equipment. We currently lease office space in the U.S. and foreign countries to support our operations as a global organization. The operating leases in the above table include our several locations with the amounts committed by each location: (1) the rental of our global headquarters in the Conventus Center for Collaborative Medicine in Buffalo, NY; (2) the rental of our research and development facility in the IC Development Centre in Hong Kong; (3) the rental of the Commercial Platform headquarters in Chicago, IL; (4) the rental of our clinical research headquarters in Cranford, NJ; (5) the rental of our clinical data management center in Taipei, Taiwan; (6) the rental of our contract research organization throughout Latin America; (7) the rental of our Global Supply Chain distribution office in Houston, TX; (8) the rental of our Global Supply Chain API manufacturing facility in Chongqing, China; and (9) the rental of other facilities and equipment located mainly in Buffalo, NY. These locations represent $4.6 million, $0.1 million, $1.6 million, $0.2 million, $0.2 million, $0.1 million, $0.2 million, $0.4 million, and $1.7 million, respectively, of the total amounts committed. In addition to the minimum rental commitments on our operating leases we may also be required to pay amounts for taxes, insurance, maintenance and other operating expenses.

The long-term debt includes our senior secured loan and the credit agreement with CQ. The finance lease obligations represent three leases of equipment in our 503B manufacturing facility outside of Buffalo, NY. The license fees in the above table represent the amount committed and accrued under in-license agreements for specialty drug products by the Commercial platform.

In addition, we have certain obligations under licensing arrangements with third parties contingent upon achieving various development, regulatory, and commercial milestones. Pursuant to our purchase agreement of Kuur Therapeutics, we may be required to make payments worth up to $115.0 million, payable in cash of shares of our common stock, upon the occurrence of certain development and regulatory milestones related to our NKT cell therapy. Pursuant to our license agreement with Polytom, we may be required to make payments worth up to $44.0 million of our common stock or cash upon the occurrence of certain regulatory milestones related to a pegylated genetically modified human arginase, and make royalty payments representing a percentage of net sales of the licensed products. Pursuant to our license agreement with Avalon HepaPOC, we may be required to make payments worth up to $4.8 million of our common stock or cash upon the occurrence of certain regulatory and sales milestones related to the meter and strips for conduct of liver function tests in humans taking our oncology drugs and make royalty payments representing a percentage of aggregate net sales of the licensed product. Pursuant to the license agreement with XLifeSc, our 55% owned joint venture Axis Therapeutics Limited, we may be required to make cash payments worth up to $108.0 million upon the occurrence of certain regulatory milestones related to XLifeSc's proprietary TCR-T technology, and make royalty payments representing a percentage of aggregate net income generated by sales of licensed products. Pursuant to our license agreements with Hanmi, we may be required to make equity payments of $24.0 million upon regulatory approval of a product within the Orasovery platform and make tiered royalty payments based on net sales of any product using the licensed intellectual property. These amounts are not included in the table above.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenue and expenses during the periods. We evaluate our estimates and judgments on an ongoing basis, including but not limited to, estimating the useful lives of long-lived assets, assessing the impairment of long-lived assets, stock-based compensation expenses, and the realizability of deferred income tax assets. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Changes in the accounting estimates are likely to occur from period to period. Actual results could be significantly different from these estimates. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgment and estimates.

Revenue Recognition

1. Oncology Innovation Platform

The Company out-licenses certain of its IP to other pharmaceutical companies in specific territories that allow the customer to use, develop, commercialize, or otherwise exploit the licensed IP. In accordance with ASC 606, *Revenue from Contracts with Customers* ("Topic 606"), the Company analyzes the contracts to identify its performance obligations within the contract. Most of the Company's out-license arrangements contain multiple performance obligations and variable pricing. After the performance obligations are identified, the Company determines the transaction price, which generally includes upfront fees, milestone payments related to the achievement of developmental, regulatory, or commercial goals, and royalty payments on net sales of licensed products. The Company considers whether the transaction price is fixed or variable, and whether such consideration is subject to return. Variable consideration is only included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. If any portion of the transaction price is constrained, it is excluded from the transaction price until the constraint no longer exists. The Company then allocates the transaction price to the performance obligation to which the consideration is related. Where a portion of the transaction price is received and allocated to continuing performance obligations under the terms of the arrangement, it is recorded as deferred revenue and recognized as revenue when (or as) the underlying performance obligation is satisfied.

The Company's contracts may contain one or multiple promises, including the license of IP and development services. The licensed IP related to the Company's approved and late-stage drug candidates is capable of being distinct from the other performance obligations identified in the contract and is distinct within the context of the contract, as upon transfer of the IP, the customer is able to use and benefit from it, and the customer could obtain the development services from other parties. The Company also considers the economic and regulatory characteristics of the licensed IP and other promises in the contract to determine if it is a distinct performance obligation. The Company considers if the IP is modified or enhanced by other performance obligations through the life of the agreement and whether the customer is contractually or practically required to use updated IP. The IP licensed by the Company has been determined to be functional IP. The IP is not modified during the license period and therefore, the Company recognizes revenues from any portion of the transaction price allocated to the licensed IP when the license is transferred to the customer and they can benefit from the right to use the IP. The Company recognized $0.5 million in license revenue from an out-license arrangement for the year ended December 31, 2021, and $37.7 million in license revenue, net of $2.3 million value added tax ("VAT"), and $1.0 million in license revenue from two of the Company's out-license arrangements for the year ended December 31, 2020. The Company recognized revenue allocated to the licensed IP performance obligation upon transfer of the license of $0.1 million for the year ended December 31, 2019. During the year ended December 31, 2021, the Company received $2.0 million in upfront fees for a license of TRC-T technology, which was deemed not to be distinct, as the IP is in an early stage and is dependent on development activities to be performed by the Company, and $0.7 million for licenses of Klisyri in territories in which it is not yet approved and further development activities are required to be performed by the Company. Therefore these licenses of IP and the development services were considered a bundled performance obligation. As of December 31, 2021, this bundle of performance obligations was not satisfied and the corresponding $2.7 million was recorded as deferred revenue on the Company's consolidated balance sheet.

Other performance obligations included in most of the Company's out-licensing agreements include performing development services to reach clinical and regulatory milestone events. The Company satisfies these performance obligations at a point-in-time, because the customer does not simultaneously receive and consume the benefits as the development occurs, the development does not create or enhance an asset controlled by the customer, and the development does not create an asset with no alternative use. The Company considers milestone payments to be variable consideration measured using the most likely amount method, as the entitlement to the consideration is contingent on the occurrence or nonoccurrence of future events. The Company allocates each variable milestone payment to the associated milestone performance obligation, as the variable payment relates directly to the Company's efforts to satisfy the performance obligation and such allocation depicts the amount of consideration to which the

Company expects to be entitled for satisfying the corresponding performance obligation. The Company re-evaluates the probability of achievement of such performance obligations and any related constraint and adjusts its estimate of the transaction price as appropriate. To date, no amounts have been constrained in the initial or subsequent assessments of the transaction price. The Company did not recognize revenue from other performance obligations included in the Company's out-licensing agreements during the years ended December 31, 2021 or 2020. The Company recognized revenue allocated to development performance obligations upon transfer to the customer of $20.0 million for the year ended December 31, 2019.

Certain out-license agreements include performance obligations to manufacture and provide drug product in the future for commercial sale when the licensed product is approved. For the commercial, sales-based royalties, the consideration is predominantly related to the licensed IP and is contingent on the customer's subsequent sales to another commercial customer. Consequently, the sales- or usage-based royalty exception would apply. Revenue will be recognized for the commercial, sales-based milestones as the underlying sales occur. The Company recognized $25.0 million in commercial milestones and $1.0 million in royalties during the year ended December 31, 2021. No such revenues were recorded during 2020.

The Company exercises significant judgment when identifying distinct performance obligations within its out-license arrangements, determining the transaction price, which often includes both fixed and variable considerations, and allocating the transaction price to the proper performance obligation. The Company did not use any other significant judgments related to out-licensing revenue during the years ended December 31, 2021 and 2020.

2. Global Supply Chain Platform

The Company's Global Supply Chain Platform manufactures API for use internally in its research and development activities as well as its clinical studies, and for sale to pharmaceutical customers globally. The Company generates additional revenue on this platform, by providing small to mid-scale cGMP manufacturing of clinical and commercial products for pharmaceutical and biotech companies and selling pharmaceutical products under 503B regulations set forth by the U.S. FDA.

Revenue earned by the Global Supply Platform is recognized when the Company has satisfied its performance obligation, which is the shipment or the delivery of drug products. The underlying contracts for these sales are generally purchase orders and the Company recognizes revenue at a point-in-time. Any remaining performance obligations related to product sales are the result of customer deposits and are reflected in the deferred revenue contract liability balance.

3. Commercial Platform

The Company's Commercial Platform generates revenue by distributing specialty products through independent pharmaceutical wholesalers. The wholesalers then sell to an end-user, normally a hospital, alternative healthcare facility, or an independent pharmacy, at a lower price previously established by the end-user and the Company. Upon the sale by the wholesaler to the end-user, the wholesaler will chargeback the difference, if any, between the original list price and price at which the product was sold to the end-user. The Company also offers cash discounts, which approximate 2.3% of the gross sales price, as an incentive for prompt customer payment, and, consistent with industry practice, the Company's return policy permits customers to return products within a window of time before and after the expiration of product dating. Further, the Company offers contractual allowances, generally in the form of rebates or administrative fees, to certain wholesale customers, group purchasing organizations ("GPOs"), and end-user customers, consistent with pharmaceutical industry practices. Revenues are recorded net of provisions for variable consideration, including discounts, rebates, GPO allowances, price adjustments, returns, chargebacks, promotional programs and other sales allowances. Accruals for these provisions are presented in the consolidated financial statements as reductions in determining net sales and as a contra asset in accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). As of December 31, 2021 and 2020, the Company's total provision for chargebacks and other deductions included as a reduction of accounts receivable totaled $22.9 million and $12.6 million, respectively. The Company's total provision for chargebacks and other revenue deductions was $129.0 million, $89.3 million, and $87.2 million for the years ended December 31, 2021, 2020, and 2019, respectively.

The Company exercises significant judgment in its estimates of the variable transaction price at the time of the sale and recognizes revenue when the performance obligation is satisfied. Factors that determine the final net transaction price include chargebacks, fees for service, cash discounts, rebates, returns, warranties, and other factors. The Company estimates all of these variables based on historical data obtained from previous sales finalized with the end-user customer on a product-by-product basis. At the time of sale, revenue is recorded net of each of these deductions. Through the normal course of business, the wholesaler will sell the product to the end-user, determining the actual chargeback, return products, and take advantage of cash discounts, charge fees for services, and claim warranties on products. The final transaction price per product is compared to the initial estimated net sale price and reviewed for accuracy. The final prices and other factors are immediately included in the Company's historical data from which it will estimate the transaction price for future sales. The underlying contracts for these sales are generally purchase orders including a single performance obligation, generally the shipment or delivery of products and the Company recognizes this revenue at a point-in-time.

Research and Development Expenses

Research and development expenses represent costs associated with developing our proprietary drug candidates, our collaboration agreements for such drugs, and our ongoing clinical studies.

Clinical trial costs are a significant component of our research and development expenses. We have a history of contracting with third parties that perform various clinical trial activities on our behalf in the ongoing development of our drug candidates. Expenses related to clinical trials are accrued based on our estimates of the actual services performed by the third parties for the respective period. If the contracted amounts are revised or the scope of a contract is revised, we will modify the accruals accordingly on a prospective basis and will do so in the period in which the facts that give rise to the revision become reasonably certain.

Goodwill

The Company tests goodwill for impairment annually on October 1st, the Company's annual goodwill impairment measurement date, or more frequently if a triggering event occurs, and it updates its test with information that becomes available through the end of the period reported. The Company has three operating segments, each of which represents a separate reporting unit: Oncology Innovation Platform, Commercial Platform, and Global Supply Chain Platform. Each of the three reporting units has discrete financial information that is reviewed by segment managers. Goodwill was assigned to two reporting units: Oncology Innovation Platform and Global Supply Chain Platform. Goodwill impairment exists when the fair value of goodwill is less than its carrying value. The Company determined that an impairment triggering event occurred during the first quarter of 2021 and, consistent with our annual policy, performed a test as of our annual goodwill impairment evaluation date, October 1, 2021, subsequently updating that analysis to December 31, 2021 using new information that became available regarding conditions that existed as of December 31, 2021, and concluded that there was goodwill impairment of $67.7 million for the three months ended December 31, 2021. No impairment of goodwill was recorded for the years ended December 31, 2020, and 2019. See Part II, Item 8, Note 8 - *Goodwill and Intangible Assets, Net*, and Note 9 -*Fair Value Measurements*, for additional information.

Intangible Assets, net

Intangible assets arising from a business acquisition are recognized at fair value as of the acquisition date. The Company amortizes intangible assets using the straight-line method. When the straight-line method of amortization is utilized, the estimated useful life of the intangible asset is shortened to assure the recognition of amortization expense corresponds with the expected cash flows. Other purchased intangibles, including certain licenses, are capitalized at cost and amortized on a straight-line basis over the license life, when a future economic benefit is probable and measurable. If a future economic benefit is not probable or measurable, the license costs are expensed as incurred within research and development expenses. In-process research and development ("IPR&D") intangible assets are not amortized, but rather are reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned, or transferred to a third party.

Impairment of Long-Lived Assets

The Company reviews the recoverability of its long-lived assets, excluding goodwill, when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. The assessment of possible impairment is based on the ability to recover the carrying value of the assets from the expected future cash flows (undiscounted and without interest expense) of the related operations. If these cash flows are less than the carrying value of such assets, an impairment loss for the difference between the estimated fair value and carrying value is recorded. The Company determined that impairment indicators occurred during the first and fourth quarters of 2021 and concluded that there was impairment of intangible assets other than goodwill amounting to $1.7 million for the year ended December 31, 2021. See Part II, Item 8, Note 8 – *Goodwill and Intangible Assets, net* for additional details.

Business Acquisitions

The Company accounts for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Identifiable amortizing intangible assets are recorded on the consolidated balance sheet at fair value and amortized over their estimated useful lives. Acquisition-related costs are expensed as incurred. Any excess of the consideration transferred over the estimated fair values of the net assets acquired is recorded as goodwill.

Contingent Consideration

Contingent consideration arising from a business acquisition is included as part of the purchase price and is recorded at fair value as of the acquisition date. Subsequent to the acquisition date, the Company remeasures contingent consideration arrangements at fair value at each reporting period until the contingency is resolved. The changes in fair value are recognized within selling, general,

and administrative expenses in the Company's consolidated statement of operations and comprehensive loss. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time.

Recent Accounting Pronouncements

In the normal course of business, we evaluate all new accounting pronouncements issued by the Financial Accounting Standards Board, SEC, or other authoritative accounting bodies to determine the potential impact they may have on our Consolidated Financial Statements. Refer to Note 2 - *Summary of Significant Accounting Policies* of the Notes to Consolidated Financial Statements contained in Item 8 of this report for additional information about these recently issued accounting standards and their potential impact on our financial condition or results of operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Foreign Currency Exchange Risk

A portion of our business is located outside the U.S. and, as a result, we generate revenue and incur expenses denominated in currencies other that the U.S. dollar, a majority of which is denominated in RMB. In 2021, 2020, and 2019, approximately 1%, 1% and 2%, respectively, of our sales, excluding intercompany sales, were denominated in foreign currencies. As a result, our revenue can be significantly impacted by fluctuations in foreign currency exchange rates. As of December 31, 2021, we had cash and cash equivalents of approximately $4.6 million at our Chinese subsidiaries. We expect that foreign currencies will represent a lower percentage of our sales in the future due to the anticipated growth of our U.S. business. Our international selling, marketing, and administrative costs related to these sales are largely denominated in the same foreign currencies, which somewhat mitigates our foreign currency exchange risk rate exposure.

Currency Convertibility Risk

A portion of our revenues and expenses, and a portion of our assets and liabilities are denominated in RMB. On January 1, 1994, the Chinese government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China, ("PBOC"). However, the unification of exchange rates does not imply that the RMB may be readily convertible into U.S. dollars or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approvals of foreign currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

Additionally, the value of the RMB is subject to changes in central government policies and international economic and political developments affecting supply and demand in the PRC foreign exchange trading system market.

Interest Rate Sensitivity

We had cash and cash equivalents of $35.2 million, restricted cash of $16.5 million, and short-term investments of $10.2 million as of December 31, 2021, which consisted primarily of U.S. government or high-quality investment grade corporate debt securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in U.S. market interest rates is not expected to have a material impact on our consolidated financial condition or results of operations. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity.

Credit Risk

We had cash and cash equivalents of $35.2 million, $69.6 million and $127.7 million and marketable securities of $10.2 million, $138.6 million, and $33.1 million at December 31, 2021, 2020, and 2019, respectively. Substantially all of our bank deposits are in major financial institutions, which we believe are of high credit quality. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk.

We make periodic assessments of the recoverability of trade and other receivables and amounts due from related parties. Our historical experience in collection of receivables falls within the recorded allowances, and we believe that we have made adequate provision for uncollectible receivables.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Athenex, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Athenex, Inc. and subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and the consolidated financial statement schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2021, and expressed an adverse opinion on the Company's internal control over financial reporting because of a material weakness.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operations, and forecasts that it will violate its debt covenants, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue Chargebacks – Refer to Note 19 (Commercial Platform) to the consolidated financial statements

Critical Audit Matter Description

The Company has revenue agreements with certain independent pharmaceutical wholesalers to sell and distribute specialty products. These wholesalers then sell these specialty drug products to an end-user (Hospital, alternative healthcare facility, etc.). In such case, sales are initially recorded at the price sold to the wholesaler. Because these prices will be reduced for the end-user, the Company records a contra asset in accounts receivable and a reduction to revenue at the time of the sale, using the difference between the list price and the estimated end-user contract price. Upon the sale by the wholesaler to the end-user, the wholesaler will chargeback the difference between the original list price and price at which the product was sold to the end-user and such chargeback is offset against the initial estimated contra asset. The provision for chargebacks as of December 31, 2021 was $22.9 million, included as a reduction of accounts receivable.

We identified the accrual for chargebacks at the balance sheet date as a critical audit matter because of the judgments necessary for management to estimate the accrual based on estimates of wholesaler inventory stocking levels and of differences between list price and price at which the product was sold to the end-user. Given the volume of transactions subject to potential chargeback at the balance sheet date and the level of uncertainty involved in the estimation of the quantity and mix of products in wholesaler inventory, this matter required a high degree of auditor judgment when performing audit procedures and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the recognition of license revenue, included the following, among others:

- We evaluated the reasonableness of the methodology and assumptions applied by management when developing their chargeback estimate. We tested the accuracy and completeness of amounts in the accrual computations, inquired of management, and reviewed source documentation – including wholesaler agreements and inventory schedules to assess that management's methodology included relevant data and assumptions to arrive at a reasonable estimation process in material respects.
- We evaluated whether the methodology and assumptions have been consistently applied, throughout the estimation process, during the course of the year and in a manner consistent with the estimation process in the prior years presented.
- We selected a sample of activity of the chargeback accrual at the balance sheet date and performed audit procedures on such sample. Such procedures included: obtaining wholesaler agreements for the samples and recalculating the year-end accrual for the selected transactions; verifying quantities-on-hand with wholesalers for the sample transactions; and performing a retrospective review of payments received subsequent to the balance sheet date to evaluate reasonableness of the Company's estimate of the chargebacks contra asset at the year-end balance sheet date.
- Additionally, we also performed procedures over the historical accuracy of the chargeback accrual through comparison of initial estimates to actual chargebacks incurred.

Accounting for Business Combinations – Refer to Note 3 (Kuur Acquisition) to the consolidated financial statements

Critical Audit Matter Description

The Company entered into an Agreement and Plan of Merger with Kuur Therapeutics, Inc. ("Kuur") in May 2021, where the Company acquired 100 percent of the outstanding shares of Kuur (the "Merger"). The Company identified the Merger as a business combination, and the purchase price consisted of 14,228,066 shares of the Company's common stock, issued at $3.71 per share, with a fair value of $52.8 million, plus the fair value of future milestone payments amounting to $19.8 million, recorded as a contingent consideration liability within the Company's consolidated balance sheet. The Merger resulted in the recognition of identifiable assets, net of liabilities assumed, of $43.9 million, plus goodwill of $28.7 million.

We identified the Company's valuation of acquired in-process research and development ("IPR&D") indefinite-lived intangible assets of $64.9 million, in addition to the contingent consideration liability recognized in connection with the Merger of $19.8 million, as a critical audit matter because of the judgments necessary for management to estimate the acquisition date fair values of such balances. The significant assumptions used to estimate the fair value of the acquired IPR&D and contingent consideration liability included discount rates, as well as certain other business-related assumptions that form the basis of forecasted financial results, including probability of success factors, revenue forecasts and anticipated market penetration rates. Given the complexity of these assumptions, as well as the use of both business-related and market-related valuation techniques, this matter required a high degree of auditor judgment, and an increased extent of effort including involvement of fair value specialists, when performing audit procedures and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Company's accounting for acquired IPR&D, as well as the contingent consideration liability recognized in connection with the Merger, included the following, among others:

- We tested the effectiveness of the Company's controls associated with accounting for business combinations. For example, we tested controls over the Company's identification and valuation of acquired IPR&D and measurement of the contingent consideration liability, including the valuation models and underlying assumptions used to develop these estimates.
- We assessed the reasonableness of management's key estimates and assumptions used in these valuation models. We met with the key individuals from the senior leadership team and key personnel involved in the forecasting process to discuss and evaluate management's evidence to support the probability of success factors, revenue forecasts and anticipated market penetration rates. We tested the completeness and accuracy of the underlying data. For example, to evaluate probability of success with a potential drug candidate, we compared the Company's probability of success factors associated with acquired IPR&D to market studies for similar products. We evaluated whether the estimated future cash flows were consistent with evidence obtained in other areas of the audit.
- With the assistance of our fair value specialists, we evaluated the reasonableness of the valuation methodologies used to determine the value of the acquired IPR&D and measurement of the contingent considerations liability, including testing the mathematical accuracy of the calculation, the discount rate and company specific risks.

Goodwill – Oncology Platform reporting unit – Refer to Note 8 to the financial statements

Critical Audit Matter Description

The Company tests goodwill for impairment annually, or more frequently if the Company identifies events or circumstances indicating that the carrying value of goodwill may be impaired. The Company identified such events or circumstances during the fourth quarter of 2021 as a result of the significant decrease in the Company's market capitalization from the impact of the receipt of a complete response letter from the U.S. Food and Drug Administration regarding the Company's new drug application for oral paclitaxel in the treatment of metastatic breast cancer, and the Company's decision to no longer pursue oral paclitaxel. As part of this impairment test, the Company considered certain qualitative and quantitative factors, such as the Company's performance, business forecasts, and expansion plans. It reviewed key assumptions, including projected cash flows and future revenue for reporting units, and compared against the results of the prior goodwill impairment test. The Company compared the fair value of its reporting units to their carrying value. As a result, the Company has reflected goodwill impairment of $41.0 million within its Oncology Platform reporting unit. Following the impairment, the Company had no remaining goodwill as of December 31, 2021

We have identified the Company's determination that the carrying value exceeded the fair value for its Oncology Platform reporting unit as a critical audit matter because of the significant judgments made by management in estimating the fair value of the reporting unit. The significant assumptions used to estimate the fair value of the reporting unit include the weighting of valuation methodologies, selection of reference transactions, and selection of market multiples. Given the complexity of these assumptions, this matter required a high degree of auditor judgment, and an increased extent of effort including involvement of fair value specialists, when performing audit procedures and evaluating the results of those procedures.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Company's goodwill impairment analysis relating to the Oncology Platform reporting unit included the following, among others:

- With the assistance of our fair value specialists, we evaluated the reasonableness of the valuation methodologies, including testing the mathematical accuracy of the calculation, the weighting of such valuation methodologies, the selection of reference transactions and the selection of market multiples.
- With the assistance of our fair value specialists, we obtained objectively verifiable information as an independent indication to evaluate the fair value of the Oncology Platform reporting unit.
- Compared an independent estimate of the carrying value to the fair value of the Oncology Platform reporting unit.

/s/ Deloitte & Touche LLP
Williamsville, New York
March 16, 2022

We have served as the Company's auditor since 2015.

ATHENEX, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 35,202	$ 69,587
Restricted cash	16,500	16,500
Short-term investments	10,207	138,636
Accounts receivable, net of chargebacks and other deductions of $22,868 and $12,552, respectively, and provision for credit losses of $9,306 and $9,637, respectively	26,637	23,603
Inventories	34,685	28,846
Prepaid expenses and other current assets	8,885	10,012
Discontinued operations, current portion	1,280	4,777
Total current assets	133,396	291,961
Property and equipment, net	27,978	23,810
Goodwill	—	38,891
Intangible assets, net	71,896	10,218
Operating lease right-of-use assets, net	6,243	7,921
Other assets	1,087	950
Discontinued operations, non-current portion	26,848	10,578
Total assets	$ 267,448	$ 384,329
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 16,742	$ 18,417
Accrued expenses	24,453	33,870
Current portion of operating lease liabilities	2,909	3,185
Current portion of long-term debt and finance lease obligations	46,881	1,910
Discontinued operations, current portion	5,062	4,759
Total current liabilities	96,047	62,141
Long-term liabilities:		
Long-term operating lease liabilities	4,494	6,355
Long-term debt and finance lease obligations	103,456	146,369
Deferred tax liabilities	1,751	56
Contingent consideration	24,076	—
Other long-term liabilities	3,046	3,852
Discontinued operations, non-current portion	126	208
Total liabilities	232,996	218,981
Commitments and contingencies (Note 20)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 250,000,000 shares authorized at December 31, 2021 and 2020; 111,802,968 and 95,066,195 shares issued at December 31, 2021 and 2020, respectively; 110,130,048 and 93,393,275 shares outstanding at December 31, 2021 and 2020, respectively	111	95
Additional paid-in capital	972,404	901,864
Accumulated other comprehensive loss	(487)	(1,134)
Accumulated deficit	(913,412)	(713,644)
Less: treasury stock, at cost; 1,672,920 shares at December 31, 2021 and 2020	(7,485)	(7,406)
Total Athenex, Inc. stockholders' equity	51,131	179,775
Non-controlling interests	(16,679)	(14,427)
Total stockholders' equity	34,452	165,348
Total liabilities and stockholders' equity	$ 267,448	$ 384,329

The accompanying notes are an integral part of these consolidated financial statements.

ATHENEX, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31,		
	2021	2020	2019
Revenue:			
Product sales, net	$ 92,264	$ 105,274	$ 80,535
License and other revenue	27,917	39,117	20,694
Total revenue	120,181	144,391	101,229
Cost of sales	82,406	95,355	69,619
Gross profit	37,775	49,036	31,610
Operating expenses:			
Research and development expenses	80,197	75,904	84,393
Selling, general, and administrative expenses	72,553	92,859	66,260
Impairments	69,419	—	—
Total operating expenses	222,169	168,763	150,653
Operating loss	(184,394)	(119,727)	(119,043)
Interest income	(227)	(874)	(1,881)
Interest expense	20,742	11,219	6,954
Loss on extinguishment of debt	—	10,278	—
Loss from continuing operations before income tax expense	(204,909)	(140,350)	(124,116)
Income tax (benefit) expense	(10,604)	4,088	928
Net loss from continuing operations	(194,305)	(144,438)	(125,044)
Loss from discontinued operations (Note 4)	7,731	3,996	489
Net loss	(202,036)	(148,434)	(125,533)
Less: net loss attributable to non-controlling interests	(2,268)	(2,255)	(1,784)
Net loss attributable to Athenex, Inc.	$ (199,768)	$ (146,179)	$ (123,749)
Unrealized gain (loss) on investment, net of income taxes	506	(5)	(97)
Foreign currency translation adjustment, net of income taxes	141	(494)	118
Comprehensive loss	$ (199,121)	$ (146,678)	$ (123,728)
Basic and diluted loss per Athenex, Inc. common share (Note 16):			
Net loss from continuing operations	$ (1.85)	$ (1.67)	$ (1.66)
Net loss from discontinued operations	(0.07)	(0.05)	(0.01)
Net loss per share attributable to Athenex, Inc. common stockholders	$ (1.92)	$ (1.72)	$ (1.67)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted (Note 16)	103,938,451	85,082,868	74,054,261

The accompanying notes are an integral part of these consolidated financial statements.

ATHENEX, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)

	Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Treasury Stock		Total Athenex, Inc. stockholders' equity	Non-controlling interests	Total stockholders' equity
	Shares	Amount				Shares	Amount			
Balance at January 1, 2019	68,668,986	69	591,064	(443,716)	(656)	(1,672,920)	(7,406)	139,355	(10,586)	128,769
Sale of common stock, net of costs of $1,103	14,006,575	14	159,963	—	—	—	—	159,977	—	159,977
Equity consideration in connection with acquisition	—	—	748	—	—	—	—	748	—	748
Stock-based compensation cost	—	—	8,219	—	—	—	—	8,219	—	8,219
Restricted stock expense	223,723	—	1,671	—	—	—	—	1,671	—	1,671
Stock options exercised	331,779	—	1,983	—	—	—	—	1,983	—	1,983
Net loss	-	—	—	(123,749)	—	—	—	(123,749)	(1,784)	(125,533)
Other comprehensive loss, net of tax	—	—	—	—	21	—	—	21	—	21
Balance at December 31, 2019	83,231,063	83	763,648	(567,465)	(635)	(1,672,920)	(7,406)	188,225	(12,370)	175,855
Sale of common stock, net of costs of $7,869	11,607,322	11	119,099	—	—	—	—	119,110	—	119,110
Issuance of warrant, net	—	—	6,544	—	—	—	—	6,544	—	6,544
Stock-based compensation cost	—	—	9,833	—	—	—	—	9,833	—	9,833
Restricted stock expense	(10,820)	—	1,017	—	—	—	—	1,017	—	1,017
Stock options exercised	238,630	1	1,723	—	—	—	—	1,724	—	1,724
Non-controlling interests	—	—	—	—	—	—	—		198	198
Net loss	—	—	—	(146,179)	—	—	—	(146,179)	(2,255)	(148,434)
Other comprehensive loss, net of tax	—	—	—	—	(499)	—	—	(499)	—	(499)
Balance at December 31, 2020	95,066,195	95	901,864	(713,644)	(1,134)	(1,672,920)	(7,406)	179,775	(14,427)	165,348
Sale of common stock through ATM and ESPP, net of costs of $35	844,382	1	1,341	—	—	—	—	1,342	—	1,342
Issuance of stock in connection with acquisition of Kuur	15,601,667	15	58,412	—	—	—	—	58,427	—	58,427
Issuance of common stock in connection with Cidal contingent consideration	11,299	—	1	—	—	—	—	1	—	1
Stock-based compensation cost	—	—	8,591	—	—	—	—	8,591	—	8,591
Restricted stock expense	—	—	616	—	—	—	—	616	—	616
Stock options exercised	279,425	—	1,579	—	—	—	—	1,579	—	1,579
Treasury stock repurchase	—	—	—	—	—	—	(79)	(79)	—	(79)
Disposal of non-controlling interest	—	—	—	—	—	—	—	—	16	16
Net loss	—	—	—	(199,768)	—	—	—	(199,768)	(2,268)	(202,036)
Other comprehensive gain, net of tax	—	—	—	—	647	—	—	647	—	647
Balance at December 31, 2021	111,802,968	$ 111	$ 972,404	$ (913,412)	$ (487)	(1,672,920)	$ (7,485)	$ 51,131	$ (16,679)	$ 34,452

The accompanying notes are an integral part of these consolidated financial statements.

ATHENEX, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities:			
Net loss from continuing operations	$ (194,305)	$ (144,438)	$ (125,044)
Net loss from discontinued operations	(7,731)	(3,996)	(489)
Adjustments to reconcile net loss to net cash used in operating activities of continuing operations:			
Depreciation and amortization	4,682	4,461	3,807
Stock-based compensation expense	9,207	10,850	9,885
Impairment of goodwill and intangible assets	69,419	—	—
Change in fair value of contingent consideration	4,237	—	—
Provision for credit losses	(331)	9,513	—
Amortization of debt discount	2,939	1,781	1,026
(Gain) loss on disposal of assets	(150)	222	232
Write off of deferred issuance costs	648	—	—
Loss on extinguishment of debt	—	10,278	—
Deferred income taxes	(10,848)	56	486
Changes in operating assets and liabilities, net of effect of acquisition:			
Receivables, net	(2,703)	(16,427)	(3,738)
Prepaid expenses and other assets	4,056	5,877	864
Inventories	(5,899)	3,784	(3,844)
Accounts payable and accrued expenses	(19,223)	(13,715)	19,345
Net cash used in operating activities of continuing operations	(138,271)	(127,758)	(96,981)
Cash flows from investing activities of continuing operations:			
Purchase of property and equipment	(8,398)	(8,622)	(9,714)
Payments for licenses	(2,137)	(214)	(4,175)
Acquisition activity	1,425	—	853
Disposal activity	101	—	—
Purchases of short-term investments	(68,672)	(161,847)	(74,697)
Sale of short-term investments	197,608	56,345	99,090
Net cash provided by (used in) investing activities of continuing operations	119,927	(114,338)	11,357
Cash flows from financing activities of continuing operations:			
Proceeds from sale of stock	1,343	126,980	161,080
Proceeds from issuance of debt	783	145,126	6,464
Proceeds from issuance of warrants	—	7,039	—
Costs incurred related to the sale of stock	—	(7,869)	(1,103)
Costs incurred related to the issuance of debt and warrants	—	(9,363)	—
Proceeds from exercise of stock options	1,579	1,723	1,983
Investment from non-controlling interest	—	198	—
Repurchase of treasury stock	(79)	—	—
Repayment of finance lease obligations and long-term debt	(986)	(54,315)	(972)
Net cash provided by financing activities of continuing operations	2,640	209,519	167,452
Net (decrease) increase in cash, cash equivalents, and restricted cash from continuing operations	(15,704)	(32,577)	81,828
Net cash used in operating activities of discontinued operations	(4,108)	(3,486)	(479)
Net cash used in investing activities of discontinued operations	(14,943)	(4,634)	(3,858)
Net cash used in financing activities of discontinued operations	(178)	(91)	—
Net decrease in cash and cash equivalents from discontinued operations	(19,229)	(8,211)	(4,337)
Cash, cash equivalents, and restricted cash beginning of period	86,087	127,674	49,794
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	548	(799)	389
Cash, cash equivalents, and restricted cash, end of period (See Note 5)	$ 51,702	$ 86,087	$ 127,674
Supplemental cash flow disclosures			
Interest paid	$ 20,336	$ 6,056	$ 4,925
Income taxes paid	$ 108	$ 3,066	$ 448
Non-cash investing and financing activities:			
Accrued purchases of property and equipment from continuing operations	$ 246	$ 439	$ 113
Accrued purchases of property and equipment from discontinued operations	$ 1,679	$ 39	$ 370
Equity consideration in connection with acquisition	$ 52,786	$ —	$ 748
Accrued purchases of licenses	$ 1,350	$ 2,850	$ —
Accrued cost of debt issuance	$ —	$ 750	$ —
Property and equipment financed under finance leases from discontinued operations	$ —	$ 848	$ —
ROU assets derecognized from modification of operating lease obligations	$ (114)	$ (468)	$ —

The accompanying notes are an integral part of these consolidated financial statements.

1. COMPANY AND NATURE OF BUSINESS

Description of Business

Athenex, Inc. (the "Company" or "Athenex"), originally under the name Kinex Pharmaceuticals LLC ("Kinex"), formed in November 2003, commenced operations on February 5, 2004, and operated as a limited liability company until it was incorporated in the State of Delaware under the name Kinex Pharmaceuticals, Inc. on December 31, 2012. The Company changed its name to Athenex, Inc. on August 26, 2015.

Athenex is a biopharmaceutical company dedicated to becoming a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer. The Company's mission is to improve the lives of cancer patients by creating more effective, safer and tolerable treatments. The Company has assembled a strong and experienced leadership team and has established operations across the pharmaceutical value chain to execute its goal of becoming a leader in bringing innovative cancer treatments to the market and improving health outcomes.

The Company is organized around three operating segments: (1) its Oncology Innovation Platform, dedicated to the research and development of our proprietary drugs; (2) its Commercial Platform, focused on the sales and marketing of our specialty drugs and the market development of proprietary drugs; and (3) its Global Supply Chain Platform, dedicated to providing a stable and efficient supply of APIs for clinical and commercial efforts. The Company's current clinical pipeline in the Oncology Innovation Platform is derived from the following core technologies: (1) Cell Therapy, (2) Orascovery, based on a P-glycoprotein ("P-gp") pump inhibitor, and (3) Src Kinase inhibition.

The Company is primarily engaged in conducting research and development activities through corporate collaborators, in-licensing and out-licensing pharmaceutical compounds and technology, conducting preclinical and clinical testing, identifying and evaluating additional drug candidates for potential in-licensing or acquisition, and raising capital to support development and commercialization activities. The Company also conducts commercial sales of specialty products through its wholly owned subsidiary, Athenex Pharmaceutical Division ("APD"), and 503B products through its wholly owned subsidiary, Athenex Pharma Solutions ("APS").

Going Concern

These consolidated financial statements have been prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company has incurred operating losses since its inception and, as a result, as of December 31, 2021 and 2020 had an accumulated deficit of $913.4 million and $713.6 million, respectively. As of December 31, 2021, the Company had cash and cash equivalents of $35.2 million, restricted cash of $16.5 million, and short-term investments of $10.2 million. The Company projects insufficient liquidity to fund its operations through the next twelve months beyond the date of the issuance of these consolidated financial statements. This condition raises substantial doubt about the Company's ability to continue as a going concern.

Additionally, the Company has financial covenants associated with its Senior Credit Agreement with Oaktree that are measured each quarter. The Company is in compliance with such financial covenants as of December 31, 2021. However, the Company is forecasting that it will be in violation of both the minimum liquidity and revenue covenant included within the Senior Credit Agreement during the twelve month period subsequent to the date of this filing. Pursuant to ASC 205-40-50, the Company's forecast does not reflect management's plans that are outside of the Company's control as described below. Violation of any covenant under the Credit Agreement provides the lenders with the option to accelerate the maturity of the Credit Facility, which carried an outstanding balance of $150.0 million as of December 31, 2021. Should the lenders accelerate the maturity of the Credit Facility, the Company would not have sufficient cash on hand or available liquidity to repay the outstanding debt in the event of default. These conditions and events raise substantial doubt about the Company's ability to continue as a going concern.

In response to these conditions, management's plans include seeking additional funding through planned product launches, raising capital, including leveraging the existing sales agreement with SVB Leerink (described below), asset monetization and/or seeking funding through alternative means. There can be no assurances, however, that additional funding will be available on favorable terms, or at all. Because management's plans have not yet been finalized and are not within the Company's control, such plans cannot be considered probable of being achieved. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

These consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Other Significant Risks and Uncertainties

In February 2021, the Company received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding the Company's New Drug Application ("NDA") for oral paclitaxel and encequidar ("Oral Paclitaxel") for the treatment of metastatic breast cancer ("mBC"). The FDA issues a CRL to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form. In the CRL, the FDA indicated its concern of safety risk to patients in terms of an increase in neutropenia-related sequelae on the Oral Paclitaxel arm compared with the IV paclitaxel arm in the Phase III study. The FDA also expressed concerns regarding the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by blinded independent central review ("BICR"). The FDA stated that the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR. The FDA recommended that Athenex conduct a new adequate and well-conducted clinical trial in a patient population with mBC representative of the population in the U.S. The FDA determined that adequate risk mitigation strategies to improve toxicity, which may involve dose optimization as well as, or in addition to, exclusion of patients deemed to be at higher risk of toxicity, would be required in any new clinical trial of Oral Paclitaxel. During the second quarter of 2021, the Company held a Type A meeting with the FDA. At the meeting, the Company provided additional analyses, including overall survival (OS) data on patient subgroups, to provide a more comprehensive summary of the risk/benefit assessment. The Company also proposed to collect additional OS data that could inform the design of a new clinical study. In October 2021, the Company held another Type A meeting with the FDA, and the purpose of the meeting was to review with the FDA a proposed design for a new clinical trial intended to address the deficiencies raised in the CRL and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S. After careful consideration of the feedback provided by the FDA, the Company decided that it will not currently be pursuing regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S. and determined to redeploy its resources to focus on other ongoing studies of Oral Paclitaxel and its cell therapy platform.

The Company is subject to a number of risks similar to other biopharmaceutical companies, including, but not limited to, the lack of available capital; possible failure of preclinical testing or clinical trials; inability to obtain regulatory approval of product candidates; competitors developing new technological innovations; potential interruptions in the manufacturing and commercial supply operations; unsuccessful commercialization strategy and launch plans for its proprietary drug candidates; risks inherent in litigation, including purported class actions; market acceptance of the Company's products; and protection of proprietary technology. If the Company or its partners do not successfully commercialize any of the Company's product candidates, it will be unable to generate sufficient revenue and might not, if ever, achieve profitability and positive cash flow. If the Company or its partners experience significant disruptions from macroeconomic factors, it could have a material adverse impact on the Company's operations and financial condition and results.

Recent Financing Activity

At-the-market offering

On August 20, 2021, the Company entered into a sales agreement (the "Sales Agreement") with SVB Leerink LLC, in connection with the offer and sale of up to $100,000,000 of shares of the Company's common stock, par value $0.001 per share ("ATM Shares"). The ATM Shares to be offered and sold under the Sales Agreement will be issued and sold pursuant to a registration statement on Form S-3 (File No. 333-258185) that became effective on August 12, 2021. During the year ended December 31, 2021, we sold 762,825 shares of our common stock for an average price of $1.49 per share under the Sales Agreement.

Senior Secured Loan Agreement and Detachable Warrants

On June 19, 2020, the Company entered into a senior secured loan agreement and related security agreements (the "Senior Credit Agreement") with Oaktree Fund Administration, LLC as administrative agent, and the lenders party thereto (collectively "Oaktree") to borrow up to $225.0 million in five tranches with a maturity date of June 19, 2026, bearing interest at a fixed annual rate of 11.0%. The first tranche of $100.0 million was drawn by the Company prior to June 30, 2020, with the proceeds used in part to repay in full the outstanding loan and fees under the credit agreement with Perceptive Advisors LLC and its affiliates ("Perceptive"), which resulted in a loss on extinguishment of debt of $7.2 million. The second tranche of $25.0 million was drawn by the Company prior to September 30, 2020 and the third tranche of $25.0 million was drawn by the Company prior to December 31, 2020. The additional debt tranches amounting to an aggregate of $75.0 million were subject to the approval Oral Paclitaxel in the treatment of mBC, and therefore, became unavailable to the Company when it decided to no longer pursue regulatory approval in the U.S. The Company is required to make quarterly interest-only payments until June 19, 2022, after which the Company is required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. The loan agreement contains specified financial maintenance covenants. The Company was in compliance with such covenants as of December 31, 2021.

In connection with the Senior Credit Agreement, the Company granted warrants to Oaktree to purchase an aggregate of up to 908,393 shares of the Company's common stock at a purchase price of $12.63 per share. This transaction was accounted for as a detachable warrant at its fair value, using the relative fair value method, which is based on a number of unobservable inputs, and is recorded as an increase to additional paid-in-capital on the consolidated statement of stockholders' equity. The fair value of the warrants was reflected as a discount to the term loan and amortized over the life of the term loan.

On January 19, 2022, the Company entered into an amendment to the Senior Credit Agreement with Oaktree (the "Amendment"). The Amendment also amended the warrants held by Oaktree that were issued on June 19, 2020 and August 4, 2020. The Amendment became effective on February 14, 2022, upon the closing of the Company's sale of its leasehold interest in the manufacturing facility in Dunkirk, New York and certain other related assets (the "Dunkirk Transaction," see Note 4 - *Discontinued Operations*). The Amendment provides that the Company make mandatory prepayment of principal to Oaktree equal to 62.5% of the cash proceeds of the Dunkirk Transaction. The Company was also required to pay (i) accrued and unpaid interest and (ii) a 7.0% fee, allocated as a 2.0% Exit Fee and a 5.0% Prepayment Fee (each as defined in the Senior Credit Agreement), on the principal amount being repaid. The Company was required to pay Oaktree an amendment fee of $0.3 million and certain related expenses upon the closing of the Dunkirk Transaction. The Amendment requires the Company to make an additional mandatory prepayment of $12.5 million in principal plus the costs and fees described above by June 14, 2022, within 120 days of the closing of the Dunkirk Transaction. Consistent with the Company's decision to not pursue regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the United States, the Amendment reduced to zero the amount of the last two tranches of borrowing that had been available under the Senior Credit Agreement upon the achievement of commercial milestones. The warrants were amended to change the exercise price to be paid per share upon exercise of the warrants. The original exercise price of the warrants was $12.63 per share. The Amendment provides that the exercise price for 50% of the shares underlying the warrants will be $1.10 per share. The Dunkirk Transaction closed on February 14, 2021. The Company received proceeds of $40.0 million and used these proceeds to repay $27.4 million of the Senior Credit Agreement with Oaktree according to the terms of the Amendment.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements reflect the accounts and operations of the Company and those of its subsidiaries in which the Company has a controlling financial interest. Intercompany transactions and balances have been eliminated.

Discontinued Operations

The Company reports components or groups of components as discontinued operations when such component or components are sold, disposed of other than by sale, or classified as held for sale, and the disposal of such component or components represents a strategic shift that will have a major effect on the Company's operations. Assets or asset groups classified as held-for-sale or discontinued operations are recorded at the lower of cost or fair value less cost to sell.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amount of revenue and expenses during the reporting period. Such management estimates include those relating to assumptions used in clinical research accruals, chargebacks, measurement of acquired assets and assumed liabilities in business combinations, provision for credit losses, inventory reserves, deferred income taxes, the estimated useful life and recoverability of long-lived assets, contingent consideration, and the valuation of stock-based awards and other items as appropriate. Actual results could differ from those estimates.

Functional Currency

Assets and liabilities of subsidiaries that prepare financial statements in currencies other than the U.S. dollar are translated using rates of exchange as of the balance sheet date and the statements of operations and comprehensive loss are translated at the average rates of exchange for each reporting period. The Company recorded a foreign currency translation loss in accumulated other comprehensive gain of $0.1 million for the year ended December 31, 2021, a loss of $0.5 million for the year ended December 31, 2020 and a gain of $0.1 million for the year ended December 31, 2019.

Cash, Cash Equivalents, Restricted Cash, and Short-term Investments

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. The Company deposits its cash primarily in checking and money market accounts, as well as short-term investments including certificates of deposit. Funds held in foreign accounts that are subject to regulations governing transfers oversees are included within cash and cash equivalents. As of December 31, 2021 and 2020, the Company had $4.6 million and $42.5 million, respectively, at its Chinese subsidiaries, which were subject to Chinese funds transfer limitations, but available for the Company's general use. Restricted cash consists of deposits that are restricted as to their withdrawal or use. Restricted cash primarily include amounts held in a controlled bank account in connection with the Senior Credit Agreement. The Company generally does not enter into investments for trading or speculative purposes, rather to preserve its capital for the purpose of funding operations.

Accounts Receivable, net

Accounts receivable are recorded at the invoiced amount. On a periodic basis, the Company evaluates its accounts receivable and establishes a provision for credit losses, based upon a history of past write-offs, the age of the receivables, and current credit conditions.

Credit Losses

The Company estimates and records a provision for its expected credit losses related to its financial instruments, including its trade receivables and contract assets recorded under Financial Accounting Standards Board ("FASB") ASC 606, Revenue from Contracts with Customers ("Topic 606"). The Company considers historical collection rates, current financial status of its customers, macroeconomic factors, and other industry-specific factors when evaluating for current expected credit losses. Forward-looking information is also considered in the evaluation of current expected credit losses. However, because of the short time to the expected receipt of accounts receivable and contract assets, the Company believes that the carrying value, net of excepted losses, approximates fair value and therefore, relies more on historical and current analysis of such financial instruments.

To determine the provision for credit losses for accounts receivable, the Company has disaggregated its accounts receivable by class of customer, as the Company determined that risk profile of its customers is consistent based on the type and industry in which they operate. These customer classes include pharmaceutical wholesalers for specialty product sales, drug manufacturers for active pharmaceutical ingredient (API) sales, and hospitals and end-users for 503B sales. Each class of customer is analyzed for estimated credit losses individually. In doing so, the Company establishes a historical loss matrix, based on the previous collections of accounts receivable by the age of such receivables, and evaluates the current and forecasted financial position of its customers, as available. Further, the Company considers macroeconomic factors and the status of the pharmaceutical industry, including unemployment rates, industry indices, and other factors, to estimate if there are current expected credit losses within its trade receivables based on the trends and the Company's expectation of the future status of such economic and industry-specific factors. The Company believes that its customers, the majority of which are in the pharmaceutical industries with sound financial condition, and therefore, the Company's evaluation of macroeconomic and industry-specific factors did not have a significant impact on the provision for credit losses. As of December 31, 2021 and 2020, the Company recorded a provision for credit losses of $0.4 million and $0.7 million, respectively, for accounts receivable related to the customer classes of pharmaceutical wholesalers, drug manufacturers, and hospitals and end users.

Expected credit losses related to contract assets are evaluated on an individual basis. The Company's contract assets relate to upfront fees or milestone payments due from licensees for which the underlying performance obligations have been satisfied. The Company evaluates the financial status of the licensee and any historical payment activity from them. Macroeconomic and industry-specific factors are considered when estimated current expected credit losses related to contract assets. Contract assets are generally classified as short-term, and the Company is in frequent communication with licensees to establish timely payment terms. If the

Company expects that credit losses exist for license-related contract assets, it will record provision for such losses against the contract asset. In the third quarter of 2020, pursuant to the Xiangxue License, the Company recognized $9.4 million in license revenue, net of $0.6 million value added tax, for a milestone achievement. During 2021, the Company only received $1.5 million of the $10.0 million milestone achievement. After consideration of historical collection rates, the current financial status of the counterparty, and other macroeconomic factors, the Company recorded a provision for its expected credit losses for the outstanding balance of $8.5 million and $0.4 million related to currency conversion in its consolidated financial statements for the three months and year ended December 31, 2020, respectively. No additional provision for credit losses was recorded for contract assets during the year ended December 31, 2021.

Business Acquisitions

The Company accounts for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Identifiable amortizing intangible assets are recorded on the consolidated balance sheet at fair value and amortized over their estimated useful lives. Acquisition-related costs are expensed as incurred. Any excess of the consideration transferred over the estimated fair values of the net assets acquired is recorded as goodwill.

Contingent Consideration

Contingent consideration arising from a business acquisition is included as part of the purchase price and is recorded at fair value as of the acquisition date. Subsequent to the acquisition date, the Company remeasures contingent consideration arrangements at fair value at each reporting period until the contingency is resolved. The changes in fair value are recognized within selling, general, and administrative expenses in the Company's consolidated statement of operations and comprehensive loss. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time.

Inventories

Prior to the regulatory approval of product candidates, the Company may incur expenses for the manufacture of drug product to support the commercial launch of those products. Until the date at which regulatory approval has been received or is otherwise considered probable, all such costs are recorded as research and development expenses as incurred. Inventories for special products and 503B products are stated at the lower of cost and net realizable value, with approximate cost being determined on a first-in-first-out basis. API inventory is stated at the lower of cost and net realizable value, with approximate cost being determined on a weighted average basis.

The Company provides inventory write-downs based on excess and obsolete inventories determined primarily by future demand forecasts. The write-down is measured as the difference between the cost of the inventory and market, based upon assumptions about future demand, and is charged to the provision for inventory, which is a component of cost of sales. At the point of the loss recognition, a new, lower cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis. Reserves for inventory amounted to $6.0 million and $6.2 million as of December 31, 2021 and 2020, respectively.

Property and Equipment, net

Property and equipment are recorded at cost or acquisition date fair value in a business acquisition. Depreciation is recorded over the estimated useful lives of the related assets using the straight-line method. Leasehold improvements are amortized on a straight-line basis over the shorter of the useful life or term of the lease. Upon retirement or disposal, the cost and related accumulated depreciation are removed from the consolidated balance sheets and the resulting gain or loss is recorded to general and administrative expense in the consolidated statements of operations and comprehensive loss. Routine expenditures for maintenance and repairs are expensed as incurred.

Estimated useful lives for property and equipment are as follows:

Property and Equipment	Estimated Useful Life
Land	Not depreciated
Equipment	5 - 8 years
Furniture and fixtures	5 years
Computer hardware	3 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term
Construction in process	Not depreciated

Leases

On January 1, 2019, the Company adopted FASB Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* on a modified retrospective basis and did not restate comparative periods as permitted under the transition guidance. The Company elected the package of practical expedients as permitted, which carries forward the Company's assessments prior to the date of initial application with respect to lease classifications, initial direct costs as well as whether an existing contract contains a lease. The Company recognizes operating leases with terms greater than one year as right-of-use ("ROU") assets and lease liabilities on its consolidated balance sheet. A majority of the Company's operating leases are for real estate properties used in operations located in the U.S. and Asia. The Company's finance leases are included in property and equipment, net and long-term debt and finance lease obligations on the consolidated balance sheet. The Company's finance leases are for manufacturing equipment in the U.S.

The lease liabilities are determined as the present value of future fixed minimum lease payments. In determining the discount rate, the Company uses rates implicit in the lease, or if not readily available, the Company uses an estimated incremental borrowing rate based on yield trends in the biotechnology and healthcare industry and debt instruments held by the Company with stated interest rates. The Company uses the stated rate per lease agreement in determining the finance lease liabilities. The lease term is determined at the commencement date and considers whether it is reasonably certain that the Company will exercise renewal options or termination options. The lease liabilities and ROU asset are amortized over the term of the lease with operating lease expenses being recognized on a straight-line basis over the lease terms.

Leases with an initial lease term of 12 months or less are not recorded on the consolidated balance sheet. Lease expense for these leases is recognized on a straight-line basis over the lease term.

Fair Value of Financial Instruments

The Company has certain financial assets and liabilities recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements. Financial instruments consist of cash and cash equivalents, restricted cash, short-term investments, accounts receivable, other current assets, accounts payable, accrued expenses, and contingent consideration. These financial instruments are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date of such amounts.

Goodwill

The Company tests goodwill for impairment annually on October 1st, the Company's annual goodwill impairment measurement date, or more frequently if a triggering event occurs and it updates its test with information that becomes available through the end of the period reported. The Company has three operating segments, each of which represents a separate reporting unit: Oncology Innovation Platform, Commercial Platform, and Global Supply Chain Platform. Each of the three reporting units has discrete financial information that is reviewed by segment managers. Goodwill is assigned to two reporting units: Oncology Innovation Platform and Global Supply Chain Platform. Goodwill impairment exists when the fair value of goodwill is less than its carrying value. The Company determined that an impairment triggering event occurred during the first quarter of 2021 and, consistent with our annual policy, performed a test as of our annual goodwill impairment evaluation date, October 1, 2021, subsequently updating that analysis to December 31, 2021 using new information that became available regarding conditions that existed as of December 31, 2021, and concluded that there was goodwill impairment of $67.7 million for the three months ended December 31, 2021. No impairment of goodwill was recorded for the years ended December 31, 2020, and 2019. See Note 8 - *Goodwill and Intangible Assets, Net*, and Note 9 - *Fair Value Measurements*, for additional information.

Intangible Assets, net

Intangible assets arising from a business acquisition are recognized at fair value as of the acquisition date. The Company amortizes intangible assets using the straight-line method. When the straight-line method of amortization is utilized, the estimated useful life of the intangible asset is shortened to assure the recognition of amortization expense corresponds with the expected cash flows. Other purchased intangibles, including certain licenses, are capitalized at cost and amortized on a straight-line basis over the license life, when a future economic benefit is probable and measurable. If a future economic benefit is not probable or measurable, the license costs are expensed as incurred within research and development expenses. In-process research and development ("IPR&D") intangible assets are not amortized, but rather are reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned, or transferred to a third party.

Impairment of Long-Lived Assets

The Company reviews the recoverability of its long-lived assets, excluding goodwill, when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. The assessment of possible impairment is based on the ability to recover the carrying value of the assets from the expected future cash flows (undiscounted and without interest expense) of the related operations. If these cash flows are less than the carrying value of such assets, an impairment loss for the difference between the estimated fair value and carrying value is recorded. The Company determined that impairment indicators occurred during the first and fourth quarters of 2021 and concluded that there was impairment of intangible assets other than goodwill amounting to $1.7 million for the three months ended December 31, 2021. During the years ended December 31, 2020 and 2019, the Company recorded $0 and $0.2 million of impairment, respectively, for intangible assets other than goodwill. See Note 8 – *Goodwill and Intangible Assets, net* for additional details.

Treasury Stock

The Company records treasury stock activities at the cost of the acquired stock. The Company's accounting policy upon the formal retirement of treasury stock is to deduct the par value from common stock and to reflect any excess of cost over par value as a reduction to additional paid-in capital (to the extent created by previous issuances of the stock) and then accumulated deficit.

Revenue Recognition

Under Topic 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identifies the contract(s) with a customer; (ii) identifies the performance obligations in the contract; (iii) determines the transaction price; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract to identify the performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for product sales, license fees and consulting revenue, and grant revenue, see Note 19 – *Revenue Recognition*. The Company did not record an adjustment to revenue upon adoption.

Research and Development Expenses

Costs for research and development ("R&D") of products, including payroll, contractor expenses, and supplies, are expensed as incurred. Clinical trial and other development costs incurred by third parties are expensed as the contracted work is performed. Where contingent milestone payments are due to third parties under research and development arrangements, the obligations are recorded when the milestone results are probable of being achieved.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Changes in unrealized gains and losses on investments and foreign currency translation adjustments represent the differences between the Company's net loss and comprehensive loss.

Stock-Based Compensation

Awards granted to employees

The Company recognizes stock-based compensation based on the grant date fair value of stock options granted to employees, officers, and directors. The Company used the Black-Scholes option pricing model to calculate the grant date fair value of stock options. The Black-Scholes option pricing model requires inputs for risk-free interest rate, dividend yield, volatility, fair value of common stock, and expected lives of the stock options. The risk-free rate for periods within the expected life of the stock option is based on the U.S. Treasury yield curve in effect at the time of the grant. No dividend yield is used, consistent with the Company's history. Expected volatility is based on historical volatilities of the stock prices of peer biopharmaceutical companies. The fair value of common stock is based on the quoted market price of the Company's common stock on grant date. The Company uses the simplified method for determining the expected lives of stock options. The Company recognizes compensation expenses based on the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting period.

Stock grants and restricted stock awards

The Company grants common stock and restricted stock awards to employees, officers, and directors and records the fair value of these grants, based on the fair value of the common stock on the grant date, as compensation expense throughout the requisite service period.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred income tax expense or benefit is the result of changes in the deferred income tax assets and liabilities. Valuation allowances are established when necessary to reduce deferred income tax assets where, based upon the available evidence, management concludes that it is more-likely-than not that the deferred income tax assets will not be realized. In evaluating its ability to recover deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. Because of the uncertainty of the realization of the deferred income tax assets, the Company has recorded a valuation allowance against its deferred income tax assets.

Reserves are provided for tax benefits for which realization is uncertain. Such benefits are only recognized when the underlying tax position is considered more likely than not to be sustained on examination by a taxing authority, assuming they possess full knowledge of the position and facts. Interest and penalties related to uncertain tax positions are recognized in income tax expense; however, the Company currently has no interest or penalties related to income taxes.

Segment and Geographic Information

The Company’s chief operating decision-maker, its Chief Executive Officer, reviews its operating results on an aggregate basis and at the operating segment level for purposes of allocating resources and evaluating financial performance. The Company has three business platforms which are the operating segments: (1) Oncology Innovation Platform, for the discovery and development of cancer supportive therapies, (2) Commercial Platform, the manufacturing and selling of commercial pharmaceutical products, and (3) Global Supply Chain Platform, the cGMP manufacturing and marketing of API, and clinical products. Each operating segment has a segment manager who is held accountable for operations and operating results. Accordingly, the Company operates in three reportable segments.

Concentration of Credit Risk, Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, and short-term investments. The Company deposits its cash equivalents in interest-bearing money market accounts and certificates of deposit and invests in highly liquid U.S. Treasury notes, commercial paper, and corporate bonds. The Company deposits its cash with multiple financial institutions. Cash balances exceed federally insured limits. The primary focus of the Company’s investment strategy is to preserve capital and meet liquidity requirements. The Company’s investment policy addresses the level of credit exposure by limiting the concentration in any one corporate issuer and establishing a minimum allowable credit rating. The Company also has significant assets and liabilities held in its overseas manufacturing facility, and research and development facility in China, and therefore is subject to foreign currency fluctuation and regulatory uncertainties.

Recent Accounting Pronouncements Not Yet Adopted

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832), Disclosures by Business Entities About Government Assistance*, which requires entities to provide disclosures on material government assistance transactions for annual reporting periods. The disclosures include information around the nature of the assistance, the related accounting policies used to account for government assistance, the effect of government assistance on the entity’s financial statements, and any significant terms and conditions of the agreements, including commitments and contingencies. The new standard is effective for the Company on January 1, 2022 and only impacts annual financial statement footnote disclosures. Therefore, the adoption will not have a material effect on the Company's consolidated financial statements.

3. BUSINESS COMBINATION

On May 4, 2021, the Company entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Kuur Therapeutics, Inc., a Delaware corporation (“Kuur”) whereby it acquired 100% of the outstanding shares of Kuur (the “Merger”). Under the terms of the Merger Agreement, the Company’s wholly owned subsidiary, Athenex Pharmaceuticals LLC, a Delaware limited liability company, merged with and into Kuur, with Kuur surviving as a wholly owned subsidiary of the Company. Kuur is a leading developer of off-the-shelf CAR-NKT cell immunotherapies for the treatment of solid and hematological malignancies.

Pursuant to the Merger Agreement, an upfront fee of $70.0 million was paid to Kuur shareholders and its former employees and directors, comprised primarily of equity in the Company's common stock. Additionally, Kuur shareholders and its former employees and directors are eligible to receive up to $115.0 million of milestone payments, which may be paid, at the Company's sole discretion, in either cash or additional common stock of the Company (or a combination of both).

The Company identified the Merger as a business combination pursuant to ASC 805 and used the acquisition method of accounting to account for the transaction. The purchase price, after adjusted for closing conditions, consisted of 14,228,066 shares of the Company's common stock issued at $3.71 per share with a fair value of $52.8 million, plus the fair value of the future milestone payments amounting to $19.8 million, recorded as contingent consideration. The Company recorded the fair value of this contingent consideration as a liability based on the probabilities of Kuur achieving the milestones and the present value of such payments. These inputs are not observable in the market and therefore are considered Level 3 inputs.

The Company estimated fair values on May 4, 2021 for the allocation of consideration to the net tangible and intangible assets acquired and liabilities assumed in connection with the Merger. During the measurement period, the Company continued to obtain information to assist in finalizing the fair value of assets acquired and liabilities assumed. Measurement period adjustments were applied in the reporting period in which the adjustments were determined. During the year ended December 31, 2021, the Company recorded a measurement period adjustment to reflect the estimated fair value of IPR&D, as a result of changes in the underlying assumptions, including projected expenses and the estimated discount rate. This measurement period adjustment resulted in the increase of IPR&D of $1.4 million, a decrease in the deferred tax liability assumed of $0.2 million, and a decrease in goodwill of $1.6 million from the initial measurement reported as of June 30, 2021. To estimate the fair value of the identifiable intangible assets acquired, the Company used projected discounted cash flow method, which requires assumptions of projected revenues and expenses and an estimated discount rate, among other inputs, each of which is not observable in the market and thus are considered Level 3 inputs. The Company assumed $8.9 million of transaction incentive liability to Kuur's key employees and independent company directors, of which $3.3 million was paid in cash and $5.6 million was paid in 1,373,601 shares of the Company's common stock at $4.11 per share. The following table summarizes the final purchase price allocation to the fair value of assets and liabilities acquired at the date of acquisition (in thousands):

Allocation of Consideration:		
Stock issued (14,228,066 shares at $3.71)	$	52,786
Contingent consideration		19,839
Purchase price:	$	72,625
Net assets acquired:		
Cash and cash equivalents	$	1,425
Prepaid expenses and other current assets		133
In-process research & development		64,900
Accounts payable		(39)
Accrued expenses		(1,037)
Deferred income tax liability		(12,543)
Transaction incentive liability		(8,925)
Total identifiable net assets		43,914
Goodwill		28,711
Total purchase price allocation	$	72,625

Goodwill in the amount of $28.7 million was recorded for the excess of the purchase price over the fair value of the assets acquired and liabilities assumed. The goodwill recorded in connection with this acquisition is not deductible for income tax purposes. A deferred tax liability in the amount of $12.5 million was recorded related to the future taxable income as a result of the book to tax basis difference arising from the IPR&D.

The fair value of the acquired IPR&D relates to two products, including (a) an allogenic product in which NKT cells are engineered with a CAR targeting CD19, and (b) an allogenic product in which NKT cells are engineered with a CAR targeting GPC3. These IPR&D projects were valued using an income approach, specifically a projected discounted cash flow method, adjusted for the probability of technical success (PTS). The projected discounted cash flow models used to estimate the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make in order to evaluate a drug development asset including the following:

- Estimates of potential cash flows to be generated by the project and resulting asset, which was developed utilizing estimates of total patient population, market penetration rates, demand risk adjustment factors, and product pricing;
- Estimates regarding the timing of and the expected cost of goods sold, research and development expenses, selling, general, and administrative expenses to advance the clinical programs to commercialization;

- Estimates of profit sharing and cash flow adjustments;
- The projected cash flows were then adjusted using PTS factors that were selected considering both the current state of development and the nature of the proposed indication; and
- Finally, the resulting probability-adjusted cash flows were discounted to present value using a risk-adjusted discount rate, developed considering the market risk present in the forecast and the size of the asset.

This acquisition is included in the Oncology Innovation Platform. The operating results of Kuur have been included within the Company's Oncology Innovation Platform operating segment from the date of acquisition. Kuur added revenue of $0 for the year ended December 31, 2021 and contributed a net loss of $34.9 million for the year ended December 31, 2021, $28.7 million of which was related to the goodwill impairment for the Oncology Innovation Platform reporting unit.

Acquisition-related costs, including legal, regulatory, and consulting costs, amounted to $3.5 million, and are included within selling, general, and administrative expenses in the Company's consolidated statement of operations and comprehensive loss.

Unaudited Pro Forma Financial Results

The following table presents supplemental unaudited pro forma information for the acquisition as if it had occurred on January 1, 2020. The unaudited pro forma financial results for the year ended December 31, 2021 include the following adjustments: (1) removal of direct acquisition-related costs which would not have been incurred had the businesses been owned on the beginning of the prior reporting period, (2) the deferred tax effect if the intangible assets and purchase accounting were recorded as of the beginning of the prior reporting period, and (3) the removal of the change in fair value of Kuur convertible debt which was converted prior to the consummation of the acquisition. The pro forma results do not include any anticipated synergies or other expected benefits of the acquisitions. The unaudited pro forma financial information is for informational purposes only and is not necessarily indicative of either future results of operations of the combined entity or results that might have been achieved had the acquisitions been consummated as of the beginning of the prior reporting period. The following table presents the unaudited pro forma consolidated financial information for the years ended December 31, 2021 and 2020 (in thousands):

Unaudited pro forma financial information (Athenex and Kuur Consolidated)	**Year ended December 31,**	
	2021	**2020**
Consolidated revenue	$ 120,181	$ 145,441
Consolidated net loss	$ (209,430)	$ (134,450)

4. DISCONTINUED OPERATIONS

On January 7, 2022, the Company entered into a definitive agreement (the "Agreement") with ImmunityBio, Inc. (the "Buyer") whereby the Company agreed to sell to the Buyer its leasehold interest in a manufacturing facility in Dunkirk, New York (the "Dunkirk Facility") and certain other related assets, as described below, in exchange for reimbursement of certain expenditures that the Company made in the Dunkirk Facility totaling $40 million. The transaction closed on February 14, 2022 and was subject to approval from the Company's lender, Oaktree. The provisions of this approval included prepayment of the senior secured loans, as described in Note 12 - Debt and Lease Obligations. The Buyer has agreed to manufacture 503B products for the Company on mutually agreed upon commercial terms.

In addition to the leasehold interest in the Dunkirk Facility, the Buyer purchased the Company's interests in certain leased manufacturing equipment and personal property, and owned personal property and inventory at the Dunkirk Facility, along with the Company's rights in and obligations under its agreements relating to the Dunkirk Facility with Empire State Development ("ESD"), Fort Schuyler Management Corporation ("FSMC"), and County of Chautauqua Industrial Development Agency ("CCIDA") and other parties (collectively, the "Dunkirk Operations"). The Buyer will assume all capital expenditure and hiring obligations of the Company related to the Dunkirk Operations pursuant to the Company's existing agreements with ESD and FSMC. The Company has not assigned any of its rights to its corporate headquarters in Buffalo, New York, under this Agreement and will retain all of its rights and obligations with respect to its corporate headquarters.

As of December 31, 2021, the Dunkirk Operations met all conditions required to be classified as discontinued operations. Therefore, the operating results of the Dunkirk Operations are reported as loss from discontinued operations in the accompanying consolidated statements of operations and comprehensive loss. The assets and liabilities related to the Dunkirk Operations are reported as assets and liabilities of discontinued operations in the accompanying balance sheets as of December 31, 2021 and 2020. These assets are recorded at the lesser of cost or fair value less cost to sell. The Dunkirk Operations have historically been included within the Global Supply Chain Platform on its consolidated financial statements.

The following table presents the financial results of the discontinued operations (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Selling, general, and administrative expenses	$ 10,190	$ 3,996	$ 489
Income from government grant	(2,459)	—	—
Loss from discontinued operations	$ 7,731	$ 3,996	$ 489

The selling, general, and administrative costs during the years presented was comprised primarily of compensation and consultant expenses, as well as operating expenses needed to prepare the facility.

The consolidated statements of cash flows include cash flows related to the discontinued operations due to the Company's centralized treasury and cash management processes. The following table presents additional cash flow information for the discontinued operations (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Depreciation expense	$ 321	$ 31	$ 10
Cash paid for capital expenditures	(14,943)	(4,634)	(3,858)
Property and equipment financed under finance leases	—	848	—
Repayment of finance lease obligations	(178)	(92)	—

The following table presents the aggregate carrying amounts of the classes of assets and liabilities of discontinued operations (in thousands):

	December 31,	
	2021	2020
Prepaid expenses and other current assets	$ 1,280	$ 4,777
Property and equipment, net	26,848	10,578
Total assets attributable to discontinued operations	$ 28,128	$ 15,355
Accounts payable	$ 3,763	$ 255
Accrued expenses	1,198	4,403
Current portion of finance lease obligations	101	101
Long-term finance lease obligations	126	208
Total liabilities attributable to discontinued operations	$ 5,188	$ 4,967

5. RESTRICTED CASH

The Company has a restricted cash balance of $16.5 million as of December 31, 2021 held in a controlled bank account in connection with the Senior Credit Agreement, which requires the Company to maintain, in a debt service reserve account, a minimum cash balance equal to twelve months of interest on the outstanding loans under the Senior Credit Agreement.

6. INVENTORIES

Inventories consist of the following (in thousands):

	December 31,	
	2021	2020
Raw materials and purchased parts	$ 9,163	$ 6,498
Work in progress	4,157	776
Finished goods	21,365	21,572
Total inventories	$ 34,685	$ 28,846

7. PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consists of the following (in thousands):

	December 31,	
	2021	2020
Land	$ —	$ 1,190
Equipment	19,207	10,972
Furniture and fixtures	843	933
Computer hardware	4,702	4,169
Leasehold improvements	13,755	2,933
Construction in process	1,185	12,292
Property and equipment, gross	39,691	32,489
Less: accumulated depreciation	(11,713)	(8,679)
Property and equipment, net	$ 27,978	$ 23,810

Depreciation expense amounted to $2.8 million, $2.6 million, and $2.0 million for the years ended December 31, 2021, 2020, and 2019, respectively.

8. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

The changes in the carrying amount of goodwill for each reporting unit to which goodwill is assigned for the periods indicated are as follows (in thousands):

	Global Supply Chain	Oncology Innovation Platform	Total
Balance as of January 1, 2020	$ 26,169	$ 12,344	$ 38,513
Effect of currency translation adjustment	327	51	378
Balance as of December 31, 2020	26,496	12,395	38,891
Goodwill acquired in connection with acquisition of Kuur	—	28,711	28,711
Effect of currency translation adjustment	142	(65)	77
Impairment	(26,638)	(41,041)	(67,679)
Balance as of December 31, 2021	$ —	$ —	$ —

Intangible Assets, Net

The Company's identifiable intangible assets, net, consist of the following (in thousands):

	December 31, 2021			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets				
Licenses	$ 12,654	$ 6,376	$ —	$ 6,278
Polymed customer list	1,593	1,581	12	—
Polymed technology	3,712	1,984	1,728	—
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	728	—	—	728
Kuur IPR&D	64,900	—	—	64,900
Effect of currency translation adjustment	(10)	—	—	(10)
Total intangibles, net	$ 83,577	$ 9,941	$ 1,740	$ 71,896

	December 31, 2020			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets				
Licenses	$ 12,641	$ 5,157	$ —	$ 7,484
Polymed customer list	1,593	1,418	—	175
Polymed technology	3,712	1,685	—	2,027
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	728	—	—	728
Effect of currency translation adjustment	(196)	—	—	(196)
Total intangibles, net	$ 18,478	$ 8,260	$ —	$ 10,218

In connection with the acquisition of Kuur, the Company identified three drug candidate projects and two were classified as IPR&D and recorded at their fair value on the acquisition date. Included in the IPR&D is the historical know-how, cell treatment protocols, and procedures expected to be needed to complete the related phase of testing. The fair value of IPR&D was determined for each project, or unit of account, using unobservable, level 3 inputs (see Note 3—*Business Combination*). IPR&D intangible assets are not amortized, but rather are reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned, or transferred to a third party. During the fourth quarter of 2021, the Company identified an impairment triggering event, as described below, and therefore assessed the recoverability of the Kuur IPR&D. The Company determined the fair value considering the future discounted cash flows associated with each unit of account, which utilized the assumptions, including unobservable level 3 inputs, described in Note 3 - *Business Combination*. The fair value associated with the acquired IPR&D exceeded its carrying value, and therefore, the Company concluded that there was no impairment of Kuur IPR&D.

As of December 31, 2021, licenses at cost include an Orascovery license of $0.4 million and licenses purchased from Gland Pharma Ltd (“Gland”) of $3.8 million, a license purchased from MAIA Pharmaceuticals, Inc. (“MAIA”) for $4.0 million, licenses purchased from Ingenus Pharmaceuticals, LLC (“Ingenus”) for $3.0 million, and licenses of other specialty products of $1.5 million. The Orascovery license with Hanmi Pharmaceuticals Co. Ltd. (“Hanmi”) was purchased directly from Hanmi and is being amortized on a straight-line basis over a period of 12.75 years, the remaining life of the license agreement at the time of purchase. The licenses purchased from Gland are being amortized on a straight-line basis over a period of 5 years, the remaining life of the license agreement at the time of purchase. The license purchased from MAIA is being amortized over a period of 7 years, the remaining life of the license agreement at the time of purchase. The licenses purchased from Ingenus are being amortized over a period of 5 years and 3 years, the estimated useful life of the license agreements.

The remaining intangible assets were acquired in connection with the acquisitions of Polymed Therapeutics, Inc. (“Polymed”) and Comprehensive Drug Enterprises (“CDE”). Intangible assets are amortized using the straight-line method over their useful lives. The Polymed customer list and technology are amortized on a straight-line basis over 6 and 12 years, respectively. These were evaluated for impairment during 2021, as discussed below. The CDE IPR&D will not be amortized until the related projects are completed. IPR&D is tested annually for impairment, unless conditions exist causing an earlier impairment test (e.g., abandonment of project). The Company recorded no impairments of IPR&D during the year ended December 31, 2021 or 2020. During year ended December 31, 2019, the Company abandoned projects within IPR&D and therefore, the related balances of $0.2 million was written-off as impaired and was included within research and development expenses in the consolidated statement of operations and comprehensive loss. The weighted-average useful life for all intangible assets was 6.53 years as of December 31, 2021.

The Company recorded $1.9 million, $1.8 million, and $1.9 million of amortization expense for the years ended December 31, 2021, 2020, and 2019, respectively.

The Company expects amortization expense related to its finite-lived intangible assets for the next 5 years and thereafter to be as follows as of December 31, 2021 (in thousands):

Year ending December 31:	Estimated Amortization Expense
2022	$ 1,600
2023	1,570
2024	1,247
2025	1,178
2026	590
Thereafter	93
	$ 6,278

As a result of the significant decrease in the Company's market capitalization from the impact of the CRL and the Company's decision to no longer pursue oral paclitaxel for mBC, the Company evaluated the impact on each of its reporting units to assess whether there was an impairment triggering event requiring it to perform a goodwill impairment test (ASC 350-20-35). The Company determined that impairment triggering events occurred during the first quarter of 2021 and, consistent with our annual policy, performed a test as of our annual goodwill impairment evaluation date, October 1, 2021, subsequently updating that analysis to December 31, 2021 using new information that became available regarding conditions that existed as of December 31, 2021. As part of this impairment test, the Company considered certain qualitative factors, such as the Company's performance, business forecasts, and expansion plans. It reviewed key assumptions, including projected cash flows and future revenue for reporting units, and compared against the results of the prior goodwill impairment tests performed on March 31, 2021. Using both the income approach and the market approach for its Global Supply Chain Platform and Oncology Innovation Platform, with the discount rate selected considering and capturing the related risk associated with the forecast, the Company compared the fair value of the two reporting units to carrying value. Based on the results, the carrying value of each of our reporting units exceeded their fair value and the goodwill was determined to be impaired. $26.6 million, representing the full amount of goodwill allocated to the Global Supply Chain Platform, was written off as impaired during the fourth quarter of 2021. Additionally, $41.1 million, representing the full amount of goodwill allocated to the Oncology Innovation Platform was written off as impaired during the fourth quarter of 2021. These impairment charges were the result of the Company's Step-1 goodwill impairment test, which reflected a decrease in the future expected cash flows related to oral paclitaxel, along with increases in discount rates to reflect the uncertainty of future cash flows. Additionally, in the market approaches used, including the guideline company and guideline transaction methods, the Company utilized greater size & risk discounts to reflect the additional risk associated with the Company's performance. Estimating the fair value of goodwill requires the use of estimates and significant judgments that are based on a number of factors, including unobservable level 3 inputs. These estimates and judgments may not be within the control of the Company and accordingly it is reasonably possible that the judgments and estimates could change in future periods.

In connection with the impairment triggering event identified above, the Company evaluated the recoverability of its long-lived assets to determine whether any assets or asset groups were impaired. The Company compared the undiscounted cash flows to the carrying value of each asset group, and if the undiscounted cash flows were less than its carrying value, the asset or asset group was impaired by the excess of its carrying value over its fair value. During the fourth quarter of 2021, the Company determined that the carrying value of the Polymed technology and customer list were greater than their fair value, as these intangible assets related to the Chongqing Taihao manufacturing facility, which is being phased-out with the addition of the new API manufacturing facility in Chongqing, China. Therefore, the corresponding values of $1.7 million and less than $0.1 million, respectively, were written off as impaired. The evaluation of the long-lived assets requires the use of estimates and significant judgments that are based on a number of factors, including unobservable level 3 inputs. These estimates and judgments may not be within the control of the Company and accordingly it is reasonably possible that the judgments or estimates could change in future periods.

9. FAIR VALUE MEASUREMENTS

Financial instruments consist of cash and cash equivalents, restricted cash, short-term investments, an equity investment, accounts receivable, accounts payable, accrued expenses, contingent consideration, and debt. Short-term investments and the equity investment are stated at fair value. Cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses, and debt, are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date of such amounts.

ASC 820, *Fair Value Measurements*, establishes a framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy under the ASC 820 are described as follows:

Level 1—Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the plan has the ability to access.

Level 2—Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in inactive markets;
- Inputs other than quoted prices that are observable for the asset or liability;
- Inputs that are derived principally from or corroborated by observable market data by correlation or other means; and
- If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

Level 3—Inputs to the valuation methodology are unobservable, supported by little or no market activity, and that are significant to the fair value measurement.

Transfers between levels, if any, are recorded as of the beginning of the reporting period in which the transfer occurs; there were no transfers between Levels 1, 2 or 3 of any financial assets or liabilities during the years ended December 31, 2021, 2020, or 2019.

The following tables represent the fair value hierarchy for those assets and liabilities that the Company measures at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2021 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Financial assets included within cash and cash equivalents				
Money market funds	$ 7,937	$ 7,937	$ —	$ —
Short-term investments - certificates of deposit	2,000	—	2,000	—
Short-term investments - commercial paper	10,446	—	10,446	—
Financial assets included within short-term investments				
Short-term investments - certificates of deposit	9,488	—	9,488	—
Available-for-sale investment	719	719	—	—
Total assets	$ 30,590	$ 8,656	$ 21,934	$ —
Liabilities:				
Contingent consideration - Kuur	$ 24,076	$ —	$ —	$ 24,076
Total liabilities	$ 24,076	$ —	$ —	$ 24,076

	Fair Value Measurements at December 31, 2020 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Financial assets included within cash and cash equivalents				
Money market funds	$ 5,615	$ 5,615	$ —	$ —
Short-term investments - certificates of deposit	4,070	—	4,070	—
Short-term investments - U.S. government bonds	5,000	—	5,000	—
Short-term investments - commercial paper	34,860	—	34,860	—
Financial assets included within short-term investments				
Short-term investments - certificates of deposit	20,696	—	20,696	—
Short-term investments - U.S. government bonds	14,998	—	14,998	—
Short-term investments - commercial paper	102,715	—	102,715	—
Available-for-sale investment	227	227	—	—
Total assets	$ 188,181	$ 5,842	$ 182,339	$ —

The following tables represent the fair value hierarchy for those assets that the Company measured at fair value on a non-recurring basis as of December 31, 2021 (in thousands):

	Fair Value Measurements at December 31, 2021 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Intangible assets, net	71,896	—	—	71,896
Total assets	$ 71,896	$ —	$ —	$ 71,896

The Company classifies its money market funds within Level 1 because it uses quoted market prices to determine their fair value. The Company classifies its commercial paper, corporate notes, certificates of deposit, and U.S. government bonds within Level 2 because it uses quoted prices for similar assets or liabilities in active markets and each has a specified term and all level 2 inputs are observable for substantially the full term of each instrument.

The Company owns 68,000 shares of PharmaEssentia Corp. (“PharmaEssentia”), a company publicly traded on the Taiwan OTC Exchange. As of December 31, 2021 and 2020, the Company’s investment in PharmaEssentia is valued at the reported closing price. This investment is classified as a level 1 investment and is recorded as an available-for-sale investment within short-term investments on the Company’s consolidated balance sheet.

During the year ended December 31, 2021, the Company recorded a goodwill impairment loss of $67.7 million (See Note 8 - *Goodwill and Intangible Assets, Net*. This non-financial asset was measured at fair value on a non-recurring basis subsequent to its initial recognition. The Company considers the fair value of goodwill to be a level 3 measurement due to the presence of significant unobservable inputs that are based on estimates. See Note 8 for a discussion on the valuation methodologies used to measure goodwill.

10. ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	December 31,	
	2021	2020
Accrued wages and benefits	$ 2,047	$ 6,421
Accrued selling fees, rebates, and royalties	6,890	9,046
Accrued inventory purchases	4,217	3,714
Deferred revenue	3,291	1,147
Accrued clinical expenses	3,116	2,949
Accrued operating expenses	2,706	3,222
Accrued tax withholdings	1,804	1,948
Accrued interest	266	3,583
Accrued R&D licensing fees	116	366
Accrued costs for product launch	—	1,474
Total accrued expenses	$ 24,453	$ 33,870

11. INCOME TAXES

The Company recorded income tax benefit from continuing operations of $10.6 million during the year ended December 31, 2021 and income tax expense of $4.1 million and $0.9 million during the years ended December 31, 2020 and 2019, respectively. The current year income tax benefit is primarily the result of the taxable temporary difference due to the deferred tax liability recognized for the indefinite lived intangible assets acquired in connection with the acquisition of Kuur’s IPR&D. This taxable temporary difference is considered a source of taxable income to support the realization of deferred tax assets from the acquirer which resulted in a reversal of the Company’s valuation allowance. The prior years' income tax expense is attributable to foreign withholding taxes. The Company and its other subsidiaries were in a cumulative loss position as of December 31, 2021.

The components of loss before income tax (benefit) expense from continuing operations consist of the following (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Domestic	$ (175,867)	$ (133,929)	$ (109,769)
Foreign	(29,042)	(10,417)	(14,836)
	$ (204,909)	$ (144,346)	$ (124,605)

The components of loss before income tax (benefit) expense from discontinued operations consist of the following (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Domestic	$ (7,731)	$ (3,996)	$ (489)
Foreign	—	—	—
	$ (7,731)	$ (3,996)	$ (489)

The components of the income tax (benefit) expense from continuing operations consist of the following (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Current:			
Federal	$ —	$ —	$ —
State	15	4	23
Foreign	234	4,026	419
	249	4,030	442
Deferred:			
Federal	7,723	(26,262)	(26,775)
State	(283)	(869)	(2,562)
Foreign	257	(1,424)	(2,411)
	7,697	(28,555)	(31,748)
Change in valuation allowance	(18,550)	28,613	32,234
	$ (10,604)	$ 4,088	$ 928

The components of the income tax (benefit) expense from discontinued operations consist of the following (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Foreign	—	—	—
	—	—	—
Deferred:			
Federal	(1,624)	(1,017)	(103)
State	(52)	(47)	(5)
Foreign	—	—	—
	(1,676)	(1,064)	(108)
Change in valuation allowance	1,676	1,064	108
	$ —	$ —	$ —

The income tax (benefit) expense from continuing operations differs from the federal statutory rate due to the following:

	Year Ended December 31,		
	2021	2020	2019
Statutory rate	21.0%	21.0%	21.0%
State taxes, net of federal benefit	0.1	0.7	2.0
Foreign rate differential	(0.1)	—	0.1
Valuation allowance	9.1	(20.2)	(25.9)
Stock-based compensation	(0.5)	(2.7)	—
Goodwill impairment	(6.5)	—	—
Section 382 limitation	(11.2)	—	—
Tax credits	(5.1)	1.6	3.1
Foreign tax withholdings	—	(2.3)	(0.2)
Other	(1.6)	1.0	(0.8)
	5.2%	(2.9)%	(0.7)%

Net deferred income tax liabilities consist of the following (in thousands):

	December 31,	
	2021	2020
Intangible assets	$ 11,675	$ 11,372
Property and equipment	40	51
Stock-based compensation	7,743	7,148
Net operating loss carryforwards	108,762	106,342
Tax credit carryforwards	956	11,472
Research and development deduction	458	1,859
Reserves and accruals	20,090	13,528
Gross deferred income tax assets	149,724	151,772
Less: valuation allowance	(137,742)	(150,864)
Net deferred income tax assets	11,982	908
Intangible assets	(13,341)	(821)
Property and equipment	(392)	(143)
Gross deferred income tax liabilities	(13,733)	(964)
Net deferred income tax liabilities	$ (1,751)	$ (56)

As of December 31, 2021, there exists $452.4 million federal net operating losses and $99.0 million of state net operating losses. Of the federal net operating losses, $93.7 million expire beginning in 2033 and $358.7 million have an indefinite life. In addition, there exists $39.6 million of foreign net operating losses as of December 31, 2021 which may be carried forward with various years of expiration.

The valuation allowance for deferred tax assets decreased by $13.1 million for the year ended December 31, 2021 and increased by $29.7 million for the year ended December 31, 2020. The decrease in the valuation allowance in the current year was due to a reversal of a valuation allowance in connection with the acquisition of Kuur of $10.8 million and the reduction of reported net operating losses in the U.S. as a result of a Section 382 and 383 limitation of $32.2 million, offset by an increase in the valuation allowance for current year activity for additional net operating losses and tax credit carryforwards of $26.2 million and an increase recorded though purchase accounting for net operating losses of $3.7 million acquired as part of the Kuur acquisition. The increase in the prior year was due to an increase of deferred tax assets mainly for additional net operating losses and tax credit carryforwards. The Company has provided a full valuation allowance against its remaining deferred tax assets as it has determined that it is not more likely than not that recognition of such deferred tax assets will be utilized in the foreseeable future.

The Company considers whether any positions taken on the Company's income tax returns would be considered uncertain tax positions that may require the recognition of a liability. The Company has concluded that there are no material uncertain tax positions as of December 31, 2021, 2020, and 2019. The Company recognizes interest and penalties related to unrecognized tax benefits as a component of income tax benefit in the consolidated statement of operations and comprehensive loss. There were no amounts recognized for interest and penalties related to unrecognized tax benefits during the years ended December 31, 2021, 2020, and 2019. The income tax returns for the taxable years 2013 to 2020 in the U.S., China, and Hong Kong remain open and subject to income tax audits.

Provision has not been made for U.S. taxes on undistributed earnings of foreign subsidiaries. Those earnings, if any, have been and will continue to be indefinitely reinvested.

Under the provisions of Section 382 and Section 383 of the Internal Revenue Code ("IRC"), net operating loss and credit carryforwards and other tax attributes may be subject to limitation if there has been a significant change in ownership of the Company, as defined by the IRC. Changes in ownership of our common stock could result in limitations on net operating loss carryforwards. For the year ended December 31, 2021, ownership changes triggered a limitation of our net operating losses and research and development credits in the amount of $108.9 million and $9.3 million, respectively. The reduction of these net operating losses created a reduction in the deferred tax asset and related valuation allowance, as reflected in the table above.

12. DEBT AND LEASE OBLIGATIONS

Debt

The Company's debt as of December 31, 2021 and 2020, consists of the following (in thousands):

	December 31,	
	2021	2020
Current portion of mortgage	$ —	$ 731
Current portion of bank loan	784	764
Current portion of senior secured loan	45,938	70
Current portion of finance lease obligations	159	345
Current portion of operating lease obligations	2,909	3,185
Long-term portion of finance lease obligations	207	329
Long-term portion of operating lease obligations	4,494	6,355
Chongqing Maliu credit agreement	7,849	7,641
Senior secured loan, net of debt discount and financing fees of $8,663 and $11,601, respectively	95,400	138,399
Total	$ 157,740	$ 157,819

Senior Credit Agreements

During 2018, Perceptive issued a senior secured loan to the Company with a principal value of $50.0 million and a maturity date of June 30, 2023. The loan bore interest at a floating per annum rate equal to LIBOR (with a floor of 2.0%) plus 9.0%. The Company was required to make monthly interest-only payments with a bullet payment of the principal at maturity. On June 19, 2020, the Company paid off all obligations owing under, and terminated, the senior secured loan agreement with Perceptive. The secured interests were terminated in connection with the Company's payoff of all obligations. In connection with the repayment of the Perceptive loan, the Company incurred a $3.8 million prepayment fee, the unamortized debt discount of $3.1 million, and $0.3 million in other charges. The Perceptive debt extinguishment resulted in a $7.2 million loss that was included in loss on extinguishment of debt, in the consolidated statements of operations and comprehensive loss.

On June 19, 2020 ("Closing Date"), the Company entered into the Senior Credit Agreement with Oaktree to borrow up to $225.0 million in five tranches, with a maturity date of June 19, 2026. Three tranches ("Tranche A", "Tranche B", and "Tranche D") of the term loans with an aggregate principal amount of $150.0 million were drawn by the Company in 2020. The last two tranches ("Tranche C" and "Tranche E"), amounting to an aggregate of $75.0 million, were dependent on the approval of oral paclitaxel for the treatment of mBC. Under the Amendment to the Senior Credit Agreement on January 19, 2022, the amount of these tranches was reduced to $0 and are no longer available to the Company. The loan bears interest at a fixed annual rate of 11.0%. The Company allocated the proceeds of the drawn tranches between liability and equity components and the fair value of such equity components, along with the direct costs related to the issuance of the debt were recorded as an offset to long-term debt on the consolidated balance sheets. The debt discount and financing fees are amortized on a straight-line basis, which approximates the effective interest method, over the remaining maturity of the Senior Credit Agreement. The effective interest rate of Tranches A, B and D, including the amortization of debt discount and financing fees amounts to 13.3% annually. The Company is required to make quarterly interest-only payments until June 19, 2022, after which the Company is required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. Beginning on September 17, 2020, the Company was required to pay a commitment fee on any undrawn commitments equal to 0.6% per annum, payable on each subsequent funding date or the commitment termination date. Under the Amendment, the Company was required to make a mandatory prepayment of principal to Oaktree equal to 62.5% of the cash proceeds of the Dunkirk Transaction. The Company was also required to pay (i) accrued and unpaid interest and (ii) a 7.0% fee, allocated as a 2.0% Exit Fee and a 5.0% Prepayment Fee, on the principal amount being repaid. The Company was required to pay Oaktree an amendment fee of $0.3 million and certain related expenses upon the closing of the Dunkirk Transaction. The Amendment requires the Company to make an additional mandatory prepayment of $12.5 million in principal plus the costs and fees described above by June 14, 2022. Additional prepayments of the loan, in whole or in part, will be subject to early prepayment fee which declines each year until the fourth anniversary date of the Closing Date, after which no prepayment fee is required. Upon the final payment, the Company must also pay an exit fee calculated based on a percentage of the aggregate principal amount of all tranches advanced to the Company, and as of December 31, 2021, the Company has reflected an exit fee liability of $3.0 million. As of December 31, 2021, the Company has classified $45.9 million of the senior secured loan as current portion of long-term debt, comprised of three quarterly payments of $2.8 million each, due in 2022, $25.0 million due upon closing of the Dunkirk Transaction, and $12.5 million due 120 days after the closing of the Dunkirk Transaction, and it has classified $95.4 million of the senior secured loan as long-term debt on the consolidated balance sheet, comprised of the remaining principal due, less debt discount and financing fees of $8.7 million.

The Senior Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that were customarily required for similar financings. The Company is subject to certain financial covenants under the Senior Credit Agreement, including (1) a minimum liquidity amount in cash or permitted cash equivalent investments of $20.0 million from the closing date until the date on which the aggregate principal amount of loans outstanding is greater than or equal to $150.0 million (the "First Step-Up Date"), $25.0 million from the First Step-Up Date until the date on which the aggregate principal amount of loans outstanding balance is equal to $225.0 million (the "Second Step-Up Date"), and $30.0 million from the Second Step-up Date until the maturity date; (2) minimum revenue no less than 50% of target revenue beginning with the fiscal quarter ended on December 31, 2020 and with respect to each such subsequent fiscal quarter prior to the revenue covenant termination date; (3) leverage ratio covenant not to exceed 4.50 to 1.00 as of the last day of any fiscal quarter beginning with the first fiscal quarter following the revenue covenant termination date. At December 31, 2021, the Company was in compliance with all applicable debt covenants.

Revenue Interest Financing Agreement

On August 4, 2020, the Company entered into a Revenue Interest Financing Agreement with Sagard Healthcare Royalty Partners, LP ("Sagard"), pursuant to which Sagard agreed to pay the Company $50.0 million to provide funding for the Company's development and commercialization of Oral Paclitaxel upon receipt of marketing authorization for Oral Paclitaxel by the U.S. FDA for the treatment of mBC. The Company did not obtain marketing authorization for Oral Paclitaxel by the U.S. FDA by December 31, 2021, and therefore, a termination right became available to Sagard. Therefore, the Company is unable to draw funds from the Revenue Interest Financing and wrote off the deferred debt issuance costs related to the Revenue Interest Financing for $0.6 million during the three months ended June 30, 2021, and has included such expense within interest expense on its consolidated statement of operations and comprehensive loss for the year ended December 31, 2021. This Revenue Interest Financing Agreement was formally terminated in March 2022.

Credit Agreements, Bank Loan and Mortgage

During the second quarter of 2019, the Company entered into a credit agreement which amended the existing partnership agreement with Chongqing Maliu Riverside Development and Investment Co., LTD ("CQ"), for a Renminbi ¥50.0 million (USD $7.7 million at December 31, 2020) line of credit to be used for the construction of the new API plant in China. The Company is required to repay the principal amount with accrued interest within three years after the plant receives the cGMP certification, with 20% of the total loan with accrued interest is due within the first twelve months following receiving the certification, 30% of the total loan with accrued interest due within twenty-four months, and the remaining balance with accrued interest due within thirty-six months. Interest accrues at the three-year loan interest rate by the People's Bank of China for the same period on the date of the deposit of the full loan amount, which is expected to approximate 4.75% annually. If the Company fails to obtain the cGMP certification within three years upon the acceptance of the plant, it shall return all renovation costs with the accrued interest to CQ in a single transaction within the first ten business days. As of December 31, 2021, the balance due to CQ was $7.8 million.

On May 15, 2020, the Company entered into a credit agreement with China Merchants Bank, enabling the Company to draw up to a Renminbi ¥5.0 million (USD $0.8 million at December 31, 2021) during the period through May 14, 2021. The Company drew the entire available credit in July 2020 and repaid the credit agreement in full on May 14, 2021. On May 28, 2021, the Company entered into a credit agreement on the same terms as that which was repaid, and withdrew the full Renminbi ¥5.0 million (USD $0.8 million at December 31, 2021) on that date. This loan has a maturity date of May 28, 2022 and bears interest at a fixed rate of 4.35% annually. The Company is required to pay the outstanding principal and all accrued interest at maturity.

During the fourth quarter of 2021, the Company sold its controlling interest in Chongqing MJ Medical Devices Co., Ltd, a subsidiary of CDE, to the non-controlling interest, for consideration of $0.1 million. The mortgage, assumed in connection with the acquisition of CDE, was transferred to the buyer in connection with the sale.

Lease Obligations

The Company has operating leases for office and manufacturing facilities in several locations in the U.S., Asia, and Latin America, and has three finance leases for manufacturing equipment used in its facilities near Buffalo, NY (see Note 20 – *Commitments and Contingencies)*. The components of lease expense are as follows (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating lease cost	$ 2,971	$ 3,041
Finance lease cost:		
Amortization of assets	256	223
Interest on lease liabilities	54	61
Total net lease cost	$ 3,281	$ 3,325

The Company has elected to exclude short-term leases from its operating lease ROU assets and lease liabilities. Lease costs for short-term leases were not material to the financial statements for the years ended December 31, 2021, 2020, and 2019. Variable lease costs for the years ended December 31, 2021, 2020, and 2019 were not material to the financial statements.

Supplemental balance sheet information related to leases is as follows (in thousands, except lease term and discount rate):

	December 31, 2021	December 31, 2020
Finance leases:		
Property and equipment, at cost	$ 1,203	$ 1,203
Accumulated amortization, net	(585)	(333)
Property and equipment, net	$ 618	$ 870
Current obligations of finance leases	$ 159	$ 345
Long-term portion of finance leases	207	329
Total finance lease obligations	$ 366	$ 674
Weighted average remaining lease term (in years):		
Operating leases	3.53	4.23
Finance leases	2.25	3.40
Weighted average discount rate:		
Operating leases	12.9%	12.8%
Finance leases	9.8%	10.4%

Supplemental cash flow information related to leases is as follows (in thousands):

	Year Ended December 31, 2021
Cash paid for amount included in the measurements of lease liabilities:	
Operating cash flows from operating leases	$ (3,416)
Operating cash flows from finance leases	(384)
Financing cash flows from finance leases	(84)
ROU assets recognized in exchange for new operating lease obligations	$ 89

Future minimum payments and maturities of leases is as follows (in thousands):

Year ending December 31:	Operating Leases	Finance Leases
2022	$ 3,020	$ 168
2023	2,184	147
2024	2,034	109
2025	1,472	—
2026	347	—
Thereafter	132	—
Total lease payments	9,189	424
Less: Imputed interest	(1,786)	(58)
Total lease obligations	7,403	366
Less: Current obligations	(2,909)	(159)
Long-term lease obligations	$ 4,494	$ 207

On January 5, 2021, Chongqing Sintaho Pharmaceuticals Co., Ltd. (“CQ Sintaho”), a subsidiary of the Company in China, entered into a lease agreement with Chongqing International Biological City Development & Investment Co., Ltd (“CQ D&I”). Under the lease agreement, the provisions of which are consistent with those agreed upon in the 2015 Agreement, CQ Sintaho leased the newly constructed API facility, or Sintaho API Facility, of 34,517 square meters rent-free, for the first 10-year term, with an option to extend the lease for an additional 10-year term, during which, if CQ Sintaho is profitable, it will pay a monthly rent of 5 RMB per

square meter of space occupied. The Company determined the lease commenced in the first quarter of 2021, as it was operational and CQ Sintaho could direct the use of the facility. The Company also evaluated the probability of exercising the renewal and purchase options, and determined that it is not reasonably certain whether it will exercise those options. Therefore, the lease term is comprised only of the rent-free period and the recognition of the right-of-use asset and liability did not have a significant effect on the Company's consolidated financial statements.

On October 1, 2021, the Company entered into a lease agreement with FSMC, a not-for-profit corporation affiliated with the State of New York, to lease the 409,000 square feet, newly constructed cGMP ISO Class 5 high potency pharmaceutical manufacturing facility located in Dunkirk, NY. The lease agreement calls for annual rent payments of $2 for an initial 10-year term, with the option for the Company to renew under the same terms and conditions for an additional 10-year term. The provisions of the lease agreement are consistent with those agreed upon in the 2015 Agreement for Medical Technology Research, Development, and Innovation and Commercial Alliance ("Alliance Agreement"), and subsequent amendments, under which FSMC agreed to fund the construction costs of a new manufacturing facility in Dunkirk, NY, up to $208.0 million. Under the terms of the lease agreement and 2015 Alliance Agreement, the Company committed to spend $1.52 billion on operational expenses during the initial 10-year term, and an additional $1.5 billion on operational expenses if the Company elects to extend the lease for a second 10-year term. The Company also committed to hiring 450 employees at the Dunkirk facility within the first 5 years of operations, including hiring at least 300 new employees within 2.5 years of the Dunkirk facility becoming operational. The Company has identified this as an operating lease with a commencement date of October 1, 2021 when it could direct the use of the facility. The Company also evaluated the probability of exercising its renewal option after ten years, and determined that it is not reasonably certain whether it will exercise that option. Therefore, the lease term is comprised of the first ten-year term and the recognition of the right-of-use asset and liability did not have a significant effect on the Company's consolidated financial statements. This operating lease was transferred to ImmunityBio, Inc. upon execution of the sale of the Dunkirk Operations in February 2022 (see Note 4 - *Discontinued Operations*).

The Company exercises judgment in determining the discount rate used to measure the lease liabilities. When rates are not implicit within an operating lease, the Company uses its incremental borrowing rate as its discount rate, which is based on yield trends in the biotechnology and healthcare industry and debt instruments held by the Company with stated interest rates. The Company re-assesses its incremental borrowing rate when new leases arise, or existing leases are modified.

13. CONTINGENT CONSIDERATION

The fair value measurements of contingent consideration liabilities are determined using unobservable Level 3 inputs. These inputs include (a) the estimated amount and timing of projected cash flows; (b) the probability of the achievement of the factors on which the contingency is based; and (c) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases (decreases) in any of those inputs could result in a lower or higher fair value measurement. The Company expects that these milestones will be achieved at varying times between 2023 and 2027.

The following table represents a reconciliation of the contingent consideration liability related to the acquisition of Kuur measured on a recurring basis using level 3 inputs as of December 31, 2021 (in thousands):

Balance as of May 4, 2021	$	19,839
Adjustment to fair value		4,237
Balance as of December 31, 2021	$	24,076

The increase of the contingent consideration was due to the time value of money from the initial measurement date (Kuur acquisition date) to December 31, 2021, as well as updated probabilities of future cash flows related to R&D milestones. The discount rate used in measuring the fair value of this liability is the Company's incremental borrowing rate, which is updated on a quarterly basis. The probabilities of the R&D milestones represent the probability of technical success for each therapy to which the milestones are related, and these probabilities are updated on a quarterly basis, based on the clinical stage of the therapy, along with consideration of any additional clinical data obtained during each quarter. The adjustment to the contingent consideration liability is included within selling, general, and administrative expenses in the Company's consolidated statements of operations and comprehensive loss.

14. RELATED PARTY TRANSACTIONS

During the years ended December 31, 2021, 2020, and 2019, the Company entered into transactions with individuals and other companies that have financial interests in the Company. Related party transactions included the following:

a) In June 2018, the Company entered into two in-licensing agreements with Avalon BioMedical (Management) Limited ("Avalon") wherein the Company obtained certain IP from Avalon to develop and commercialize the underlying products. Under these agreements the Company is required to pay upfront fees and future milestone payments and sales-based royalties. During the year ended December 31, 2021 and 2020, the Company recorded $2.0 million and $0 million milestone fees paid to Avalon, respectively, as research and development expenses on its consolidated statement of operations and comprehensive loss. Certain members of the Company's board and management collectively have a controlling interest in Avalon. The Company does not hold any interest in Avalon and does not have any obligations to absorb losses or any rights to receive benefits from Avalon. As of December 31, 2021 and 2020, Avalon held 786,061 shares of the Company's common stock, which represented less than 1% of the Company's total issued shares for both periods. Balances due from Avalon recorded on the consolidated balance sheets were not significant.

   In June 2019, the Company entered into an agreement whereby Avalon would hold a 90% ownership interest and the Company would hold a 10% ownership interest of the newly formed entity under the name Nuwagen Limited ("Nuwagen"), incorporated under the laws of Hong Kong. Nuwagen is principally engaged in the development and commercialization of herbal medicine products for metabolic, endocrine, and other related indications. The Company contributed nonmonetary assets in exchange for the 10% ownership interest.

b) The Company earns licensing revenue from PharmaEssentia, an entity in which the Company has an investment classified as available-for-sale (see Note 9 – *Fair Value Measurements*). Funds paid to PharmaEssentia under the license and cost-sharing agreements amounted to $0.1 in the year ended December 31, 2021 and $0.4 million in each of the years ended December 31, 2020 and 2019. Pursuant to out-license agreements, the Company received $3.0 million, $2.0 million, and $0 for the years ended December 31, 2021, 2020, and 2019, respectively. Of the $3.0 million in milestone payments received in 2021, $0.5 million was recognized as revenue and $2.5 million was recognized as deferred revenue (refer to Note 19 - *Revenue Recognition*).

c) Certain family members of our executive officers work as employees or consultants of the Company. Such services were not significant to the consolidated financial statements.

15. STOCK-BASED COMPENSATION

Common Stock Option Plans

The Company has four equity compensation plans, adopted in 2017, 2013, 2007 and 2004 (the "Plans") which, taken together, authorize the grant of up to 16,000,000 shares of common stock to employees, directors, and consultants. On June 5, 2020, the amendment and restatement of the 2017 Omnibus Incentive Plan (the "2017 Plan"), which increased the number of shares available for issuance under the plan by up to 500,000 shares, became effective, and was further amended as of June 18, 2021 to increase the number of shares available for issuance under the plan by up to an additional 5 million shares. Additionally, on June 14, 2017, the Company adopted its 2017 Employee Stock Purchase Plan (the "ESPP"), which authorizes the issuance of up to 1,000,000 shares of common stock for future issuances to eligible employees.

Stock Options

The total fair value of stock options vested and recorded as compensation expense during the years ended December 31, 2021, 2020, and 2019 was $8.4 million, $9.6 million, and $7.9 million, respectively. As of December 31, 2021, $11.1 million of unrecognized cost related to non-vested stock options was expected to be recognized over a weighted-average period of approximately 1.71 years. The total intrinsic value of options exercised was approximately $0.2 million and $1.5 million for the years ended December 31, 2021 and 2020, respectively.

The following table summarizes the status of the Company's stock option activity granted under the Plans and 2017 Plan to employees, directors, and consultants (in thousands, except stock option amounts and exercise price): Stock options granted have a contractual term of 10 years and generally vest over a 2-4 year period. A limited number of stock options vest immediately in certain circumstances. The following table summarizes the status of the Company's stock option activity granted under the Plans and 2017 Plan to employees, directors, and consultants (in thousands, except stock option amounts):

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2020	12,496,888	$ 9.26	5.42	$ 22,463
Granted	944,095	3.77	—	—
Exercised	(279,425)	5.64	—	—
Forfeited and expired	(499,488)	9.03	—	—
Outstanding at December 31, 2021	12,662,070	$ 8.96	4.88	$ —
Vested and exercisable at December 31, 2021	9,934,435	$ 8.78	3.91	$ —

The Company determines the fair value of stock option awards on the grant date using the Black-Scholes option pricing model, which is impacted by assumptions regarding a number of highly subjective variables. The following table summarizes the weighted-average assumptions used as inputs to the Black-Scholes option pricing model during the periods indicated:

	Year Ended December 31,		
	2021	2020	2019
Weighted average grant date fair value	$ 3.77	$ 6.93	$ 8.06
Expected dividend yield	—%	—%	—%
Expected stock price volatility	68%	67%	64%
Risk-free interest rate	1.29%	0.91%	2.60%
Expected life of options (in years)	6.2	6.2	6.3

Restricted Stock Awards

The total fair value of restricted stock awards vested and recorded as compensation expense during the years ended December 31, 2021, 2020, and 2019 was $0.6 million, $1.0 million, and $0.6 million, respectively. Restricted stock awards cliff vest on the anniversaries of their grant date. As of December 31, 2021, $3.1 million of unrecognized cost related to non-vested restricted stock awards were expected to be recognized over a weighted-average period of approximately 2.05 years.

The following table summarizes the status of the Company's restricted stock awards.

	Shares of Restricted Stock	Weighted Average Fair Value
Nonvested at December 31, 2020	22,500	$ 15.65
Granted	933,595	3.69
Vested	(31,500)	7.29
Nonvested at December 31, 2021	924,595	$ 3.86

Employee Stock Purchase Plan

The ESPP is available to eligible employees (as defined in the plan document). Under the ESPP, shares of the Company's common stock may be purchased at a discount (15%) of the lesser of the closing price of the Company's common stock on the first trading or the last trading day of the offering period. The current offering period extends from December 1, 2021 to May 31, 2022. The Company expects to offer six-month offering periods after the current period. The 2017 Plan reserved 1,000,000 shares of common stock for issuance under the ESPP. Stock-based compensation related to the ESPP amounted to $0.2 million for the year ended December 31, 2021 and $0.3 million for each of the years ended December 31, 2020 and 2019. The Company issued 81,557, 50,827, and 60,825 shares of common stock to participants during the years ended December 31, 2021, 2020, and 2019, respectively.

Stock-Based Compensation Cost

The components of stock-based compensation and the amounts recorded within research and development expenses and selling, general, and administrative expenses in the Company's consolidated statements of operations and comprehensive loss consisted of the following for the years ended December 31, 2021, 2020, and 2019 (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Stock options	$ 8,441	$ 9,557	$ 7,887
Restricted stock expense	616	1,017	566
Stock awarded to directors and officers	—	—	1,105
Employee stock purchase plan	150	276	327
Total stock-based compensation expense	$ 9,207	$ 10,850	$ 9,885
Cost of sales	$ 208	$ 249	$ 248
Research and development expenses	2,700	3,647	3,251
Selling, general, and administrative expenses	6,299	6,954	6,386
Total stock-based compensation expense	$ 9,207	$ 10,850	$ 9,885

16. NET LOSS PER SHARE ATTRIBUTABLE TO ATHENEX, INC. COMMON STOCKHOLDERS

Basic net loss per share is calculated by dividing net loss attributable to Athenex, Inc. common stockholders by the weighted-average number of common shares issued, outstanding, and vested during the period. Net loss from continuing operations per share is calculated by dividing the net loss from continuing operations, less, net loss attributable to non-controlling interests, by the weighted-average number of common shares issued, outstanding, and vested during the period. Net loss from discontinued operations per share is calculated by dividing the loss from discontinued operations by the weighted-average number of common shares issued, outstanding, and vested during the period. Diluted net loss per share is computed by dividing net loss attributable to Athenex, Inc. common stockholders by the weighted-average number of common share and common shares equivalents for the period using the treasury-stock method. For the purposes of this calculation, warrants for common stock and stock options are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following weighted average outstanding shares of common stock equivalents were excluded from the calculation of diluted net loss per share attributable Athenex, Inc. to common stockholders for the periods presented because including them would have been antidilutive:

	Year Ended December 31,		
	2021	2020	2019
Stock options and other common stock equivalents	13,624,025	12,748,882	10,814,635
Unvested restricted common shares	353,148	76,750	45,581
Total potential dilutive common shares	13,977,173	12,825,632	10,860,216

17. ACCUMULATED OTHER COMPREHENSIVE LOSS

The components and changes of accumulated other comprehensive loss, net of related income tax effects, are as follows (in thousands):

Balance as of January 1, 2019	$ (656)
Foreign currency translation adjustment	118
Unrealized loss on investment	(97)
Balance as of December 31, 2019	(635)
Foreign currency translation adjustment	(494)
Unrealized loss on investment	(5)
Balance as of December 31, 2020	(1,134)
Foreign currency translation adjustment	141
Unrealized gain on investment	506
Balance as of December 31, 2021	$ (487)

18. BUSINESS SEGMENT, GEOGRAPHIC, AND CONCENTRATION RISK INFORMATION

The Company has three operating segments, which are organized based mainly on the nature of the business activities performed and regulatory environments in which they operate. The Company also considers the types of products from which the reportable segments derive their revenue. Each operating segment has a segment manager who is held accountable for operations and has discrete financial information that is regularly reviewed by the Company's chief operating decision-maker. Consequently, the Company has concluded each operating segment to be a reportable segment. The Company's operating segments are as follows:

Oncology Innovation Platform— This operating segment performs research and development on certain of the Company's proprietary drugs, from the preclinical development of its chemical compounds, to the execution and analysis of its several clinical trials. It focuses specifically on Orascovery and Src Kinase Inhibition research platforms, and TCR-T immunotherapy and arginine deprivation therapy. This segment operates in the U.S., Taiwan, Hong Kong, mainland China, the United Kingdom, and Latin America.

Global Supply Chain Platform— This operating segment includes APS and Polymed and the construction of the manufacturing facility in Chongqing, China. APS is a manufacturing company that supplies sterile injectable drugs to hospital pharmacies across the U.S. APS manufactures products under Section 503B of the Compounding Quality Act within the Federal Food, Drug & Cosmetic Act ("FDCA"). Additionally, APS provides products for the development and manufacturing of the Company's proprietary drug candidates as well as providing the Company with a cGMP analytical services function. Polymed is primarily in the business of marketing and selling API in North America, Europe, and Asia from its locations in Texas and China. Polymed also develops new compounds and processing techniques and is in the final phase of completion of the new API manufacturing facility in Chongqing, China.

Commercial Platform— This operating segment includes APD and Athenex Oncology, which focus on the manufacturing, distribution, and sales of specialty pharmaceuticals and the pre-launch commercial activities for the Company's proprietary drugs, respectively. This segment provides services and products to external customers based mainly in the U.S.

The Company's Oncology Innovation Platform segment operates and holds long-lived assets located in the U.S., Taiwan, Hong Kong, mainland China, the United Kingdom, and Latin America. The Global Supply Chain Platform segment operates and holds long-lived assets located in the U.S. and China. The Commercial Platform segment operates and holds long-lived assets located in the U.S. For geographic segment reporting, product sales have been attributed to countries based on the location of the customer.

Segment information is as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Total revenue:			
Oncology Innovation Platform	$ 26,866	$ 38,851	$ 20,562
Global Supply Chain Platform	28,471	20,491	33,970
Commercial Platform	66,991	89,572	50,427
Total revenue for reportable segments	122,328	148,914	104,959
Intersegment revenue	(2,147)	(4,523)	(3,730)
Total consolidated revenue	$ 120,181	$ 144,391	$ 101,229

Intersegment revenue eliminated in the above table reflects sales from the Global Supply Chain Platform to the Oncology Innovation Platform.

	Year Ended December 31,		
	2021	2020	2019
Total revenue by product group:			
Commercial product sales	$ 86,766	$ 101,590	$ 67,411
License fees	26,832	38,827	20,100
API sales	3,986	3,599	12,733
Contract manufacturing revenue	1,512	85	391
Medical device sales	—	—	—
Other revenue	1,085	290	594
Total consolidated revenue	$ 120,181	$ 144,391	$ 101,229

Intersegment revenue is recorded by the selling segment when it is realized or realizable and all revenue recognition criteria are met. Upon consolidation, all intersegment revenue and related cost of sales are eliminated from the selling segment's ledger.

	Year Ended December 31,		
	2021	2020	2019
Net loss attributable to Athenex, Inc.:			
Oncology Innovation Platform	$ (118,089)	$ (89,189)	$ (100,919)
Global Supply Chain Platform	(38,566)	(15,404)	(8,086)
Commercial Platform	(35,382)	(37,590)	(14,255)
Segment total	(192,037)	(142,183)	(123,260)
Discontinued operations	(7,731)	(3,996)	(489)
Total consolidated net loss attributable to Athenex, Inc.	$ (199,768)	$ (146,179)	$ (123,749)

	Year Ended December 31,		
	2021	2020	2019
Total depreciation and amortization			
Oncology Innovation Platform	$ 879	$ 776	$ 762
Global Supply Chain Platform	1,982	2,017	1,479
Commercial Platform	1,821	1,668	1,566
Segment total	4,682	4,461	3,807
Discontinued operations	321	31	10
Total depreciation and amortization	$ 5,003	$ 4,492	$ 3,817

	December 31,	
	2021	2020
Total assets:		
Oncology Innovation Platform	$ 131,432	$ 234,153
Global Supply Chain Platform	54,775	83,732
Commercial Platform	53,113	51,089
Segment total	239,320	368,974
Discontinued operations	28,128	15,355
Total assets	$ 267,448	$ 384,329

	Year Ended December 31,		
	2021	2020	2019
Total revenue			
United States	$ 114,457	$ 82,362	$ 67,794
China	2,666	39,796	2,105
South Korea	1,112	2,354	513
India	906	—	3,066
Austria	115	226	4,422
Spain	47	—	20,000
United Kingdom	—	19,289	1,023
Other foreign countries	878	364	2,306
Total consolidated revenue	$ 120,181	$ 144,391	$ 101,229

	December 31,	
	2021	2020
Total property and equipment, net:		
United States	$ 4,196	$ 4,933
China	23,782	18,877
Total property and equipment, net	$ 27,978	$ 23,810

Customer revenue and accounts receivable concentration amounted to the following for the identified periods:

	Year Ended December 31,		
	2021	2020	2019
Percentage of total revenue by customer:			
Customer A	23%	—	20%
Customer B	17%	10%	14%
Customer C	16%	14%	15%
Customer D	16%	14%	16%
Customer E	—	26%	0%
Customer F	—	13%	0%

	December 31,	
	2021	2020
Percentage of total accounts receivable by customer:		
Customer A	35%	24%
Customer B	29%	33%
Customer C	15%	16%

19. REVENUE RECOGNITION

The Company records revenue in accordance with ASC, Topic 606, *Revenue from Contracts with Customers*. Under Topic 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which it expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of Topic 606, the entity performs the following five steps: (i) identifies the contract(s) with a customer; (ii) identifies the performance obligations in the contract; (iii) determines the transaction price; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Below is a description of principal activities – separated by reportable segments – from which the Company generates its revenue (See Note 18 – *Business Segment, Geographic, and Concentration Risk Information*).

1. Oncology Innovation Platform

The Company out-licenses certain of its IP to other pharmaceutical companies in specific territories that allow the customer to use, develop, commercialize, or otherwise exploit the licensed IP. In accordance with Topic 606, the Company analyzes the contracts to identify its performance obligations within the contract. Most of the Company's out-license arrangements contain multiple performance obligations and variable pricing. After the performance obligations are identified, the Company determines the transaction price, which generally includes upfront fees, milestone payments related to the achievement of developmental, regulatory, or commercial goals, and royalty payments on net sales of licensed products. The Company considers whether the transaction price is fixed or variable, and whether such consideration is subject to return. Variable consideration is only included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. If any portion of the transaction price is constrained, it is excluded from the transaction price until the constraint no longer exists. The Company then allocates the transaction price to the performance obligation to which the consideration is related. Where a portion of the transaction price is received and allocated to continuing performance obligations under the terms of the arrangement, it is recorded as deferred revenue and recognized as revenue when (or as) the underlying performance obligation is satisfied.

The Company's contracts may contain one or multiple promises, including the license of IP and development services. The licensed IP related to the Company's approved and late-stage drug candidates is capable of being distinct from the other performance obligations identified in the contract and is distinct within the context of the contract, as upon transfer of the IP, the customer is able to use and benefit from it, and the customer could obtain the development services from other parties. The Company also considers the economic and regulatory characteristics of the licensed IP and other promises in the contract to determine if it is a distinct performance obligation. The Company considers if the IP is modified or enhanced by other performance obligations through the life of the agreement and whether the customer is contractually or practically required to use updated IP. The IP licensed by the Company has been determined to be functional IP. The IP is not modified during the license period and therefore, the Company recognizes revenues from any portion of the transaction price allocated to the licensed IP when the license is transferred to the customer and they can benefit from the right to use the IP. The Company recognized $0.5 million in license revenue from and out-license arrangement for the year ended December 31, 2021, and $37.7 million in license revenue, net of $2.3 million value added tax ("VAT"), and $1.0 million in license revenue from two of the Company's out-license arrangements for the year ended December 31, 2020. The Company recognized revenue allocated to the licensed IP performance obligation upon transfer of the license of $0.1 million for the year ended December 31, 2019. During the year ended December 31, 2021, the Company received $2.0 million in upfront fees for a license of TRC-T technology, which was deemed not to be distinct, as the IP is in an early stage and is dependent on development activities to be performed by the Company, and $0.7 million for licenses of Klisyri in territories in which it is not yet approved and further development activities are required to be performed by the Company. Therefore these licenses of IP and the development services were considered a bundled performance obligation. As of December 31, 2021, this bundle of performance obligations was not satisfied and the corresponding $2.7 million was recorded as deferred revenue on the Company's consolidated balance sheet.

Other performance obligations included in most of the Company's out-licensing agreements include performing development services to reach clinical and regulatory milestone events. The Company satisfies these performance obligations at a point-in-time, because the customer does not simultaneously receive and consume the benefits as the development occurs, the development does not create or enhance an asset controlled by the customer, and the development does not create an asset with no alternative use. The Company considers milestone payments to be variable consideration measured using the most likely amount method, as the entitlement to the consideration is contingent on the occurrence or nonoccurrence of future events. The Company allocates each variable milestone payment to the associated milestone performance obligation, as the variable payment relates directly to the Company's efforts to satisfy the performance obligation and such allocation depicts the amount of consideration to which the Company expects to be entitled for satisfying the corresponding performance obligation. The Company re-evaluates the probability of achievement of such performance obligations and any related constraint and adjusts its estimate of the transaction price as appropriate. To date, no amounts have been constrained in the initial or subsequent assessments of the transaction price. The Company did not recognize revenue from other performance obligations included in the Company's out-licensing agreements during the years ended December 31, 2021 or 2020. The Company recognized revenue allocated to development performance obligations upon transfer to the customer of $20.0 million for the year ended December 31, 2019.

Certain out-license agreements include performance obligations to manufacture and provide drug product in the future for commercial sale when the licensed product is approved. For the commercial, sales-based royalties, the consideration is predominantly related to the licensed IP and is contingent on the customer's subsequent sales to another commercial customer. Consequently, the sales- or usage-based royalty exception would apply. Revenue will be recognized for the commercial, sales-based milestones as the underlying sales occur. The Company recognized $25.0 million in commercial milestones and $1.0 million in royalties during the year ended December 31, 2021. No such revenues were recorded during 2020.

The Company exercises significant judgment when identifying distinct performance obligations within its out-license arrangements, determining the transaction price, which often includes both fixed and variable considerations, and allocating the transaction price to the proper performance obligation. The Company did not use any other significant judgments related to out-licensing revenue during the years ended December 31, 2021 and 2020.

2. Global Supply Chain Platform

The Company's Global Supply Chain Platform manufactures API for use internally in its research and development activities as well as its clinical studies, and for sale to pharmaceutical customers globally. The Company generates additional revenue on this platform, by providing small to mid-scale cGMP manufacturing of clinical and commercial products for pharmaceutical and biotech companies and selling pharmaceutical products under 503B regulations set forth by the U.S. FDA.

Revenue earned by the Global Supply Platform is recognized when the Company has satisfied its performance obligation, which is the shipment or the delivery of drug products. The underlying contracts for these sales are generally purchase orders and the Company recognizes revenue at a point-in-time. Any remaining performance obligations related to product sales are the result of customer deposits and are reflected in the deferred revenue contract liability balance.

3. Commercial Platform

The Company's Commercial Platform generates revenue by distributing specialty products through independent pharmaceutical wholesalers. The wholesalers then sell to an end-user, normally a hospital, alternative healthcare facility, or an independent pharmacy, at a lower price previously established by the end-user and the Company. Upon the sale by the wholesaler to the end-user, the wholesaler will chargeback the difference, if any, between the original list price and price at which the product was sold to the end-user. The Company also offers cash discounts, which approximate 2.3% of the gross sales price, as an incentive for prompt customer payment, and, consistent with industry practice, the Company's return policy permits customers to return products within a window of time before and after the expiration of product dating. Further, the Company offers contractual allowances, generally in the form of rebates or administrative fees, to certain wholesale customers, group purchasing organizations ("GPOs"), and end-user customers, consistent with pharmaceutical industry practices. Revenues are recorded net of provisions for variable consideration, including discounts, rebates, GPO allowances, price adjustments, returns, chargebacks, promotional programs and other sales allowances. Accruals for these provisions are presented in the consolidated financial statements as reductions in determining net sales and as a contra asset in accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). As of December 31, 2021 and 2020, the Company's total provision for chargebacks and other deductions included as a reduction of accounts receivable totaled $22.9 million and $12.6 million, respectively. The Company's total provision for chargebacks and other revenue deductions was $129.0 million, $89.3 million, and $87.2 million for the years ended December 31, 2021, 2020, and 2019, respectively.

The Company exercises significant judgment in its estimates of the variable transaction price at the time of the sale and recognizes revenue when the performance obligation is satisfied. Factors that determine the final net transaction price include chargebacks, fees for service, cash discounts, rebates, returns, warranties, and other factors. The Company estimates all of these variables based on historical data obtained from previous sales finalized with the end-user customer on a product-by-product basis. At the time of sale, revenue is recorded net of each of these deductions. Through the normal course of business, the wholesaler will sell the product to the end-user, determining the actual chargeback, return products, and take advantage of cash discounts, charge fees for services, and claim warranties on products. The final transaction price per product is compared to the initial estimated net sale price and reviewed for accuracy. The final prices and other factors are immediately included in the Company's historical data from which it will estimate the transaction price for future sales. The underlying contracts for these sales are generally purchase orders including a single performance obligation, generally the shipment or delivery of products and the Company recognizes this revenue at a point-in-time.

Disaggregation of revenue

The following represents the Company's revenue for its reportable segment by country, based on the locations of the customer (in thousands).

	For the Year Ended December 31, 2021			
	Oncology Innovation Platform	**Global Supply Chain Platform**	**Commercial Platform**	**Consolidated Total**
United States	$ 26,202	$ 21,264	$ 66,991	$ 114,457
China	33	2,633	—	2,666
South Korea	—	1,112	—	1,112
India	—	906	—	906
Other Foreign Countries	631	409	—	1,040
Total Revenue	$ 26,866	$ 26,324	$ 66,991	$ 120,181

	For the Year Ended December 31, 2020			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	$ —	$ 12,079	$ 70,283	$ 82,362
China	38,760	1,036	—	39,796
United Kingdom	—	—	19,289	19,289
South Korea	—	2,354	—	2,354
Other Foreign Countries	91	499	—	590
Total Revenue	$ 38,851	$ 15,968	$ 89,572	$ 144,391

	For the Year Ended December 31, 2019			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	$ —	$ 17,367	$ 50,427	$ 67,794
Spain	20,000	—	—	20,000
Austria	—	4,422	—	4,422
India	—	3,066	—	3,066
China	562	1,543	—	2,105
United Kingdom	—	1,023	—	1,023
Other Foreign Countries	—	2,819	—	2,819
Total Revenue	$ 20,562	$ 30,240	$ 50,427	$ 101,229

The Company also disaggregates its revenue by product group which can be found in Note 18 – *Business Segment, Geographic, and Concentration Risk Information.*

Contract balances

The following table provides information about receivables and contract liabilities from contracts with customers. The Company has not recorded any contract assets from contracts with customers (in thousands).

	December 31,	
	2021	2020
Accounts receivable, gross	$ 58,811	$ 45,792
Chargebacks and other deductions	(22,868)	(12,552)
Provision for credit losses	(9,306)	(9,637)
Accounts receivable, net	$ 26,637	$ 23,603
Deferred revenue	3,291	1,147
Total contract liabilities	$ 3,291	$ 1,147

The following tables illustrate accounts receivable by reportable segments (in thousands).

	December 31, 2021			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Accounts receivable, gross	$ 10,069	$ 4,444	$ 44,298	$ 58,811
Chargebacks and other deductions	—	—	(22,868)	(22,868)
Provision for credit losses	(8,919)	(290)	(97)	(9,306)
Accounts receivable, net	$ 1,150	$ 4,154	$ 21,333	$ 26,637

	December 31, 2020			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Accounts receivable, gross	$ 10,783	$ 4,074	$ 30,935	$ 45,792
Chargebacks and other deductions	—	(1)	(12,551)	(12,552)
Provision for credit losses	(8,919)	(164)	(554)	(9,637)
Accounts receivable, net	$ 1,864	$ 3,909	$ 17,830	$ 23,603

The Company incurs contract obligations on general customer purchase orders that have been accepted but unfulfilled. Due to the short duration of time between order acceptance and delivery of the related product or service, the Company has determined that the balance related to these contract obligations is generally immaterial at any point in time. The Company monitors the value of orders accepted but unfulfilled at the close of each reporting period to determine if disclosure is appropriate. As of December 31, 2021, $2.7 million and $0.6 million of contract liabilities related to customer deposits were made by customers of the Oncology Innovation Platform and the Global Supply Chain Platform, respectively, and as of December 31, 2020, $1.0 million and $0.1 million of contract liabilities related to customer deposits were made by customers of the Oncology Innovation Platform and the Global Supply Chain Platform, respectively.

20. COMMITMENTS AND CONTINGENCIES

Rental and lease commitments

In August 2015, the Company entered into a lease agreement with FSMC to occupy a portion of the Conventus Center for Collaborative Medicine in Buffalo, NY. Total rent expense related to this location, recognized on a straight-line basis, was $1.0 million for the each of the years ended December 31, 2021, 2020, and 2019.

In November 2019, CDE entered into an agreement to lease facilities in Hong Kong with monthly payments of less than $0.1 million extending through November 2022. Total rent expense related to this location, recognized on a straight-line basis, amounted to $0.1 million for each of the years ended December 31, 2021, and 2020, and 2019 (previous lease in Hong Kong during 2019).

In October 2016, the Company's Commercial Platform entered into an agreement to lease office space in Chicago, IL. Under the lease agreement, the Company will make monthly payments based on an escalating scale over ten years. Total rent expense related to this location, recognized on a straight-line basis, amounted to $0.3 million for each of the years ended December 31, 2021, 2020, and 2019. In lieu of a security deposit, an irrevocable letter of credit was issued to the landlord in the amount of $0.2 million.

The Company leases its manufacturing and office facilities in Chongqing, China, where it produces API and performs research and development. Rent expense is recognized on a straight-line basis and amounted to $0.6 million for each of the years ended December 31, 2021, 2020, and 2019.

The Company entered into additional leases for lab space, warehouse facilities, and various equipment in, Houston, TX; Cranford, NJ; Taipei, Taiwan; Latin America; and Buffalo, NY, during 2020 and 2021 which expire at various times through 2026. Rent expense recognized for these operating leases was not material to the financial statements for the years ended December 31, 2021, 2020, and 2019.

Future minimum payments under the non-cancelable operating leases consists of the following as of December 31, 2021 (in thousands):

Year ending December 31:	Minimum payments
2022	$ 3,020
2023	2,184
2024	2,034
2025	1,472
2026	347
Thereafter	132
	$ 9,189

Commitments under New York State and Chongqing Partnerships

Pursuant to the arrangement with New York State, the Company was committed to bear the costs of the construction of the facility in Dunkirk, NY in excess of approximately $208.0 million. The Company was leasing the facility and all equipment at a rate of $2 per year for an initial 10-year term and for the same rate if elected to extend the lease for an additional 10-year term. The Company was responsible for all operating costs and expenses for the facility and is committed to spending $1.52 billion on operational expenses in the first 10-year term in the facility, and an additional $1.5 billion on operational expenses if elected to extend the lease for a second 10-year term. These commitments were transferred to ImmunityBio, Inc. upon execution of the sale of the Dunkirk Operations and the Company's Dunkirk Operations have been presented as a discontinued operation (see Note 4 - *Discontinued Operations*).

Pursuant to the arrangement with CQ, the Finance Bureau of Banan District of Chongqing is responsible for investing in the construction of the API and formulation plants and completing renovation in accordance with U.S. cGMP standards. The Company is leasing the facility rent free, for the first 10-year term, with an option to extend the lease for an additional 10-year term, during which, if the Company is profitable, it will pay a monthly rent of 5 RMB per square meter of space occupied or, it will have the option to purchase the land and building. If the Company does not purchase the land and building after 20 years at the price described above, it will have the option to lease the land and building with rental fee charged at market price of construction area. The Company is responsible for the costs of all equipment and technology for the facilities. The leases for these facilities commenced during the year ended December 31, 2021.

Legal Proceedings

Securities Litigation

Following our receipt of the CRL in February 2021 and the subsequent decline of the market price of the Company’s common stock, two purported securities class action lawsuits were filed in the U.S. District Court for the Western District of New York on March 3, 2021 and March 22, 2021, respectively, against the Company and certain members of its management team seeking to recover damages for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

The complaints generally allege that between August 7, 2019 and February 26, 2021 (the purported class period), the Company and the individual defendants made materially false and misleading statements regarding the Company's business in connection with the Company’s development of Oral Paclitaxel for the treatment of metastatic breast cancer and the likelihood of FDA approval, and that the plaintiffs suffered losses when the Company’s stock price dropped after its announcement on February 26, 2021 regarding receipt of the CRL. The complaints seek class certification, damages, fees, costs, and expenses. On August 5, 2021, the Court consolidated the two actions and appointed a lead plaintiff and lead counsel. Pursuant to a stipulated scheduling order, the lead plaintiff filed an amended complaint on November 19, 2021. Defendants filed their motion to dismiss on January 25, 2022. Plaintiffs’ opposition to that motion is due by March 28, 2022 and the defendants’ reply is due by May 20, 2022. The Company and the individual defendants believe that the claims in the consolidated lawsuits are without merit, and the Company has not recorded a liability related to these shareholder class actions as the risk of loss is remote. The Company and the individual defendants intend to vigorously defend against these claims but there can be no assurances as to the outcome.

Shareholder Derivative Lawsuit

On June 3, 2021, a shareholder derivative lawsuit was filed in the United States District Court for the District of Delaware by Timothy J. Wonnell, allegedly on behalf of the Company, that piggy-backs on the securities class actions referenced above. The complaint names Johnson Lau, Rudolf Kwan, Timothy Cook, and members of the Board as defendants, and generally alleges that they caused or failed to prevent the securities law violations asserted in the securities class actions. On September 13, 2021, the Court (i) granted the defendants’ motion to stay the derivative action until after resolution of the motion to dismiss the consolidated securities class actions, and (ii) administratively closed the derivative litigation, directing the parties to promptly notify the Court when the related securities class action has been resolved so the derivative action can be reopened. The Company and the individual defendants believe the claims in the shareholder derivative action are without merit, and the Company has not recorded a liability related to this lawsuit as the risk of loss is remote. The Company and the individual defendants intend to vigorously defend against these claims should the case be reopened, but there can be no assurances as to the outcome.

From time to time, the Company may become subject to other legal proceedings, claims and litigation arising in the ordinary course of business. In addition, the Company may receive letters alleging infringement of patent or other intellectual property rights. The Company is not currently a party to any other material legal proceedings, nor is it aware of any pending or threatened litigation that, in the Company's opinion, would have a material adverse effect on the business, operating results, cash flows or financial condition should such litigation be resolved unfavorably.

21. SUBSEQUENT EVENTS

On January 7, 2022, the Company entered into a definitive agreement with ImmunityBio, Inc. whereby the Company agreed to sell to the Buyer its leasehold interest in a manufacturing facility in Dunkirk, New York and certain other related assets, as described below, in exchange for reimbursement of certain expenditures that the Company made in the Dunkirk Facility totaling approximately $40.0 million. The transaction closed on February 14, 2022 and was subject to approval from the Company's lender, Oaktree. The provisions of this approval included prepayment of a portion of the senior secured loans, as described in Note 12 - *Debt and Lease Obligations*. In addition to the leasehold interest in the Dunkirk Facility, the Buyer purchased the Company's interests in certain leased manufacturing equipment and personal property, and owned personal property and inventory at the Dunkirk Facility, along with the Company's rights in and obligations under its agreements relating to the Dunkirk Facility with ESD, FSMC and CCIDA and other parties (collectively, the "Dunkirk Operations"). The Buyer assumed all capital expenditure and hiring obligations of the Company related to the Dunkirk Operations pursuant to the Company's existing agreements with ESD and FSMC. The Company has not assigned any of its rights to its corporate headquarters in Buffalo, New York, under this Agreement and will retain all of its rights and obligations with respect to its corporate headquarters. The Company has presented the financial results of the Dunkirk Facility as discontinued operations (see Note 4 - *Discontinued Operations*).

On January 19, 2022, the Company entered into an amendment to the Senior Credit Agreement with Oaktree. The Amendment also amended the warrants held by Oaktree that were issued on June 19, 2020 and August 4, 2020. The Amendment became effective upon the closing of the Dunkirk Transaction on February 14, 2022. The Amendment provides that the Company make a mandatory prepayment of principal to Oaktree equal to 62.5% of the cash proceeds of the Dunkirk Transaction. The Company was also required to pay (i) accrued and unpaid interest and (ii) a 7.0% fee, allocated as a 2.0% Exit Fee and a 5.0% Prepayment Fee (each as defined in the Senior Credit Agreement), on the principal amount being repaid. The Company was required to pay Oaktree an amendment fee of $0.3 million and certain related expenses upon the closing of the Dunkirk Transaction. The Amendment requires the Company to make an additional mandatory prepayment of $12.5 million in principal plus the costs and fees described above by June 14, 2022, within 120 days of the closing of the Dunkirk Transaction. Consistent with the Company's decision to not pursue regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the United States at this time, the Amendment reduced to zero the amount of the last two tranches of borrowing that had been available under the Senior Credit Agreement upon the achievement of commercial milestones. The warrants were amended to change the exercise price to be paid per share upon exercise of the warrants. The original exercise price of the warrants was $12.63 per share. The Amendment provides that the exercise price for 50% of the shares underlying the warrants will be $1.10 per share. The exercise price for the remaining 50% of the warrants was not changed by the Amendment. The Company reclassified a portion of the senior secured loan to current portion of long-term debt within the consolidated balance sheet in connection with this amendment. See Note 12 - *Debt and Lease Obligations* for further information. The Dunkirk Transaction closed on February 14, 2022.

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2021. Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were not effective as of December 31, 2021 due to material weaknesses in our internal control over financial reporting, which are described below in "Management's Annual Report on Internal Control over Financial Reporting".

Management's Annual Report on Internal Control over Financial Reporting

Our management, including our CEO and CFO, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021 based on the framework and criteria established in the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

We acquired Kuur Therapeutics, Inc. ("Kuur") on May 4, 2021. Accordingly, due to the timing and complexity of the acquisition, as permitted by SEC guidance, management's assessment of the Company's internal control over financial reporting as of December 31, 2021 excludes Kuur. Kuur's total assets constituted 25% and its total revenues constituted 0% of our consolidated financial condition and results of operations as of the year ended December 31, 2021. Our management is currently in the process of evaluating Kuur's controls and procedures and integrating Kuur into our system of internal control over financial reporting.

As a result of management's evaluation of the effectiveness of our internal control over financial reporting, our CEO and CFO concluded that as of December 31, 2021, the Company had a material weakness related to our control over the review of the annual goodwill impairment analysis, and, as a result, our internal control over financial reporting was not effective as of December 31, 2021. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

As of December 31, 2021, management identified the following material weakness:

- The Company's review of the annual goodwill impairment analysis did not operate effectively in 2021 as management did not ensure the completeness and accuracy over the information used in the control, did not identify errors contained in information obtained from a third-party specialist, and also did not review the annual goodwill impairment analysis at a sufficiently precise level to prevent or detect a material misstatement within the Company's recorded goodwill balance as of December 31, 2021. The errors were identified by our independent registered public accounting firm and were corrected by management and are reflected within the Company's financial statements.

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report included in this Annual Report. This report contains an adverse opinion on the effectiveness of our internal control over financial reporting.

Remediation Efforts to Address the Material Weaknesses

The material weakness identified is unremediated as of December 31, 2021 and the Company's remediation efforts will continue to take place in 2022.

The Company plans to strengthen its internal control over financial reporting, updating the operating effectiveness of its internal control over financial reporting to remediate the identified material weakness. Remediation activities include the following:

- The Company will evaluate the assignment of responsibilities, internal and external, associated with the performance of management's review of the annual goodwill impairment analysis and consider hiring additional resources, contracting external resources, or providing additional training to existing resources.
- The Company will pursue a process of implementing or enhancing the operating effectiveness of management's review of the annual goodwill impairment analysis, including potentially contracting with specialists to assist with technical aspects

of management review, which is expected to help increase the efficiency of processing transactions and produce accurate and timely financial information.

In addition, under the direction of the audit committee of the Board of Directors, management will refine policies and procedures to improve the overall effectiveness of internal control over financial reporting of the Company.

As we continue our evaluation and assess the effectiveness of our internal control over financial reporting going forward, management may modify the actions described above or identify and take additional measures to address control deficiencies. While we prioritize achieving the effectiveness of our internal control over financial reporting and disclosure controls, until our remediation efforts, including any additional measures management identifies as necessary, are complete and operate for a sufficient period of time, the material weakness described above will continue to exist and management will not be able to conclude that it is remediated.

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and management must apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Control over Financial Reporting

Except as noted above, there were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended December 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Athenex, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Athenex, Inc. and subsidiaries (the "Company") as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, because of the effect of the material weakness identified below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2021, of the Company and our report dated March 16, 2022, expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding a going concern uncertainty.

As described in Management's Annual Report on Internal Control Over Financial Reporting, management excluded from its assessment the internal control over financial reporting at Kuur Therapeutics, Inc., which was acquired on May 4, 2021, and whose financial statements constitute, in aggregate, 25% of total assets and 0.0% of revenues of the consolidated financial statement amounts as of and for the year ended December 31, 2021. Accordingly, our audit did not include the internal control over financial reporting at Kuur Therapeutics, Inc.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Material Weakness

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment: the Company's review of the annual goodwill impairment analysis did not operate effectively in 2021 as management did not ensure the completeness and accuracy over the information used in the control, did not identify errors contained in information obtained from a third-party specialist, and also did not review the annual goodwill impairment analysis at a sufficiently precise level to prevent or detect a material misstatement within the Company's recorded goodwill balance as of December 31, 2021. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 31, 2021, of the Company, and this report does not affect our report on such financial statements.

/s/ Deloitte & Touche LLP

Williamsville, New York
March 16, 2022

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated by reference from the sections captioned “Election of Directors,” “Executive Officers,” “Corporate Governance Matters,” and “Delinquent Section 16(a) Reports” contained in our proxy statement related to the 2022 Annual Meeting of Stockholders (the “Proxy Statement”), which we intend to file with the Securities and Exchange Commission within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference from the information under the sections captioned “Executive Compensation,” “Director Compensation” and “Compensation Committee Interlocks and Insider Participation” in the Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference from the information under the sections captioned “Executive Compensation,” “Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” contained in the Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference from the information under the sections captioned “Certain Relationships and Related-Party Transactions” and “Corporate Governance Matters” in the Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated by reference from the information under the section captioned “Audit Committee Report” in the Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this report.

1. Financial Statements.

The financial statements of the Company and the related report of the Company's independent registered public accounting firm thereon have been filed under Item 8 hereof.

2. Financial Statement Schedules.

Schedule II—Valuation and Qualifying Accounts

Activity in the following valuation and qualifying accounts consisted of the following (in thousands):

Col. A Description	Col. B Balance at Beginning of Period	Col. C - Additions: Charged to Costs & Expenses	Col. C - Additions: Charged to Other Accounts - Describe	Col. D Deductions - Describe	Col. E Balance at End of Period
December 31, 2021					
Provision for credit losses	$ 9,637	$ 29 (1)	$ —	$ (360) (1)	$ 9,306
Allowance for chargebacks and other deductions	$ 12,552	$ 129,425 (2)	$ —	$ (119,109) (2)	$ 22,868
Deferred tax asset valuation allowance	$ 150,864	$ —	$ (13,122) (3)	$ —	$ 137,742
December 31, 2020					
Provision for credit losses	$ 124	$ 9,577 (1)	$ —	$ (64) (1)	$ 9,637
Allowance for chargebacks and other deductions	$ 14,394	$ 90,237 (2)	$ —	$ (92,079) (2)	$ 12,552
Deferred tax asset valuation allowance	$ 120,805	$ —	$ 30,059 (3)	$ —	$ 150,864
December 31, 2019					
Provision for credit losses	$ 9	$ 488 (1)	$ —	$ (373) (1)	$ 124
Allowance for chargebacks and other deductions	$ 13,101	$ 95,100 (2)	$ —	$ (93,807) (2)	$ 14,394
Deferred tax asset valuation allowance	$ 88,455	$ —	$ 32,350 (3)	$ —	$ 120,805

(1) Increases in the provision for credit losses consist of our provision for credit losses, which is included within selling, general, and administrative expenses on the consolidated statements of operations and comprehensive loss. Decreases in the provision for credit losses consist of the write-off of specific accounts and the recovery of previously reserved receivables.

(2) Increases in the allowance for chargebacks and other deductions consist of our provision for chargebacks, cash discounts, returns, fees, and other credits, which are a deduction from product sales on the consolidated statements of operations and comprehensive loss. Decreases in the allowances for chargebacks and other deduction consist of the collection of the underlying accounts and advances received on chargebacks.

(3) Increases and decreases in the valuation allowance for deferred income tax assets offset the increases and decreases in our gross deferred tax assets, based on the expected realization of those future tax benefits.

(b) Exhibits.

Exhibit Number	Exhibit Title	Incorporated by Reference (Unless Otherwise Indicated)			
		Form	File	Exhibit	Filing Date
1.1	Sales Agreement, dated August 20, 2021, by and between Athenex, Inc. and SVB Leerink LLC as sales agent.	Form 8-K	001-38112	1.1	August 20, 2021
2.1	Agreement and Plan of Merger, by and among Athenex, Inc., Athenex Pharmaceuticals LLC, Kuur Therapeutics, Inc., Shareholder Representative Services LLC, solely as representative, agent and attorney-in-fact of the Merger Stockholders, Key Employees and Individual Company Directors, dated May 4, 2021.	Form 8-K	001-38112	10.1	May 5, 2021
3.1	Amended and Restated Certificate of Incorporation of the Company, effective as of June 19, 2017.	Form 8-K	001-38112	3.1	June 22, 2017
3.2	Amended and Restated Bylaws of the Company, effective as of June 19, 2017.	Form 8-K	001-38112	3.2	June 22, 2017
4.1	Specimen Common Stock Certificate.	Form S-1	333-217928	4.1	May 12, 2017
4.2	Form of Warrant to Purchase Common Stock (Oaktree).	Form 8-K	001-38112	4.1	June 22, 2020
4.3	Form of Warrant to Purchase Common Stock (Sagard and IMCO Investors).	Form 8-K	001-38112	4.1	August 6, 2020
4.4	Description of Securities	Form 10-K	001-38112	4.2	March 2, 2020
10.1+	Form of Director and Officer Indemnification Agreement.	Form S-1	333-217928	10.1	May 12, 2017
10.2+	First Amended and Restated 2004 Common Unit Option Plan and Form of Unit Option Agreement.	Form S-1	333-217928	10.2	May 12, 2017
10.3+	First Amended and Restated 2007 Common Unit Option Plan and Form of Unit Option Agreement.	Form S-1	333-217928	10.3	May 12, 2017
10.4+	2013 Common Stock Option Plan and Form of Common Stock Option Agreement.	Form S-1	333-217928	10.4	May 12, 2017
10.5+	Amended and Restated 2017 Omnibus Incentive Plan.	Form 10-Q	001-38112	10.4	August 6, 2020
10.6+	First Amendment to the Athenex, Inc. Amended and Restated 2017 Omnibus Incentive Plan.	Form S-8	333-258192	4.6	July 27, 2021
10.7+	Form of Stock Option Award Agreement pursuant to the 2017 Omnibus Incentive Plan.	Form S-1/A	333-217928	10.5	June 2, 2017
10.8+	Form of Restricted Stock Award Agreement pursuant to the 2017 Omnibus Incentive Plan.	Form 10-K	001-38112	10.7	March 1, 2021
10.9+	2017 Employee Stock Purchase Plan.	Form S-1/A	333-217928	10.6	June 2, 2017
10.10^	License Agreement by and between Hanmi Pharmaceutical Ltd. and Kinex Pharmaceuticals, LLC, effective as of December 16, 2011.	Form S-1	333-217928	10.7	May 12, 2017

10.11	First Amendment to License Agreement by and between Kinex Pharmaceuticals, LLC and Hanmi Pharmaceutical Co., Ltd., effective as of November 9, 2012.	Form S-1	333-217928	10.7.1	May 12, 2017
10.12	Second Amendment to License Agreement by and between Kinex Pharmaceuticals, LLC and Hanmi Pharmaceutical Ltd., effective as of October 21, 2013.	Form S-1	333-217928	10.7.2	May 12, 2017
10.13	Third Amendment to License Agreement by and between Kinex Pharmaceuticals, Inc. and Hanmi Pharmaceutical Ltd., effective as of March 3, 2015.	Form S-1	333-217928	10.7.3	May 12, 2017
10.14^	Fourth Amendment to License Agreement by and between Athenex, Inc. and Hanmi Pharmaceutical Co., Ltd., effective as of March 7, 2017.	Form S-1	333-217928	10.7.4	May 12, 2017
10.15	Fifth Amendment to License Agreement by and between Athenex, Inc. and Hanmi Pharmaceutical Co. Ltd., effective as of September 4, 2018.	Form 10-K	001-38112	10.45	March 11, 2019
10.16^	License Agreement by and among Hanmi Pharmaceutical Co., Ltd., Kinex Therapeutics (HK) Limited, and Kinex Pharmaceuticals, Inc., effective as of June 28, 2013.	Form S-1	333-217928	10.8	May 12, 2017
10.17^	License Agreement by and between Kinex Pharmaceuticals, LLC and PharmaEssentia Corp., effective as of December 8, 2011.	Form S-1	333-217928	10.10	May 12, 2017
10.18	First Amendment to License Agreement by and between Athenex, Inc. and PharmaEssentia Corp., effective as of December 23, 2016.	Form S-1	333-217928	10.10.1	May 12, 2017
10.19	Second Amendment to License Agreement dated as of February 15, 2021 by and between Athenex, Inc. and PharmaEssentia Corp.	Form 10-Q	001-38112	10.2	May 6, 2021
10.20^	License Agreement by and between Kinex Pharmaceuticals, Inc. and PharmaEssentia Corp., effective as of December 16, 2013.	Form 10-Q	001-38112	10.11	May 7, 2020
10.21	First Amendment to License Agreement by and between Athenex, Inc. and PharmaEssentia Corp., effective as of December 23, 2016.	Form S-1	333-217928	10.11.1	May 12, 2017
10.22^	Second Amendment to License Agreement by and between Athenex, Inc. and PharmaEssentia Corp., effective as of November 27, 2018.	Form 10-Q	001-38112	10.11.2	May 7, 2020
10.23^	License Agreement by and between Kinex Pharmaceuticals, Inc. and ZenRx Limited, effective as of April 25, 2013.	Form S-1	333-217928	10.12	May 12, 2017
10.24^	License Agreement by and between Kinex Pharmaceuticals, LLC and Guangzhou Xiangxue New Drug Discovery and Development Company Limited, effective as of May 6, 2012.	Form 10-Q	001-38112	10.13	May 7, 2020
10.25^	Binding Term Sheet for License by and between Athenex Pharmaceutical Division, LLC and Gland Pharma Limited, effective as of August 1, 2016.	Form S-1	333-217928	10.14	May 12, 2017

10.26^	Binding Term Sheet for License by and between Athenex Pharmaceutical Division, LLC and Gland Pharma Limited, effective as of August 26, 2016.	Form S-1	333-217928	10.14.1	May 12, 2017
10.27^	Binding Term Sheet for License by and between Athenex Pharmaceutical Division, LLC and Gland Pharma Limited, effective as of February 22, 2017.	Form S-1	333-217928	10.14.2	May 12, 2017
10.28^	Binding Term Sheet for License by and between Athenex Pharmaceutical Division, LLC and Gland Pharma Limited, effective as of May 5, 2017.	Form S-1/A	333-217928	10.14.3	June 2, 2017
10.29^	Joint Venture Agreement by and between SunGen Pharma LLC and Athenex Pharmaceutical Division, effective as of September 22, 2016.	Form S-1	333-217928	10.15	May 12, 2017
10.30^	Addendum to Joint Venture Agreement by and between SunGen Pharma LLC and Athenex Pharmaceutical Division, LLC, effective November 29, 2016.	Form S-1	333-217928	10.15.1	May 12, 2017
10.31	Limited Liability Company Agreement of Peterson Athenex Pharmaceuticals, LLC, effective as of October 4, 2016.	Form S-1	333-217928	10.15.2	May 12, 2017
10.32^	Service Agreement by and between Dohmen Life Science Services, LLC and Athenex Pharmaceutical Division, LLC, effective as of August 9, 2016.	Form S-1	333-217928	10.16	May 12, 2017
10.33^	Clinical Trial Collaboration and Supply Agreement by and among Athenex, Inc., Eli Lilly and Company and ImClone LLC, effective as of October 24, 2016.	Form S-1	333-217928	10.17	May 12, 2017
10.34	Sublease Agreement by and between Fort Schuyler Management Corporation and Kinex Pharmaceuticals, Inc., effective as of July 21, 2015.	Form S-1	333-217928	10.19	May 12, 2017
10.35	Athenex Pharmaceutical Base Project Located in the Chongqing Maliu Riverside Development Zone Agreement with Chongqing Maliu Riverside Development and Investment Co., Ltd., effective as of October 16, 2015 (English translation of original foreign language agreement).	Form S-1	333-217928	10.20	May 12, 2017
10.36	Supplemental Agreement to Athenex Pharmaceutical Base Project Located in the Chongqing Maliu Riverside Development Zone Agreement with Chongqing Maliu Riverside Development and Investment Co., Ltd., effective as of April 1, 2019 (English translation of original foreign language agreement).	Form 10-Q	001-38112	10.20.1	August 7, 2019
10.37^	Binding Term Sheet for License, Supply and Distribution Agreement by and among Athenex API Limited, Nang-Kuang Pharmaceutical Co., LTD and CANDA NK-2, LLC, effective as of December 29, 2016.	Form S-1	333-217928	10.21	May 12, 2017
10.38	Asset Purchase Agreement by and between Athenex, Inc. and Amphastar Pharmaceuticals, Inc., dated February 1, 2017.	Form S-1	333-217928	10.22	May 12, 2017

10.39+	Amended and Restated Employment Agreement by and between Johnson Lau and Kinex Pharmaceuticals, Inc., effective as of June 1, 2015.	Form S-1	333-217928	10.23	May 12, 2017
10.40+	Employment Agreement by and between Athenex, Inc. and Dr. Rudolf Min-Fun Kwan, effective as of February 21, 2017.	Form S-1	333-217928	10.25	May 12, 2017
10.41+	Consulting Agreement, dated as of January 1, 2022 between Athenex, Inc. and Simon Pedder	Form 8-K	001-38112	10.1	December 28, 2021
10.42+	Employment Agreement by and between Athenex, Inc. and Jeffrey Yordon, effective as of February 21, 2017.	Form S-1	333-217928	10.28	May 12, 2017
10.43+	Consulting Agreement, dated September 1, 2021, between Athenex, Inc. and Randoll Sze.	Form 8-K	001-38112	10.1	September 3, 2021
10.44^	License and Development Agreement by and between Athenex, Inc., Almirall, S.A. and Aqua Pharmaceuticals LLC., dated as of December 11, 2017.	Form 8-K	001-38112	10.1	December 15, 2017
10.45^	First Amendment to License and Development Agreement by and between Athenex, Inc., Almirall, S.A., and Aqua Pharmaceuticals LLC, dated as of September 26, 2018.	Form 10-Q	001-38112	10.3	November 14, 2018
10.46^	Letter Agreement by and between Athenex, Inc., Almirall, S.A. and Aqua Pharmaceuticals LLC, dated as of September 26, 2018.	Form 10-Q	001-38112	10.4	November 14, 2018
10.47	Second Amendment to License and Development Agreement by and between Athenex, Inc., Almirall, S.A., and Aqua Pharmaceuticals LLC, dated as of June 18, 2019.	Form 10-Q	001-38112	10.30.2	August 7, 2019
10.48^	License Agreement dated as of June 29, 2018 by and between Xiangxue Life Sciences Ltd. and Axis Therapeutics Limited.	Form 8-K	001-38112	10.3	July 2, 2018
10.49^	License Agreement dated as of June 29, 2018 by and between Athenex Therapeutics Limited and Avalon Polytom (HK) Limited Pegtomarginase.	Form 8-K	001-38112	10.4	July 2, 2018
10.50^	License and Supply Agreement dated as of June 29, 2018 by and between Athenex Therapeutics Limited and Avalon HepaPOC Limited Galactose Meter and Strip.	Form 8-K	001-38112	10.5	July 2, 2018
10.51**	License Agreement between the Company and Guangzhou Xiangxue Pharmaceutical Co., Ltd., dated December 12, 2019.	Form 8-K	001-38112	10.1	December 16, 2019
10.52	First Supplemental Agreement to License Agreement by and among Athenex, Inc. and Chongqing Taihao Pharmaceutical Co. Ltd. and Guangzhou Xiangxue Pharmaceutical Co., Ltd., dated June 30, 2020.	—	—	—	Filed herewith
10.53	Second Supplemental Agreement to License Agreement by and among Athenex, Inc. and Chongqing Taihao Pharmaceutical Co. Ltd. and Guangzhou Xiangxue Pharmaceutical Co., Ltd., dated June 30, 2020.	Form 8-K	001-38112	10.5	August 6, 2020

10.54	Third Supplemental Agreement and Amendment to License Agreement by and among Athenex, Inc. and Chongqing Guangzhou Xiangxue Pharmaceutical Co., Ltd., dated November 8, 2021.	—	—	—	Filed herewith
10.55	Registration Rights Agreement dated as of July 3, 2018 by and between Athenex, Inc. and Perceptive Life Sciences Master Fund Ltd.	Form 10-Q	001-38112	10.7	August 14, 2018
10.56	Registration Rights Agreement by and among Athenex, Inc., Perceptive Life Sciences Master Fund, Ltd., venBio Select Fund LLC, OrbiMed Partners Master Fund Limited, and The Biotech Growth Trust PLC, dated as of May 7, 2019.	Form S-3	333-232772	4.2	July 23, 2019
10.57	Registration Rights Agreement by and among Athenex, Inc., M. Kingdon Offshore Master Fund, LP, Schonfeld Strategic 460 Fund LLC, Point72 Associates, LLC, J. Goldman Master Fund, L.P., and Avoro Life Sciences Fund LLC, dated as of December 9, 2019.	Form S-3	333-236104	4.2	January 28, 2020
10.58#	Credit Agreement and Guaranty dated as of June 19, 2020, by and among Athenex, Inc., the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto, and Oaktree Fund Administration, LLC, as administrative agent.	Form 8-K	001-38112	10.1	June 22, 2020
10.59	First Amendment and Limited Waiver to Credit and Guaranty Agreement between Athenex and Oaktree, dated June 3, 2021.	Form 10-Q	001-38112	10.4	August 5,2021
10.60	Second Amendment to Credit and Guaranty Agreement between Athenex and Oaktree, dated December 14, 2021.	—	—	—	Filed herewith
10.61	Third Amendment to Credit and Guaranty Agreement and First Amendment to the Warrants between Athenex and Oaktree, dated January 19, 2022	—	—	—	Filed herewith
10.62	Security Agreement dated as of June 19, 2020, by and among Athenex, Inc., the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto, and Oaktree Fund Administration, LLC, as administrative agent.	Form 10-Q	001-38112	10.2	August 6, 2020
10.63	Registration Rights Agreement by and among Athenex, Inc. and the purchasers named therein, dated as of June 19, 2020.	Form 10-Q	001-38112	10.3	August 6, 2020
10.64#	Revenue Interest Financing Agreement dated as of August 4, 2020, by and between Athenex, Inc. and Sagard Healthcare Royalty Partners, LP.	Form 8-K	001-38112	10.1	August 6, 2020
10.65#	Security Agreement dated as of August 4, 2020, by and between Athenex, Inc. and Sagard Healthcare Royalty Partners, LP.	Form 10-Q	001-38112	10.2	November 5, 2020
10.66#	Intercreditor Agreement dated as of August 4, 2020, by and among Oaktree Fund Administration, LLC, as administrative agent, and Sagard Healthcare Royalty Partners, LP, and as acknowledged by Athenex, Inc.	Form 10-Q	001-38112	10.3	November 5, 2020

10.67	Assignment and Assumption dated as of August 4, 2020, by and among Athenex, Inc, as the borrower, Sagard Healthcare Royalty Partners, LP, OPB SHRP Co-Invest Credit Limited and SIMCOE SHRP Co-Invest Credit Ltd,, as assignees, and the affiliates of Oaktree Capital Management, L.P. party thereto as assignors, and the other assignees party thereto.	Form 10-Q	001-38112	10.4	November 5, 2020
10.68**	Asset Purchase and Sale Agreement dated as of September 1, 2020 by and between Athenex Pharmaceutical Division, LLC and Ingenus Pharmaceuticals, LLC.	Form 10-K	001-38112	10.50	March 1, 2021
10.69**	Co-Marketing, Manufacture and Supply Agreement dated as of November 2, 2020 by and between Athenex Pharmaceutical Division, LLC and Ingenus Pharmaceuticals, LLC.	Form 10-K	001-38112	10.51	March 1, 2021
10.70**	Manufacture and Supply Agreement dated as of January 15, 2021 by and between Athenex Pharmaceutical Division, LLC and Ingenus Pharmaceuticals, LLC.	Form 10-K	001-38112	10.52	March 1, 2021
10.71**#	Second Amended and Restated Co-Development Agreement between Baylor College of Medicine and Kuur Therapeutics Limited, dated October 12, 2021.	—	—	—	Filed herewith
10.72**	Second Amended and Restated Exclusive License and Option Agreement between Baylor College of Medicine and Kuur Therapeutics Limited, dated October 12, 2021.	—	—	—	Filed herewith
10.73#	Purchase Agreement, by and between Athenex, Inc. and ImmunityBio, Inc. dated January 7, 2022.	Form 8-K	001-38112	10.1	January 12, 2022
21.1	Subsidiaries of Athenex, Inc.	—	—	—	Filed herewith
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.	—	—	—	Filed herewith
24.1	Power of Attorney (included on signature page hereto).	—	—	—	Filed herewith
31.1	Certification of the Chief Executive Officer and Board Chairman (Principal Executive Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
31.2	Certification of the Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
32.1	Certification of the Chief Executive Officer and Board Chairman (Principal Executive Officer) and Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
101.INS	Inline XBRL Instance Document.	—	—	—	Filed herewith
101.SCHY	Inline XBRL Taxonomy Extension Schema Document.	—	—	—	Filed herewith

101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Filed herewith
104	Cover Page Interactive Data File	___	—	—	Filed herewith

+ Indicates management contract or compensatory plan.
^ Confidential treatment has been granted for certain confidential portions of this exhibit pursuant to Rule 406 under the Securities Act. In accordance with Rule 406, these confidential portions have been omitted from this exhibit and filed separately with the Securities and Exchange Commission.
** Certain portions of this exhibit have been omitted (indicated by asterisks) pursuant to Item 601(b) of Regulation S-K of the Securities Act of 1933, as amended, because such omitted information is (i) not material and (ii) would be competitively harmful if publicly disclosed.
# Schedules and similar attachments have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company will furnish a copy of any omitted schedule or similar attachment to the Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Sections 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 16, 2022

ATHENEX, INC.

By: /s/ Johnson Y.N. Lau
Johnson Y.N. Lau
Chief Executive Officer and Board Chairman

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Johnson Y. N. Lau and Joe Annoni, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Johnson Y.N. Lau Johnson Y.N. Lau	Chief Executive Officer and Board Chairman (Principal Executive Officer)	March 16, 2022
/s/ Joe Annoni Joe Annoni	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2022
/s/ Kim Campbell Kim Campbell	Director	March 16, 2022
/s/ Stephanie Davis Stephanie Davis	Director	March 16, 2022
/s/ Manson Fok Manson Fok	Director	March 16, 2022
/s/ Jordan Kanfer Jordan Kanfer	Director	March 16, 2022
/s/ Robert Spiegel Robert Spiegel	Director	March 16, 2022
/s/ Benson Tsang Benson Tsang	Director	March 16, 2022
/s/ John Moore Vierling John Moore Vierling	Director	March 16, 2022
/s/ Jinn Wu Jinn Wu	Director	March 16, 2022

Exhibit 10.52

SUPPLEMENTAL AGREEMENT TO
THE LICENSE AGREEMENT DATED DECEMBER 12, 2019

March 31, 2020

Guangzhou Xiangxue Pharmaceutical Co., Ltd.
2 Jinfengyuan Road
Guangzhou, China
Attn: Lun Zeng

Chongqing Taihao Pharmaceutical Co. Ltd.
C-5 # 105 C-5, Er Lang Chuang Ye Road
Jiulongo District, Chongqing, China
Attn: Dr. William Wei Zuo

Dear Dr. Lun Zeng:

Reference is made to that certain License Agreement (the "Agreement"), dated December 12, 2019, by and between Athenex, Inc. ("Athenex") and Guangzhou Xiangxue Pharmaceutical Co., Ltd. ("XPH"). Capitalized terms used but not otherwise defined herein shall have the meanings set forth in the Agreement.

We understand from XPH that (i) during XPH's board meeting conducted on March 19, 2020, XPH's board of directors designated the Upfront Payment and a portion of the Milestone Fees as part of the proposed uses of proceeds from a private placement that is currently being contemplated by XPH; (ii) the Upfront Payment shall be paid by XPH to Athenex in accordance with certain regulations of the China Securities Regulatory Commission that govern capital raising activities; (iii) in addition to the approval by the board of directors, XPH is required to obtain shareholders' approval to issue shares via the contemplated private placement and to proceed with the Agreement; and (iv) in light of the COVID-19 outbreak, XPH's shareholders' meeting has been postponed to early April 2020.

Section 5.1(a) of the Agreement requires XPH to pay to Athenex a non-refundable payment in the amount of USD $30,000,000 (the "Upfront Payment"), upon the fulfillment of certain conditions set forth in the Agreement. Section 5.7(a) of the Agreement provides that all payments under the Agreement are to be made in United States Dollars by bank wire transfer in immediately available funds to an account designated by Athenex. This letter agreement sets forth the agreement between XPH, Athenex, and Taihao (as defined below) with respect to the payment of the Upfront Payment, as follows:

1. XPH acknowledges and agrees that, as of March 15, 2020, (a) the Licensed Product Regulatory Data has been delivered to XPH in accordance with the terms of the Agreement, (b) the conditions set forth in Section 11.1 of the Agreement have been satisfied in full, and (iii) the Upfront Payment is due and payable by XPH to Athenex in accordance with the terms of Section 5.1(a) of the Agreement. XPH shall pay 10% of the Upfront Payment to Athenex by the end of March 2020.

2. To facilitate the payment of the Upfront Payment, subject to the terms of the Agreement (including, without limitation, Article 5), Athenex hereby authorizes and directs XPH to pay the Upfront Payment to Chongqing Taihao Pharmaceutical Co. Ltd. ("Taihao"), an Affiliate of Athenex with an office in Chongqing, China (on behalf of Athenex), pursuant to wire instructions that Athenex delivers to XPH for such purposes. Taihao agrees to accept the

Upfront Payment on behalf of Athenex, and to remit the Upfront Payment to Athenex when and as directed by Athenex, subject to the provisions of Section 4 of this letter agreement. Upon Taihao's receipt and invoice of the Upfront Payment, XPH shall have satisfied in full its obligation to pay to Athenex the payment required pursuant to Section 5.1(a) of the Agreement.

3. Notwithstanding the provisions of Section 5.7(a) of the Agreement (which requires payments in United States Dollars), XPH may make payments to Taihao, for the benefit of Athenex, in Renminbi ("RMB"). The amount of this 10% of the Upfront Payment payable in RMB shall be determined based on the average exchange rate of United States Dollars to RMB between March 2, 2020 and March 20, 2020 as quoted by the Federal Reserve via its website https://www.federalreserve.gov/.

4. Notwithstanding the provisions of Section 5.7(c) of the Agreement, XPH will not withhold from the Upfront Payment any income Taxes or other Taxes. If and to the extent that any Taxes are required to be withheld from the Upfront Payment under applicable Laws upon Taihao's remittance of payment to Athenex, Taihao shall withhold such amounts from the Upfront Payment and shall pay such amounts to the proper Tax Authorities. If any Tax Authority notifies XPH that it should have withheld Taxes from the Upfront Payment, or demands payment of any such Taxes from XPH, XPH shall notify Athenex in writing of such notification or demand, and XPH and Athenex shall coordinate efforts to pay, reduce or eliminate required withholding Taxes, in accordance with the provisions of Section 5.7(c) of the Agreement. If, following demand by a Tax Authority (and following such efforts to reduce or eliminate such withholding Taxes), XPH is required to pay and does pay to any Tax Authority any withholding Taxes that were required to be withheld from the Upfront Payment under applicable Law (and for which Athenex is responsible under Section 5.7(c) of the Agreement), Athenex shall reimburse XPH for the amount of such payment within 30 days after receipt of evidence of such payment. If Athenex does not reimburse XPH for such payment, XPH shall have the right to deduct the corresponding amount from future Milestone Fees payments.

5. Except as otherwise modified or supplemented in this letter agreement, the Agreement shall continue in full force and effect, in accordance with its terms.

6. This letter agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other parties. This Agreement may be executed by facsimile or .pdf signature and a facsimile or .pdf signature shall constitute an original for all purposes.

7. This letter agreement shall be governed by and construed and enforced in accordance with the laws of Singapore without reference to any choice of law principles thereof that would cause the application of the laws of a different jurisdiction.

[Signature Page Follows]

If the foregoing correctly sets forth your understanding as to the matters covered hereby, please execute and return to the undersigned a copy of this letter.

Very truly yours,

ATHENEX, INC.

By: /s/ Randoll Sze

Name: Randoll Sze

Title: CFO

ACCEPTED AND AGREED TO:
GUANGZHOU XIANGXUE PHARMACEUTICAL CO., LTD.

By: /s/ Yonghui Wang

Name: Yongui Wang

Title: CEO

ACCEPTED AND AGREED TO:
CHONGQING TAIHAO PHARMACEUTICAL CO. LTD.

By: /s/ William Wei Zuo

Name: William Wei Zuo

Title: CEO

Exhibit 10.54

THIRD SUPPLEMENTAL AGREEMENT AND AMENDMENT TO
TO LICENSE AGREEMENT DATED DECEMBER 12, 2019

THIS THIRD SUPPLEMENTAL AGREEMENT AND AMENDMENT (this "Supplement") is made and entered into effective as of November 8, 2021 (the "Effective Date"), by and among **ATHENEX, INC.**, a corporation organized and existing under the laws of the State of Delaware USA and having its principal office at Conventus Building, 1001 Main Street, Suite 600, Buffalo, New York 14203, USA ("Athenex") and **GUANGZHOU XIANGXUE PHARMACEUTICAL CO., LTD.**, a company organized and existing under the laws of China and having its principal office 2 Jinfengyuan Road, Guangzhou, China ("XPH"). Athenex and XPH are sometimes referred to herein individually as a "Party," and collectively as the "Parties."

BACKGROUND:

A. Athenex and XPH entered into a license agreement dated December 12, 2019, as supplemented by (i) a supplemental agreement dated March 31, 2020 among Athenex, XPH, and Chongqing Taihao Pharmaceutical Co. Ltd. ("Taihao") and (ii) a second supplemental agreement dated June 30, 2020 by and among Athenex, XPH, and Taihao (collectively, the "License Agreement").

B. Athenex and XPH desire to amend and supplement the terms of the License Agreement, as set forth in this Supplement.

NOW, **THEREFORE**, the Parties agree as follows:

1. **Definitions**. All capitalized terms used but not otherwise defined in this Supplement shall have the meanings given to them in the License Agreement.

2. **Amendment**. Section 1.100 of the License Agreement, which sets forth the definition of Territory, is hereby amended in its entirety to read as follows:

"1.100 "Territory" means the People's Republic of China (China)."

3. **Payment**. In consideration of the amendment to the definition of "Territory", as set forth in this Supplement, Athenex shall pay to XPH, within thirty (30) Business Days after the Effective Date, USD $1,500,000.

4. **Effect of Supplement**. Except for the terms, conditions and provisions modified or amended by this Supplement, the License Agreement shall remain in full force and effect pursuant to the terms thereof.

5. **Binding Effect.** Subject to the provisions of the License Agreement, this Supplement shall be binding upon and shall inure to the benefit of the Parties and their respective successors and permitted assigns.

6. **Counterparts; Electronic Delivery**. This Supplement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same document. This Supplement, to the extent signed and delivered by means of a facsimile machine, by electronic transmission in portable document format (pdf), or by other electronic transmission or any electronic signature complying with U.S. Federal E-Sign Act of 2000 (e.g. www.docusign.com or www.echosign.adobe.com), shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

[signature page follows]

IN WITNESS WHEREOF, the Parties hereby have executed this Supplement as of the Effective Date.

ATHENEX, INC.		**GUANGZHOU XIANGXUE PHARMACEUTICAL CO., LTD.**	
By:	/s/ Johnson Lau	By:	/s/ Wang Yonghui
Name:	Johnson Lau	Name:	Wang Yonghui
Title:	Chief Executive Officer	Title:	CEO

Exhibit 10.60

SECOND AMENDMENT TO CREDIT AND GUARANTY AGREEMENT

THIS **SECOND AMENDMENT TO CREDIT AND GUARANTY AGREEMENT** (this "**Amendment**"), dated as of December 14, 2021, is made by and among ATHENEX, INC., a Delaware corporation (the "**Borrower**"), the Lenders party hereto and OAKTREE FUND ADMINISTRATION, LLC, as administrative agent for the Lenders (in such capacity, the "**Administrative Agent**").

WHEREAS, the parties hereto are party to that certain Credit and Guaranty Agreement, dated as of June 19, 2020 (as amended by that certain First Amendment and Limited Waiver to Credit and Guaranty Agreement, dated as of June 3, 2021, and as further amended, restated or modified from time to time, the "**Credit Agreement**") by and among the Borrower, the Guarantors party thereto from time to time, the Lenders party thereto from time to time, and the Administrative Agent.

WHEREAS, the Borrower has requested that the Majority Lenders and the Administrative Agent agree to make certain amendments to the Credit Agreement, subject to the terms and conditions contained herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows.

SECTION 1.Capitalized Terms. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Credit Agreement.

SECTION 2.Amendment to the Loan Agreement. The Credit Agreement is hereby amended as set forth in Annex A attached hereto such that all of the newly inserted double-underlined text (indicated textually in the same manner as the following examples: double-underlined text and double-underlined text) and any formatting changes attached hereto shall be deemed to be inserted in the text of the Credit Agreement, and all of the deleted stricken text (indicated textually in the same manner as the following examples: ~~stricken text~~ and ~~stricken text~~) shall be deemed to be deleted from the text of the Credit Agreement.

SECTION 3.Effectiveness. This Amendment shall become effective only upon the satisfaction or waiver by the Majority Lenders of the following conditions precedent (the date of such satisfaction or waiver of the following conditions being referred herein as the "**Amendment No. 2 Effective Date**"):

(a) Each of the Borrower and the Majority Lenders shall have executed this Amendment and the Administrative Agent shall have received a fully executed copy of this Amendment.

(b) The representations and warranties of the Borrower set out in Section 4 below shall be true and correct on and as of the Amendment No. 2 Effective Date, except for any representation or warranty expressly stated to be made as of a specific date, in which case such representation or warranty shall be true and correct as of such specific date.

(c) The Administrative Agent and the Lenders shall have received on or prior to the Amendment No. 2 Effective Date reimbursement or payment of documented costs, fees and expenses incurred by the Administrative Agent and the Lenders (including the reasonable legal fees and out-of-pocket expenses of Sullivan & Cromwell LLP, as outside counsel to the Administrative Agent) in connection with the preparation, negotiation, execution and delivery of this Amendment that are required to be reimbursed or paid pursuant to Section 14.03(a) of the Credit Agreement.

SECTION 4.Representations and Warranties.

(a) **Power and Authority**. The Borrower has full power, authority and legal right to enter into and perform its obligations under this Amendment and the other Loan Documents to which it is a party.

(b) **Authorization; Enforceability**. The execution of this Amendment and performance hereunder are within the Borrower's corporate or other organizational powers and have been duly authorized by all necessary corporate or

other organizational action including, if required, approval by all necessary holders of Equity Interests. This Amendment has been duly executed and delivered by the Borrower and constitutes a legal, valid and binding obligation of the Borrower, enforceable against the Borrower in accordance with its terms, except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(c) **Governmental and Other Approvals; No Conflicts**. None of the execution, delivery and performance by the Borrower of the Amendment (i) requires any Governmental Approval of, registration or filing with, or any other action by, any Governmental Authority or any other Person, except for such as have been obtained or made and are in full force and effect, (ii) will violate (1) any Law, (2) any Organic Document of the Borrower or (3) any order of any Governmental Authority, that in the case of **clause (ii)(1)** or **clause (ii)(3)**, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect, (iii) will violate or result in a default under any Material Agreement binding upon the Borrower that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect or (iv) will result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of any Obligor or any of its Subsidiaries.

(d) **Representations and Warranties**. Except as set forth on the Disclosure Letter, dated as of the date hereof, delivered by the Borrower to the Administrative Agent, the representations and warranties contained in the Credit Agreement and in the other Loan Documents are true and correct in all material respects (or, in the case of any representation or warranty that is qualified by materiality, in all respects) on and as of the date hereof to the same extent as though made on and as of the date hereof, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties are true and correct in all material respects (or, in the case of any representation or warranty that is qualified by materiality, in all respects) on and as of such earlier date.

(e) **No Default or Event of Default**. No event has occurred and is continuing or would result after giving effect to this Amendment that would constitute an Event of Default or a Default.

SECTION 5.Miscellaneous.

(a) **References Within Loan Documents**. On and after the Amendment No. 2 Effective Date, each reference in the Credit Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan Agreement as amended by Section 2 of this Amendment.

(b) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(c) **No Waiver**. Except as specifically modified above, (i) the Credit Agreement and all other Loan Documents shall remain in full force and effect, and are hereby ratified and confirmed and (ii) the execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of the Administrative Agent or the Lenders, nor constitute a waiver of any provision of the Credit Agreement or any of the Loan Documents. None of the Administrative Agent or any Lender is under any obligation to enter into this Amendment. The entering into this Amendment by such parties shall not be deemed to limit or hinder any rights of any such party under the Loan Documents, nor, except as provided in Section 2 hereof, shall it be deemed to create or infer a course of dealing between any such party, on the one hand, and the Borrower, on the other hand, with regard to any provision of the Loan Documents.

(d) **Governing Law. THIS AMENDMENT SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAWS OF THE STATE OF NEW YORK.**

(e) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(f) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(g) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

(h) **Electronic Execution of Certain Other Documents**. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Administrative Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER: ATHENEX, INC.,
a Delaware corporation

By: */s/ Johnson Y.N. Lau*
Name: Dr. Johnson Y.N. Lau
Title: Chairman and Chief Executive Officer

[Signatures Continue on Following Page]

ADMINISTRATIVE AGENT:

OAKTREE FUND ADMINISTRATION, LLC

By: Oaktree Capital Management, L.P.
Its: Managing Member

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

LENDERS:

OAKTREE-TCDRS STRATEGIC CREDIT, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

EXELON STRATEGIC CREDIT HOLDINGS, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

[Signature Page to Second Amendment to Credit Agreement]

OAKTREE-NGP STRATEGIC CREDIT, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

OAKTREE-MINN STRATEGIC CREDIT LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

OAKTREE-FORREST MULTI-STRATEGY LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

OAKTREE-TBMR STRATEGIC CREDIT FUND C, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

OAKTREE-TBMR STRATEGIC CREDIT FUND F, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

OAKTREE-TBMR STRATEGIC CREDIT FUND G, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

OAKTREE-TSE 16 STRATEGIC CREDIT, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

INPRS STRATEGIC CREDIT HOLDINGS, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

OAKTREE HUNTINGTON-GCF INVESTMENT FUND, L.P.

By: Oaktree Huntington-GCF Investment Fund GP, L.P.
Its: General Partner

By: Oaktree Huntingon-GCF Investment Fund GP, LLC
Its: General Partner

By: Oaktree Fund GP I, L.P.
Its: Managing Member

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Authorized Signatory

By: */s/ Brian Price*
Name: Brian Price
Title: Authorized Signatory

OAKTREE STRATEGIC INCOME II, INC.

By: Oaktree Fund Advisors, LLC
Its: Investment Advisor

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

OAKTREE SPECIALTY LENDING CORPORATION

By: Oaktree Fund Advisors, LLC
Its: Investment Adviser

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

OAKTREE STRATEGIC INCOME CORPORATION

By: Oaktree Fund Advisors, LLC
Its: Investment Adviser

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Vice President

By: */s/ Brian Price*
Name: Brian Price
Title: Senior Vice President

[Signature Page to Second Amendment to Credit Agreement]

OAKTREE GILEAD INVESTMENT FUND, L.P.

By: Oaktree Gilead Investment Fund GP, L.P.
Its: General Partner

By: Oaktree Fund GP, LLC
Its: General Partner

By: Oaktree Fund GP I, L.P.
Its: Managing Member

By: */s/ Jessica Dombroff*
Name: Jessica Dombroff
Title: Authorized Signatory

By: */s/ Brian Price*
Name: Brian Price
Title: Authorized Signatory

Annex A

Conformed Credit Agreement

[See Attached]

commercially reasonable terms that would be obtained in a transaction with a Person that is an unrelated third party.

"***Axis Therapeutics***" means Axis Therapeutics Limited, a private limited company incorporated under the laws of the Hong Kong Special Administrative Region of the People's Republic of China.

"***Bail-In Action***" means the exercise of any Write-Down and Conversion Powers by the applicable EEA Resolution Authority in respect of any liability of an EEA Financial Institution.

"***Bail-In Legislation***" means, with respect to any EEA Member Country implementing Article 55 of Directive 2014/59/EU of the European Parliament and of the Council of the European Union, the implementing law for such EEA Member Country from time to time which is described in the EU Bail-In Legislation Schedule.

"***Bailee Letter***" means a bailee letter substantially in the form of Exhibit F to the Security Agreement.

"***Bankruptcy Code***" means Title 11 of the United States Code entitled "Bankruptcy." "***Benefit Plan***" means any employee benefit plan as defined in Section 3(3) of ERISA (whether governed by the laws of the United States or otherwise) to which any Obligor or Subsidiary thereof incurs or otherwise has any obligation or liability, contingent or otherwise.

"***Beneficial Ownership Certification***" means a certification regarding beneficial ownership as required by the Beneficial Ownership Regulation.

"***Beneficial Ownership Regulation***" means 31 C.F.R. § 1010.230.

"***BLA***" means (i) (x) a biologics license application (as defined in the FD&C Act) to introduce, or deliver for introduction, a biologic product, including vaccines into commerce in the U.S., or any successor application or procedure and (y) any similar application or functional equivalent relating to biologics licensing applicable to or required by any non-U.S. Governmental Authority, and (ii) all supplements and amendments that may be filed with respect to the foregoing.

"***Board***" means, with respect to any Person, the board of directors or equivalent management or oversight body of such Person or any committee thereof authorized to act on behalf of such board (or equivalent body).

"***Board Observer***" has the meaning set forth in **Section 8.14(a)**.

"***Borrower***" has the meaning set forth in the preamble hereto.

"***Borrower Party***" has the meaning set forth in **Section 14.03(b)**.

"***Borrowing***" means the borrowing of the Loans on each Applicable Funding Date.

determined by reference to the price of the Borrower's common stock or such other securities or property), and cash in lieu of fractional shares of common stock of the Borrower and (C) on terms and conditions customary for bond hedge transactions in respect of broadly distributed 144A convertible bond transactions as reasonably determined by the Borrower.

"***Permitted Axis Advances***" means payments by the Borrower or any Subsidiary of any ordinary course, operational costs or expenses of Axis Therapeutics; provided that Axis Therapeutics either prepays such amounts or repays such amounts to Borrower or such Subsidiary on or before the day that is 25 days after the end of each fiscal quarter of the Borrower; provided, further that outstanding Permitted Axis Advances that have not been prepaid or repaid shall not exceed $2,000,000 (or the Equivalent Amount in other currencies) in the aggregate at any time.

"***Permitted Cash Equivalent Investments***" means (i) marketable direct obligations issued or unconditionally guaranteed by the United States or any member states of the European Union or any agency or any state thereof having maturities of not more than one (1) year from the date of acquisition, (ii) commercial paper maturing no more than two hundred seventy (270) days after the date of acquisition thereof and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., (iii) certificates of deposit maturing no more than one (1) year after issue that are issued by any bank organized under the Laws of the United States, or any state thereof, or the District of Columbia, or any U.S. branch of a foreign bank having, at the date of acquisition thereof, combined capital and surplus of not less than $500,000,000 and (iv) any money market or similar funds that exclusively hold any of the foregoing.

"***Permitted Convertible Debt***" means unsecured Indebtedness of the Borrower that (i) contains customary conversion rights for broadly distributed 144A convertible bond transactions as of the date of issuance and (ii) is convertible into shares of common stock of the Borrower, cash or a combination thereof (such amount of cash determined by reference to the price of the Borrower's common stock or such other securities or property), or cash in lieu of fractional shares of common stock of the Borrower; provided that any such indebtedness shall (A) mature, and not be subject to mandatory repurchase or redemption (other than in connection with a customary change of control or "fundamental change" provision), at least 180 days after the Maturity Date, (B) have recourse only to the Borrower and (C) not have an all-in-yield greater than 550 basis points as determined in good faith by the Administrative Agent (with any original issue discount equated to interest based on the convertible debt maturity date and excluding any additional or special interest that may become payable from time to time).

"***Permitted Cure Securities***" means common Equity Interests of the Borrower.

"***Permitted Hedging Agreement***" means a Hedging Agreement entered into by any Obligor in such Obligor's Ordinary Course for the purpose of hedging currency risks or interest rate risks (and not for speculative purposes) and (x) with respect to hedging currency risks, in an aggregate notional amount for all such Hedging Agreements not in excess of $10,000,000 (or the Equivalent Amount in other currencies) and (y) with respect to hedging interest rate risks, in an

percentage) between (i) the Revenue for such fiscal quarter and (ii) the Target Revenue for such fiscal quarter.

"***Royalty Interest Financing***" means any sale of, or other financing transaction based on, revenues and other proceeds arising out of or relating to Oral Paclitaxel and related Intellectual Property, that is secured by Liens on (i) proceeds resulting from sales of Oral Paclitaxel in an amount not exceeding 5% of such proceeds and (ii) subject to **Section 12.13**, the Intellectual Property, Accounts (as defined in the UCC), payment intangibles arising therefrom and Proceeds (as defined in the UCC) thereof relating to Oral Paclitaxel, and which are subject to a Permitted Intercreditor Agreement.

"***Sanction***" means any international economic or financial sanction or trade embargo imposed, administered or enforced from time to time by the United States Government (including, without limitation, OFAC), the United Nations Security Council, the European Union or its Member States, Her Majesty's Treasury or other relevant sanctions authority where the Borrower is located or conducts business.

"***Second Amendment Effective Date***" means December 14, 2021.

"***Secured Parties***" means the Lenders, the Administrative Agent and any of their respective permitted transferees or assigns.

"***Securities Act***" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"***Security Agreement***" means the Security Agreement, delivered pursuant to **Section 6.01(h)**, among the Obligors and the Administrative Agent, granting a security interest in the Obligors' personal property in favor of the Administrative Agent, for the benefit of the Secured Parties.

"***Security Documents***" means, collectively, the Security Agreement, each Short-Form IP Security Agreement, each Real Property Security Document, and each other security document, control agreement or financing statement required or recommended to perfect Liens in favor of the Secured Parties for purposes of securing the Obligations.

"***Short-Form IP Security Agreements***" means short-form copyright, patent or trademark (as the case may be) security agreements, dated as of the Closing Date and substantially in the form of Exhibit C, D and E to the Security Agreement, entered into by one or more Obligors in favor of the Secured Parties, each in form and substance satisfactory to the Administrative Agent (and as amended, modified or replaced from time to time).

"***Solvent***" means, as to any Person as of any date of determination, that on such date (i) the fair value of the property of such Person is greater than the total amount of liabilities, including contingent liabilities, of such Person, (ii) the present fair saleable value of such Person is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become absolute and matured, (iii) such Person does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person's ability to pay such debts and

any Obligor, any of their respective suppliers agents, licensors or licensees with respect to any Product or any Product Commercialization and Development Activities; and (iv) without limiting the foregoing, (A) (1) there have been no material product recalls, safety alerts, corrections, withdrawals, marketing suspensions, removals or the like conducted, undertaken or issued by any Obligor or any of its Subsidiaries, whether voluntary, at the request, demand or order of any Regulatory Authority or otherwise, with respect to any Product, any Product Commercialization and Development Activities or any Product Authorization within the last two (2) years, (2) no such product recall, safety alert, correction, withdrawal, marketing suspension, removal or the like has been requested, demanded or ordered by any Regulatory Authority
within the last two (2) years, and, to the knowledge of any Obligor, there is no basis in fact for the issuance of any such product recall, safety alert, correction, withdrawal, marketing suspension, removal or the like with respect to any Product or any Product Commercialization and Development Activities, and (B) no criminal, injunctive, seizure, detention or civil penalty action has been commenced or threatened in writing by any Regulatory Authority within the last two (2) years with respect to or in connection with any Product or any Product Commercialization and Development Activities, and there are no consent decrees (including plea agreements) that relate to any Product or any Product Commercialization and Development Activities, and, to the knowledge of each Obligor, there is no basis in fact for the commencement of any criminal injunctive, seizure, detention or civil penalty action by any Regulatory Authority relating to any Product or any Product Commercialization and Development Activities or for the issuance of any consent decree. No Obligor nor any of its Subsidiaries, nor, to the knowledge of any Obligor, any of their respective agents, suppliers, licensees or licensors, is employing or utilizing the services of any individual, in connection with Product Commercialization and Development Activities, who has been debarred from any federal healthcare program.

7.19 Transactions with Affiliates. Except as set forth on **Schedule 7.19** or permitted by **Section 9.10**, no Obligor nor any of its Subsidiaries has entered into, renewed, extended or been a part to, any transaction (including the purchase, sale, lease, transfer or exchange of property or assets of any kind or the rendering of services of any kind) with any Affiliate.

7.20 OFAC; Anti-Terrorism Laws.

(a) Neither the Borrower nor any of its Subsidiaries is in violation of any Anti-Terrorism Law or engages in or conspires to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the Anti-Terrorism Laws.

(b) Neither the Borrower nor any of its Subsidiaries, nor, to the knowledge of the Borrower, any of their respective directors, officers, or employees (i) is currently the target of any Sanctions, (ii) is located, organized or residing in any Designated Jurisdiction in violation of Sanctions, or (iii) is or has been (within the previous five (5) years) engaged in any transaction with, or for the benefit of, any Person who is now or was then the target of Sanctions or who is located, organized or residing in any Designated Jurisdiction, in violation of Sanctions. No Loan, nor the proceeds from any Loan, has been or will be used, directly or, to the knowledge of the Borrower, indirectly, to lend, contribute or provide to, or has been or will be otherwise made available for the purpose of funding, any activity or business in any Designated

the Oaktree Lender, be replaced by a designee of the Oaktree Lender that is reasonably acceptable to the Borrower.

8.15 [Reserved].

8.16 Maintenance of Regulatory Approvals, Contracts, Intellectual Property, Etc.. With respect to the Products and all Product Commercialization and Development Activities, such Obligor will, and will cause each of its Subsidiaries (to the extent applicable) to, (i) maintain in full force and effect all Regulatory Approvals, Material Agreements, Material Intellectual Property and other rights, interests or assets (whether tangible or intangible) reasonably necessary for the operations of such Person's business, except as would not reasonably be expected to have a Material Adverse Effect, (ii) maintain in full force and effect, and pay all costs and expenses relating to, such Regulatory Approvals, Material Agreements and Material Intellectual Property owned, used or controlled by such Obligor or any such Subsidiary that are used in or necessary for any related Product Commercialization and Development Activities, except as would not be reasonably expected to have a Material Adverse Effect, (iii) promptly after obtaining knowledge thereof, notify the Administrative Agent of any infringement or other violation by any Person of such Obligor's or any such Subsidiaries' Material Intellectual Property, and use commercially reasonable efforts to stop, curtail or abate such infringement if determined appropriate by the Borrower in the exercise of its business judgment and (iv) promptly after obtaining knowledge thereof, notify the Administrative Agent of any Claim by any Person that the conduct of the business of any Obligor or any of its Subsidiaries, including in connection with any Product Commercialization and Development Activities, has infringed upon any Intellectual Property of such Person, where such Claim could reasonably be expected to have a Material Adverse Effect.

8.17 ERISA Compliance. Such Obligor shall comply, and shall cause each of its Subsidiaries to comply, with the provisions of ERISA with respect to any Plans to which such Obligor or such Subsidiary is a party as an employer in all material respects.

8.18 Cash Management. Such Obligor shall, and shall cause each of its Subsidiaries to:

(a) maintain at all times after the Account Control Agreement Completion Date both (i) an aggregate amount of cash of the Borrower and its Subsidiaries at least equal to the Minimum Liquidity Amount and (ii) no less than 70% of the aggregate amount of cash of the Borrower and its Subsidiaries (excluding any cash held by Axis Therapeutics, and deeming any cash paid pursuant to the ~~XHP~~XPH License Agreement being held in China that is due to be repatriated to the United States as cash held in a deposit account in the U.S. subject to the Administrative Agent's control solely to the extent (A) the amount of such deemed cash does not exceed at any time 10% of such aggregate amount, (B) the Borrower or one of its Subsidiaries is diligently pursuing any necessary or advisable applications with relevant Governmental Authorities to enable the repatriation of the funds to the United States, as evidenced to the reasonable satisfaction of the Administrative Agent and (C) such cash is repatriated to the United States within 20 Business Days of the receipt thereof), in each case, in deposit accounts, disbursement accounts, investment accounts (and other similar accounts) and lockboxes with a bank or financial institution within the U.S. which, subject to **Section 8.19(a)**,

permitted pursuant to Section 9.01(s), casualty or liability insurance or self-insurance or other reimbursement-type obligations regarding workers compensation claims;

(r) Indebtedness arising in connection with the financing of insurance premiums in the ordinary course of business;

(s) Indebtedness in respect of performance bonds, bid bonds, appeal bonds, surety bonds and completion guarantees and similar obligations arising in the ordinary course of business;

(t) Indebtedness in respect of netting services, overdraft protections, business credit cards, purchasing cards, payment processing, automatic clearinghouse arrangements, arrangements in respect of pooled deposit or sweep accounts, check endorsement guarantees, and otherwise in connection with deposit accounts or cash management services;

(u) Indebtedness in respect of Investments permitted pursuant to **Section 9.05(o)**;

(v) purchase price adjustments, indemnity payments and other Deferred Acquisition Consideration in connection with any Permitted Acquisition, in each case that are permitted pursuant to the definition of "Permitted Acquisition";

(w) Permitted Refinancings of any items of Permitted Indebtedness (a) through (v) above; and

(x) Permitted Warrant Transactions that constitute Indebtedness.

Notwithstanding anything in this Agreement to the contrary, from and after the Second Amendment Effective Date, each Obligor will not, and will not permit any of its Subsidiaries to, create, incur or assume any additional Indebtedness of Axis Therapeutics or any of its Subsidiaries owing to any Obligor or any of its Subsidiaries, other than Permitted Axis Advances.

9.02 Liens. Such Obligor will not, and will not permit any of its Subsidiaries to, create, incur, assume or permit to exist any Lien on any property now owned by it or such Subsidiary, except:

(a) Liens securing the Obligations;

(b) any Lien on any property or asset of such Obligor or any of its Subsidiaries existing on the date hereof and set forth on **Schedule 7.13(b)** and renewals and extensions thereof in connection with Permitted Refinancings of the Indebtedness being secured by such Lien; provided that (i) no such Lien (including any renewal or extension thereof) shall extend to any other property or asset of such Obligor or any of its Subsidiaries and (ii) any such Lien shall secure only those obligations which it secures on the date hereof and renewals, extensions and replacements thereof in connection with Permitted Refinancings of the Indebtedness being secured by such Lien that do not increase the outstanding principal amount thereof;

(m) Investments of any Person in existence at the time such Person becomes a Subsidiary; provided such Investment was not made in connection with or anticipation of such Person becoming a Subsidiary and any modification, replacement, renewal or extension thereof; and

(n) Investments permitted under **Section 9.03**; and

(o) Investments consisting of cash payments due to the Borrower in connection with the XPH License Agreement being held by a Subsidiary of the Borrower that is not an Obligor subject to the conditions specified in **Section 8.18(a)(i)(B)** and **(C)**.

Notwithstanding anything in this Agreement to the contrary, (i) the Borrower shall not, and shall not permit any of its Subsidiaries to (x) directly or indirectly transfer, by means of contribution, sale, assignment, lease or sublease, license or sublicense, or other disposition (which in the case of leasehold interests set forth in clause (iii) of the definition of Specified Assets, to the extent such disposition is voluntary) of any kind, any Material Intellectual Property or any Specified Asset held by the Borrower or any other Obligor to any Person other than the Borrower or a Subsidiary Guarantor, pursuant to Permitted Licenses or as permitted pursuant to **Section 9.09(g), (m)** or **(n)** or (y) permit any Person other than the Borrower or a Subsidiary Guarantor to hold any interest in such Material Intellectual Property or any Specified Asset (other than (A) pursuant to non-exclusive intercompany licenses or Permitted Licenses, (B) any Material Intellectual Property or Specified Asset held by a Subsidiary that is not an Obligor on the Closing Date or (C) as permitted by **Section 9.10(g)** or (**n)**), ~~and~~ (ii) no Material Intellectual Property or Specified Asset held by the Borrower or a Subsidiary Guarantor shall be contributed as an Investment to any Subsidiary other than a Subsidiary Guarantor (other than Permitted Licenses)~~.~~ and (iii) from and after the Second Amendment Effective Date, each Obligor shall not, and shall not permit any of its Subsidiaries to, make, directly or indirectly, any additional Investments in Axis Therapeutics or any of its Subsidiaries, other than Permitted Axis Advances.

9.06 Restricted Payments. Such Obligor will not, and will not permit any of its Subsidiaries to, declare or make, or agree to pay or make, directly or indirectly, any Restricted Payment; provided that the following Restricted Payments shall be permitted so long as no Event of Default has occurred and is continuing or could reasonably be expected to occur or result from such Restricted Payment:

(a) dividends with respect to the Borrower's Equity Interests payable solely in shares of its Qualified Equity Interests (or the equivalent thereof);

(b) the Borrower's purchase, redemption, retirement, or other acquisition of shares of its Equity Interests with the proceeds received from a substantially concurrent issue of new shares of its Qualified Equity Interests;

(c) dividends paid by any Subsidiary to any Obligor;

proceeds of such Asset Sale are utilized to repay or prepay, in whole or in part, Indebtedness under and in accordance with this Agreement and the other Loan Documents;

(m) dispositions in the ordinary course of business consisting of the abandonment of intellectual property rights (other than Material Intellectual Property) which, in the reasonable good faith determination of Borrower, are not material to the conduct of the business of the Obligors and the Subsidiaries; and

(n) any sublease or manufacturing agreement with respect to the manufacturing facility of the Borrower located in Dunkirk that is an Arm's-Length Transaction and does not exceed 50% of the capacity of the facility.

9.10 Transactions with Affiliates. Such Obligor will not, and will not permit any of its Subsidiaries to, directly or indirectly, enter into or permit to exist any transaction to sell, lease, license or otherwise transfer any assets to, or purchase, lease, license or otherwise acquire any assets from, or otherwise engage in any other transactions with, any of its Affiliates, unless such arrangement or transaction (i) is an Arm's-Length Transaction, (ii) is of the kind which would be entered into by a prudent Person in the position of the Borrower with another Person that is not an Affiliate, (iii) is between or among (x) one or more Obligors, on the one hand, and, on the other hand, one or more Obligors, (y) one or more Subsidiaries of the Obligors that are not Obligors, on the one hand, and, on the other hand, one or more Subsidiaries of the Obligors that are not Obligors and (z) one or more Obligors or their Subsidiaries that are not Obligors, on the one hand, and, on the other hand, one or more Obligors or their Subsidiaries that are Obligors (*provided* that, with respect to **clause (z)** only, the terms thereof are no less favorable than those that would be obtained in a comparable arm's-length transaction with a non-affiliated Person), (iv) is permitted under **Section 9.01, 9.03, 9.05, 9.06, 9.07** or **9.09**, (v) constitutes customary compensation and indemnification of, and other employment arrangements with, directors, officers, and employees of any Obligor or its Subsidiaries in the ordinary course of business, (vi) constitutes payment of customary fees, reimbursement of expenses, and payment of indemnification to officers and directors and customary payment of insurance premiums on behalf of officers and directors by the Obligors or their Subsidiaries, in each case, in the ordinary course of business ~~and~~, (vii) constitutes a Permitted Axis Advance, and (viii) are the transactions set forth on **Schedule 7.19**.

9.11 Restrictive Agreements. Such Obligor will not, and will not permit any of its Subsidiaries to, directly or indirectly, enter into, incur or permit to exist any Restrictive Agreement other than (i) restrictions and conditions imposed by applicable Laws or by the Loan Documents, (ii) Restrictive Agreements listed on **Schedule 7.15,** (iii) limitations associated with Permitted Liens or any document or instrument governing any Permitted Lien, (iv) any documentation governing Indebtedness referenced in clauses (l), (n) or (p) of **Section 9.01** (or any Permitted Refinancing thereof), (v) customary provisions in leases, Permitted Licenses and other Contracts restricting the assignment thereof or restricting the assignment or sublease or sublicense of the property leased, licensed or otherwise the subject thereof; (vi) any restrictions or conditions set forth in any agreement in effect at any time any Person becomes a Subsidiary (but not any modification or amendment expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person

Exhibit 10.61

THIRD AMENDMENT TO CREDIT AND GUARANTY AGREEMENT AND FIRST AMENDMENT TO THE WARRANTS

THIS **THIRD AMENDMENT TO CREDIT AND GUARANTY AGREEMENT AND FIRST AMENDMENT TO THE WARRANTS** (this "**Amendment**"), dated as of January 19, 2022, is made by and among ATHENEX, INC., a Delaware corporation (as applicable, the "**Borrower**" and "**Issuer**"), the Lenders and warrant holders party hereto and OAKTREE FUND ADMINISTRATION, LLC, as administrative agent for the Lenders (in such capacity, the "**Administrative Agent**").

WHEREAS, the parties hereto are party to that certain Credit and Guaranty Agreement, dated as of June 19, 2020 (as amended by that certain First Amendment and Limited Waiver to Credit and Guaranty Agreement, dated as of June 3, 2021, that certain Second Amendment to Credit and Guaranty Agreement, dated December 14, 2021 and as further amended, restated or modified from time to time, the "**Credit Agreement**") by and among the Borrower, the Guarantors party thereto from time to time, the Lenders party thereto from time to time, and the Administrative Agent; and

WHEREAS, the Issuer and each of the parties signatory hereto (the **"Holders**") are party as applicable to the applicable warrants (Nos. 2-16) issued on June 19, 2020 and the applicable warrants (Nos. 17-19) issued on August 4, 2020 (collectively, the **"Warrants**"); and

WHEREAS, the Borrower and Issuer have requested that the Lenders, the Administrative Agent and Holders agree to make certain amendments to the Credit Agreement and Warrants, subject to the terms and conditions contained herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows.

SECTION 1Capitalized Terms. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Credit Agreement or Warrants, as applicable.

SECTION 2Amendment to the Credit Agreement. Notwithstanding anything in the Credit Agreement or the other Loan Documents to the contrary, the Lenders and the Borrower hereby agree that on the Section 5 Effective Date, the Credit Agreement is hereby deemed amended as follows:

- The Borrower may consummate on or prior to February 14, 2022 the sale of its interests and related assets in the facility at 3718 Lakeshore Drive East, Dunkirk, NY 14048 solely in accordance with the Purchase Agreement, by and between the Borrower and ImmunityBio, Inc., dated January 7, 2022 and in the form attached hereto in Exhibit A (without giving effect to any amendment, waiver, supplement or modification, the "**Purchase Agreement**" and such transaction pursuant to the Purchase Agreement, the "**Dunkirk Transaction**");

- Concurrently with the consummation of the Dunkirk Transaction, the Borrower shall make a mandatory prepayment in cash to the Administrative Agent for the benefit of the Lenders in an amount equal to 62.5% of the cash proceeds from the Dunkirk Transaction (which shall be determined conclusively by the Administrative Agent in good faith), plus accrued and unpaid interest in respect of the principal amount being repaid, plus a 7.00% fee on the principal amount so prepaid which fee which shall be allocated as follows 2.00% to Exit Fee and 5.00% to the Prepayment Fee (collectively, the "**Mandatory Prepayment**");

- Upon making the Mandatory Prepayment no additional Prepayment Fee shall be due solely on the such principal repaid in respect of the Mandatory Prepayment;

- Within 120 days of the consummation of the Dunkirk Transaction, the Company shall make an additional mandatory payment (which shall (i) be in addition to any payment of any kind required under the Credit Agreement or the Loan Documents and shall not be offset against any other payments required under the Credit Agreement and (ii) not be made from any proceeds from any Asset Sale of or relating to all or part of Tirbanibulin (including any royalty interest therein)) of $12,500,000 of principal, plus accrued and unpaid interest in respect of the principal amount being repaid, plus Exit Fee plus Prepayment Fee plus any other amounts due and owing under the Credit Agreement in respect of a voluntary prepayment of principal (the "Additional Prepayment"), which total amount shall be conclusively determined by the Agent;

- The Applicable Commitments in respect of the Tranche C Term Loans and the Tranche E Term Loans shall be reduced to zero and cancelled; and

- Schedule 3 to the Credit Agreement shall be amended and restated in the form attached hereto as Exhibit B.

SECTION 3Amendment to the Warrants. The Issuer and Holders hereby agree that on the date hereof, each of the Warrants is hereby amended and restated so that Section 3 of each Warrant shall read as follows:

"Section 3. **Exercise Price**. The exercise price per share of Voting Common Stock for which each Underlying Share may be purchased pursuant to this Warrant shall be (x) $12.63 in respect of 50% of Underlying Shares that may be purchased pursuant to this Warrant and (y) the lesser of (1) $12.63 and (2) 30-day trailing VWAP (as conclusively determined in good faith by the Holder) (i) if the Dunkirk Transaction (as defined in the Third Amendment to the Credit and Guaranty Agreement and First Amendment to the Warrants) is consummated on or prior to February 14, 2022, at the time of the consummation of the Dunkirk Transaction or (ii) if the Dunkirk Transaction is not consummated on or prior to February 14, 2022, as of January 14, 2022, in each case, in respect of 50% of Underlying Shares that may be purchased pursuant to this Warrant, in each case, subject to adjustment pursuant to Section 7 hereof (the "**Exercise Price**")."

This Section 3 shall be effective from the date hereof in consideration for entering into this Amendment regardless of whether the Section 5 Effective Date occurs.

SECTION 4Amendment Fee. The Borrower agrees to pay to the Administrative Agent for the account of each Lender on the Section 5 Effective Date which has executed and delivered a counterpart to this Third Amendment, an amendment fee in the aggregate equal to $275,000 which shall be distributed pro rata to the Lenders in accordance with the Credit Agreement (the "**Amendment Fee**").

SECTION 5Effectiveness. Section 2 to this Amendment shall become effective only upon the satisfaction or waiver by the Lenders of the following conditions precedent on or prior to February 14, 2022 (the date of such satisfaction or waiver of the following conditions being referred herein as the "**Section 5 Effective Date**"):

(a) Each of the Borrower, Issuer, Holders and the Lenders shall have executed this Amendment and the Administrative Agent shall have received a fully executed copy of this Amendment.

(b) The representations and warranties of the Borrower and Issuer set out in Section 4 below shall be true and correct on and as of the Section 5 Effective Date, except for any representation or warranty expressly stated to be made as of a specific date, in which case such representation or warranty shall be true and correct as of such specific date.

(c) The Borrower shall have paid to the Administrative Agent the Amendment Fee.

(d) The Administrative Agent, the Lenders and Holders shall have received on or prior to the Effective Date reimbursement or payment of all documented costs, fees and expenses incurred by the Administrative Agent, the Lenders and Holders (including the legal fees and out-of-pocket expenses of Sullivan & Cromwell LLP).

(e) The Borrower shall have made the Mandatory Prepayment to the Administrative Agent concurrently with the consummation of the Dunkirk Transaction.

SECTION 6Representations and Warranties.

The Borrower and Issuer represent and warrant as of the date hereof and on the Section 5 Effective Date that:

(a) **Power and Authority**. The Borrower and Issuer has full power, authority and legal right to enter into and perform its obligations under this Amendment and the other Loan Documents to which it is a party.

(b) **Authorization; Enforceability**. The execution of this Amendment and performance hereunder are within the Borrower's and Issuer's corporate or other organizational powers and have been duly authorized by all necessary corporate or other organizational action including, if required, approval by all necessary holders of Equity Interests. This Amendment has been duly executed and delivered by the Borrower and Issuer and constitutes a legal, valid and binding obligation of the Borrower and Issuer, enforceable against the Borrower and Issuer in accordance with its terms, except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(c) **Governmental and Other Approvals; No Conflicts**. None of the execution, delivery and performance by the Borrower and Issuer of the Amendment (i) requires any Governmental Approval of, registration or filing with, or any other action by, any Governmental Authority or any other Person, except for such as have been obtained or made and are in full force and effect, (ii) will violate (1) any Law, (2) any Organic Document of the Borrower or (3) any order of any Governmental Authority, that in the case of **clause (ii)(1)** or **clause (ii)(3)**, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect, (iii) will violate or result in a default under any Material Agreement binding upon the Borrower or Issuer that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Effect or (iv) will result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of any Obligor or any of its Subsidiaries.

(d) **Representations and Warranties**. The representations and warranties contained in the Credit Agreement and in the other Loan Documents are true and correct in all material respects (or, in the case of any representation or warranty that is qualified by materiality, in all respects) on and as of the date hereof to the same extent as though made on and as of the date hereof, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties are true and correct in all material respects (or, in the case of any representation or warranty that is qualified by materiality, in all respects) on and as of such earlier date.

(e) **No Default or Event of Default**. No event has occurred and is continuing or would result after giving effect to this Amendment that would constitute an Event of Default or a Default.

SECTION 7Miscellaneous.

(a) **References Within Loan Documents**. Each reference in the (i) Credit Agreement on and after the Section 5 Effective Date to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Credit Agreement as amended by Section 2 of this Amendment, and (ii) the applicable Warrant on or after the date hereof shall mean and be a reference to the Warrant as amended by Section 3 of this Amendment.

(b) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(c) **No Waiver**. Except as specifically modified above, (i) the Credit Agreement, all other Loan Documents and the Warrants shall remain in full force and effect, and are hereby ratified and confirmed and (ii) the execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of the Administrative Agent, the Lenders or Holders nor constitute a waiver of any provision of the Credit Agreement or any

of the Loan Documents or the Warrants. None of the Administrative Agent or any Lender or any Holder is under any obligation to enter into this Amendment. The entering into this Amendment by such parties shall not be deemed to limit or hinder any rights of any such party under the Loan Documents or Warrant, nor, except as provided in Sections 2 or 3 hereof, as applicable, shall it be deemed to create or infer a course of dealing between any such party, on the one hand, and the Borrower or Issuer, on the other hand, with regard to any provision of the Loan Documents or Warrant.

(d) **Governing Law**. **THIS AMENDMENT SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAWS OF THE STATE OF NEW YORK.**

(e) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(f) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(g) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

(h) **Warrants**. The Borrower shall within three business days of the request by any Holder issue new warrants to such Holder reflecting the amendment to the Warrants above or at the option of the Holder inserting the new exercise price in clause (y) as determined in accordance with this Amendment.

(i) **Expenses**. Whether or not the Section 5 Effective Date occurs and in accordance with Section 14.03 of the Credit Agreement and the Warrant, the Administrative Agent, the Lenders and Holders be reimbursed for all documented costs, fees and expenses incurred by the Administrative Agent, the Lenders and Holders (including the legal fees and out-of-pocket expenses of Sullivan & Cromwell LLP).

(j) **Electronic Execution of Certain Other Documents**. The words “execution,” “execute”, “signed,” “signature,” and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Administrative Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER AND ISSUER: ATHENEX, INC.,
a Delaware corporation

By: /s/ Johnson Lau
Name: Johnson Lau
Title: Chief Executive Officer & Board Chairman

ADMINISTRATIVE AGENT:

OAKTREE FUND ADMINISTRATION, LLC

By: Oaktree Capital Management, L.P.
Its: Managing Member

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

LENDERS AND WARRANT HOLDERS:

OAKTREE-TCDRS STRATEGIC CREDIT, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

EXELON STRATEGIC CREDIT HOLDINGS, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

OAKTREE-NGP STRATEGIC CREDIT, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

OAKTREE-MINN STRATEGIC CREDIT LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

OAKTREE-FORREST MULTI-STRATEGY LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

OAKTREE-TBMR STRATEGIC CREDIT FUND C, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

OAKTREE-TBMR STRATEGIC CREDIT FUND F, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

OAKTREE-TBMR STRATEGIC CREDIT FUND G, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

OAKTREE-TSE 16 STRATEGIC CREDIT, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

[Signature Page to Third Amendment to Credit Agreement]

INPRS STRATEGIC CREDIT HOLDINGS, LLC

By: Oaktree Capital Management, L.P.
Its: Manager

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Vice President

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Vice President

OAKTREE HUNTINGTON-GCF INVESTMENT FUND, L.P.

By: Oaktree Huntington-GCF Investment Fund GP, L.P.
Its: General Partner

By: Oaktree Huntingon-GCF Investment Fund GP, LLC
Its: General Partner

By: Oaktree Fund GP I, L.P.
Its: Managing Member

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Authorized Signatory

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Authorized Signatory

OAKTREE STRATEGIC INCOME II, INC.

By: Oaktree Fund Advisors, LLC
Its: Investment Advisor

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Authorized Signatory

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Authorized Signatory

OAKTREE SPECIALTY LENDING CORPORATION

By: Oaktree Fund Advisors, LLC
Its: Investment Adviser

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Authorized Signatory

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Authorized Signatory

OAKTREE STRATEGIC INCOME CORPORATION

By: Oaktree Fund Advisors, LLC
Its: Investment Adviser

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Authorized Signatory

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Authorized Signatory

OAKTREE GILEAD INVESTMENT FUND, L.P.

By: Oaktree Gilead Investment Fund GP, L.P.
Its: General Partner

By: Oaktree Fund GP, LLC
Its: General Partner

By: Oaktree Fund GP I, L.P.
Its: Managing Member

By: /s/ Jessica Dombroff
Name: Jessica Dombroff
Title: Authorized Signatory

By: /s/ Maria Attaar
Name: Maria Attaar
Title: Authorized Signatory

SAGARD HEALTHCARE ROYALTY PARTNERS, LP, acting through its general partner, SAGARD HEALTHCARE ROYALTY PARTNERS GP LLC

By: /s/ Jason Sneah

Name: Jason Sneah
Title: Director

By: /s/ Colin Nestor

Name: Colin Nestor
Title: Director

OPB SHRP CO-INVEST CREDIT LIMITED

By: /s/ Jennifer Hartviksen

Name: Jennifer Hartviksen
Title: Managing Director, Global Credit

By:

Name:
Title:

SIMCOE SHRP CO-INVEST CREDIT LTD.

By: /s/ Jennifer Hartviksen

Name: Jennifer Hartviksen
Title: Managing Director, Global Credit

By:

Name:
Title:

Annex A

Dunkirk Sale Agreement

Annex B

Amended and Restated Schedule 3 to the Credit Agreement

Exhibit 10.71

Certain information in this exhibit is marked [*] has been excluded from the exhibit because it is both (i) not material, (ii) is the type that the company treats as private or confidential, and (iii) would be competitively harmful if publicly disclosed.

EXECUTION VERSION Confidential

SECOND AMENDED AND RESTATED

CO-DEVELOPMENT AGREEMENT

BY AND BETWEEN

BAYLOR COLLEGE OF MEDICINE

AND

CELL MEDICA INC.

(d/b/a KUUR THERAPEUTICS)

Original Effective Date: APRIL 29, 2016

First Restatement Effective Date: FEBRUARY 28, 2020

Second Restatement Effective Date: October 12, 2021

Table of Contents

SECOND AMENDED AND RESTATED
CO-DEVELOPMENT AGREEMENT

This Second Amended and Restated Co-Development Agreement (the "Second Restated Co-Development Agreement" or "Agreement" herein), effective as of October 12, 2021 (the "Second Restatement Effective Date" or "Effective Date" herein), is by and between (i) Baylor College of Medicine ("Baylor"), a Texas nonprofit corporation having its principal place of business at One Baylor Plaza, Cullen Building, Suite 106A, Houston, Texas 77030, and (ii) Cell Medica Inc., doing business as Kuur Therapeutics, a Texas corporation ("Kuur"). As of the Second Restatement Effective Date, this Second Restated Co-Development Agreement amends and restates that certain Amended and Restated Co-Development Agreement (the "First Restated Co-Development Agreement"), entered into on February 28, 2020 (the "First Restatement Effective Date") by Baylor and Kuur Therapeutics Ltd. (formerly known as Cell Medica Ltd.), and as assigned by Kuur Therapeutics Ltd. to Cell Medica Inc. on August 26, 2020, which First Restated Co-Development Agreement amended and restated that certain Co-Development Agreement entered into by Baylor and Kuur Therapeutics Ltd. (formerly known as Cell Medica Ltd.) dated April 29, 2016, as such agreement has been amended by that certain First Amendment dated July 12, 2017 and that certain Second Amendment dated February 28, 2019 (collectively, the "Original Co-Development Agreement").

WHEREAS, Baylor, through the Developer(s) (as defined below), has developed certain proprietary technology, expertise, information, materials and/or know-how related to NKT Cells (as defined below) and certain antigens, each potentially useful for the development of cellular immunotherapies for the treatment of certain human diseases;

WHEREAS, Kuur has developed proprietary technology, expertise, information, materials and know-how related to the discovery and development of cellular immunotherapies to treat human diseases and is engaged in the discovery, development and commercialization of such products and other biopharmaceutical products worldwide;

WHEREAS, Baylor and Kuur are entering, contemporaneously with this Agreement, into that certain Second Amended and Restated Exclusive License and Option Agreement of even date hereof (the "Second Restated License and Option Agreement" or "License and Option Agreement" herein) pursuant to which Baylor has granted to Kuur certain exclusive rights under the Core Subject Technology (as defined therein) and certain exclusive options to rights under Future Technology (as defined therein), all under the terms set forth in the Second Restated License and Option Agreement; and

WHEREAS, the Parties now wish to combine their respective technologies and expertise and collaborate in the performance of Early R&D Activities (as defined below) with respect to Licensed Core Products, Core Subject Technology, Future Technology and Future Products, to be conducted as projects under a mutually agreed Development Plan (defined below) in accordance with the terms set forth herein;

WHEREAS, Baylor and Kuur amended and restated certain terms of the Original Co-Development Agreement in its entirety as set forth in the First Restated Co-Development Agreement;

WHEREAS, Baylor and Kuur Therapeutics Ltd. (formerly known as Cell Medica Ltd.) also entered into that certain Exclusive License and Option Agreement dated April 29, 2016, as amended by that certain First Amendment dated May 26, 2017, that certain Second Amendment dated December 5, 2017, that certain Third Amendment dated May 17, 2018, that certain Fourth Amendment dated December 19, 2018, and that certain Fifth Amendment dated September 27, 2019 (collectively, the "Original License and Option Agreement");

WHEREAS, Baylor and Kuur Therapeutics Ltd. amended and restated certain terms of the Original License and Option Agreement in its entirety as set forth in that certain Amended and Restated Exclusive License and Option Agreement which was executed on an even date with the Restated Co-Development Agreement (the "First Restated License and Option Agreement"); and which was assigned to Cell Medica Inc. on August 26, 2020 and

WHEREAS, Baylor and Kuur desire to amend and restate certain terms of the First Restated Co-Development Agreement in its entirety as set forth in this Second Restated Co-Development Agreement.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth herein, and for good and valuable consideration the sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound hereto, agree as follows.

ARTICLE I
DEFINITIONS AND CONSTRUCTION

1.1 Definitions. Capitalized terms used herein and not otherwise defined shall have the meaning given in the License and Option Agreement. As used in this Agreement, the following capitalized terms not defined elsewhere (whether used in the singular or plural) shall have their respective meanings as set forth below.

"Added Amount" has the meaning set forth in Section 4.4(d)(ii).

"Allocated Amounts" means, collectively, those portions of the Annual Kuur Commitment which has been allocated in the Development Budget to achievement of each specific activity or purpose under the Development Plan as determined by the JSC.

"Annual Kuur Commitment" means, for a given Fiscal Year, the maximum financial obligation of Kuur for such Fiscal Year to support Early R&D Activities for Licensed Core Products, Core Subject Technology, Future Oncology Products (if any), and Future Oncology Technology (if any) in connection with this Agreement, as agreed by the Parties in accordance with Section 4.4(c).

"Annual Kuur Payment" means, for each Fiscal Year, the total of the Allocated Amounts for such Fiscal Year.

"Antigen Option" shall have the meaning given in the License and Option Agreement.

"Applicable Laws" means all applicable federal, state and local laws, rules, and regulations. Applicable Laws include, without limitation, relevant provisions of the U.S. FD&C Act, GCP, GLP, GMP and Privacy Laws.

"Baylor Enabling Technology" means any Technology or Technology Right, other than Core Subject Technology, Future Technology or a Patent Right, that is (a) owned or Controlled by Baylor and (b) reasonably likely to enable earlier and/or more cost-effective (i) completion of one or more of the tasks set forth in the Development Plan (in whole or in part), or (ii) commercialization (including commercial manufacture) of a Licensed Product or a Future Product.

"Baylor Target Antigen" shall have the meaning given in the License and Option Agreement.

"Business Day" shall have the meaning given in the License and Option Agreement.

"Calendar Quarter" means, within each Fiscal Year, the period commencing on July 1 and ending on September 30, commencing on October 1 and ending on December 31, commencing on January 1 and ending on March 31, or commencing on April 1 and ending on June 30, as applicable.

"Kuur Property" has the meaning given in Section 7.2.

"Kuur Successor" shall have the meaning given in the License and Option Agreement.

"Change of Control" shall have the meaning given in the License and Option Agreement.

"Commercial Manufacturing Process" shall mean a GMP-compliant process for making Licensed Products or Future Products for use in clinical trials or commercial sale.

"Commercially Reasonable Efforts" means with respect to carrying out specific tasks and obligations of a Party under this Agreement, including research, development, and manufacture, expending reasonable, diligent, good

faith and time- and cost-effective efforts and resources to accomplish such task or obligation as such Party (on its own and/or acting through any of its Affiliates, sublicensees or subcontractors) would normally use to accomplish a similar task or obligation under similar circumstances and consistent with the generally acceptable prudent medical, research, and/or business judgment followed by such Party, and comparable to similarly situated entities.

"Completion" shall mean, with respect to each Project, the completion of all Early R&D Activities for such Project specified in the Development Plan.

"Control", "Controls" or "Controlled by" shall have the meaning given in the License and Option Agreement.

"Consultancy Payment" shall have the meaning ascribed in Section 4.2(a).

"Core Subject Technology" shall have the meaning given in the License and Option Agreement.

"Data Package" means, with respect to a Product, the data package for such Product to be provided by Baylor to Kuur at the Completion of such Product's FIM Study. The specifics of the Data Package for each Product, including the format(s) in which the Data Package shall be provided, shall be set forth in the Development Plan, but each "Data Package" shall contain, at a minimum (a) all data (including anonymized patient level data) and analyses applicable to such Product, and (b) all invention disclosures and a description of all Baylor Patent Rights and Know-How and other Technology Rights relating to such Product (including Baylor Enabling Technology), and all freedom-to-operate analyses in Baylor's possession or control applicable thereto (it being understood that Baylor shall have no obligation to obtain a freedom-to-operate analysis), in addition to any other elements of such Data Package specified in the Development Plan.

"Developers" shall have the meaning given in the License and Option Agreement.

"Development Budget" means (a) the budget for the Allocated Amounts, based on commercially reasonable and documented costs, and as determined, in its sole discretion, by the JSC for execution of all activities under the Development Plan, which shall cover, without limitation, costs of personnel and facilities, allocated overheads, subcontractor amounts and the acquisition of all materials and equipment required for execution of such activities outlined in Work Plans, SICRAs included in the Development Plan, and (b) all Unallocated Amounts to be spent on such activities and/or equipment, if any, as the JSC shall designate under Section 4.4. The Development Budget includes any modifications adopted by the JSC in accordance with Section 4.4.

"Development Plan" means the written, detailed plan for the Early R&D Activities for the Licensed Products, Licensed Technology, Future Products (if any), and Future Technology (if any) to be conducted by Baylor during the Development Term, including (a) key development goals, (b) experimental plans, timeline, and workflow for meeting such goals, (c) the Party responsible for conducting or overseeing each activity; (d) performance metrics and success criteria, including go/no-go criteria, (e) a detailed description of any Work Plans to be carried out by Baylor or any Specific Industrial Clinical Research Agreements to which Baylor is a party including, in each case, the subject matter of the agreement, and any work or other obligations to be undertaken by Baylor, and (f) the Development Budget for the period covered by the Development Plan.

"Development Term" means the period during which the Parties are conducting research and development of the Licensed Products, Licensed Technology, Future Products (if any) and/or Future Technology (if any), either pursuant to this Agreement or the Development Plan, including any Work Plan or SICRA executed during the Term, whichever is longer.

"Early R&D Activities" shall have the meaning given in the License and Option Agreement.

"FDA" means the United States Food and Drug Administration.

"FD&C Act" means the United States Federal Food, Drug and Cosmetics Act in effect and as amended during the Term and rule and regulations promulgated by FDA thereunder.

"Field" shall have the meaning given in the License and Option Agreement.

"FIM Study" shall have the meaning given in the License and Option Agreement.

"Fiscal Year" means a 12-month period commencing on July 1 and ending on the following June 30.

"Future Non-Oncology Invention" shall have the meaning given in the License and Option Agreement.

"Future Oncology Invention" shall have the meaning given in the License and Option Agreement.

"Future Products" means Future Oncology Products and Future Non-Oncology Products.

"Future Technology" means Future Oncology Technology and Future Non-Oncology Technology.

"GCP" means the guidelines for good clinical practices promulgated by the FDA, and all federal, state or local laws, rules, regulations and medical and ethical standards applicable to the conduct of human clinical studies.

"GLP" means the then-current good laboratory practice standards promulgated by the FDA pursuant to 21 C.F.R. Part 58 or any successor law or regulation.

"GMP" means the then-current good manufacturing practices required by the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, as they may be updated from time to time.

"Innovation Development Center" means the unit of Baylor's Office of Research identified by Baylor as the Innovation Development Center.

"Joint Steering Committee" or "JSC" means the committee established pursuant to Section 4.1.

"Key Person" means (i) Dr. Leonid Metelitsa, (ii) such other Baylor employee(s) identified as a Principal Investigator (including any Co Investigator) for a given Work Plan or Specific Industrial Clinical Research Agreements, or (iii) such other Baylor employee(s) nominated by Baylor in accordance with Section 5.2(b)(ii), accepted by Kuur in accordance with Section 5.2(b)(iii), and charged with planning, organizing, performing, managing, or directing specific Projects or other activities under the Development Plan.

"Know-How" shall have the meaning given in the License and Option Agreement.

"Licensed Core Product" shall have the meaning given in the License and Option Agreement.

"Licensed Future Non-Oncology Technology" shall have the meaning given in the License and Option Agreement.

"Licensed Future Products" means the Licensed Future Oncology Products (as defined in the License and Option Agreement) and Licensed Future Non-Oncology Products (as defined in the License and Option Agreement).

"Licensed Product" shall have the meaning given in the License and Option Agreement.

"Licensed Technology" shall have the meaning given in the License and Option Agreement.

"Mark" shall have the meaning given in the License and Option Agreement.

"Modified NKT" shall have the meaning given in the License and Option Agreement.

"Natural Killer T Cell" or "NKT" shall have the meaning given in the License and Option Agreement.

"NKT CAR Subject Technology" shall have the meaning given in the License and Option Agreement.

"NKT Platform Subject Technology" shall have the meaning given in the License and Option Agreement.

"Option" means the Future Oncology Option and/or the Future Non-Oncology

Option granted to Kuur under Article III of the License and Option Agreement.

"Outside the Field" shall have the meaning given in the License and Option Agreement.

"Party" means either Kuur or Baylor, and "Parties" means Kuur and Baylor.

"Patent Rights" shall have the meaning given in the License and Option Agreement.

"Product" means a Licensed Core Product or Future Product.

"Privacy Laws" means all applicable state, federal and local laws, rules and regulations with respect to the collection, use, transfer, storage, deletion, processing (both by computer and manually), combination or other use of subject or other personal data as contemplated by applicable data protection or privacy laws of all data relating to any participant in, or applicant wishing to participate in, a clinical trial, including the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations.

"Project" means, with respect to a specific Product, if any, or an aspect of the Core Subject Technology or Future Technology, if any, the Early R&D Activities under the Development Plan for such Product or technology to be conducted by Baylor hereunder. Each Project may be set forth as a separate section in the Development Plan.

"Quarterly R&D Payment" means, subject to Section 3.1(b), for each Fiscal Quarter, one-fourth of the total Annual Kuur Commitment for that Fiscal Year.

"Specific Industrial Clinical Research Agreement" or "SICRA" means an agreement (a) between the Parties or (b) between Kuur (and/or its Affiliate) and a Third Party, in each case, to conduct all or a specific clinical trial portion of a Project.

"T Cell" shall have the meaning given in the License and Option Agreement. "Technology" shall have the meaning given in the License and Option Agreement.

"Technology Right" shall have the meaning given in the License and Option Agreement.

"Term" means the duration of this Agreement from the Effective Date until the date on which the termination of this Agreement becomes effective in accordance with Section 10.2.

"Third Party Enabling Technology" means any Technology or Technology Right that is (a) owned or controlled by a Third Party, (b) reasonably likely to enable earlier and/or more cost-effective (i) completion of one or more of tasks set forth in the Development Plan (in whole or in part), or (ii) commercialization of a Licensed Product or Future Product (if any), and (c) not Controlled by a Party or an Affiliate of a Party.

"Unallocated Amounts" means collectively, that portion of the Annual Kuur Commitment paid but not spent, and not allocated to the achievement of any specific activity or purpose under the Development Plan in the Fiscal Year paid, and available to the JSC for allocation during such Fiscal Year. For a given Fiscal Year, the Unallocated Amounts shall equal (a) the sum of ((x) the Annual Kuur Commitment for such Fiscal Year; plus (y) any Added Amount for carried over from the immediately prior Fiscal Year), less (b) the total Allocated Amounts for such Fiscal Year (*i.e.*, Unallocated Amount = (Annual Kuur Commitment + Added Amount) − Allocated Amounts).

"Work Plan" means a detailed, written plan approved by the JSC as part of the Development Plan which sets forth Early R&D Activities, excluding all clinical trial activity including any supporting activities, such as those outlined in SICRAs under the Development Plan, to be provided by Baylor, including any budget considerations associated with such Early R&D Activities on a Project-by-Project basis as determined by the JSC.

ARTICLE II
BAYLOR RESEARCH AND DEVELOPMENT

2.1 General. Early R&D Activities of Core Subject Technology, Licensed Core Products, Future Technology (if any) and Future Products (if any) shall be conducted in accordance with the Development Plan under the oversight of the JSC. Notwithstanding anything contained to the contrary in this Agreement or the License and Option Agreement (including anything set forth in this Article II), Baylor shall have the worldwide right to be Kuur's exclusive academic partner to conduct all preclinical, IND-enabling Early R&D Activities with respect to each Licensed Core Product, Future Oncology Product, and Future Non-Oncology Product ("Baylor's Exclusive Academic Partner Early R&D Participation Rights"); and without limiting Baylor's Exclusive Academic Partner Early R&D Participation Rights set out in the foregoing sentence, Kuur shall have the right (either itself or through any of its Affiliates or sublicensees or any other Third Parties) to conduct Early R&D Activities (including preclinical activities and to prepare and file IND applications and subsequent services and other activities, such as, for example, activities required to support clinical development with respect to each Licensed Core Product, Future Oncology Product, and Future Non-Oncology Product which is a Distinct Product). If Kuur conducts phase I clinical trial activities with respect to a Distinct Product, Baylor will be (unless Baylor notifies Kuur that it does not want to be) the lead clinical center, select the chief (lead) investigator and will be entitled to first and last authorship academic credit with respect to such Early R&D Activities, subject to the terms and conditions of this Agreement and the License and Option Agreement (including Section 17.5 therein). Baylor's rights under this Section 2.1 may be waived or amended by the JSC upon prior written request by Kuur and after such request is approved in writing by the JSC.

2.2 Implementation. Subject to Kuur's payment and Baylor's receipt of full payment of each Quarterly R&D Payment under Section 3.1, Baylor shall use Commercially Reasonable Efforts to complete the tasks allocated to it under the Development Plan in accordance with the corresponding performance criteria, and timelines therein, and the Development Budget, including:

(a) allocating, managing, and maintaining sufficient and sufficiently equipped space for all work to be performed;

(b) assigning staff with sufficient qualifications and in sufficient numbers for all work to be timely and professionally performed, and ensuring appropriate oversight for such staff;

(c) distributing and reporting all data and results promptly to Kuur subject to any applicable Privacy Laws;

(d) conducting all Early R&D Activities assigned to it pursuant to the Development Plan; and

(e) disbursing Allocated Amounts in accordance with the Development Plan and Development Budget.

For the avoidance of doubt, nothing in this Agreement shall obligate Baylor to begin, continue, or complete Early R&D Activities if Kuur fails to timely deliver to Baylor the Quarterly R&D Payments in accordance with Sections 3.1 and 3.2 and the Development Budget.

2.3 Administrative Support. Baylor shall and Kuur may designate a "Project Manager" to act as a project manager for all activities assigned to such Party under the Development Plan, ensure the appropriate management of resources, reporting of progress and results, including pre-clinical and clinical data reporting requirements as set forth in Section 5.3 herein, under the Development Plan, and assist the JSC in the administration of the Development Plan as it relates to the activities assigned to such Party pursuant to the Development Plan. Each such Project Manager shall be subject to the other Party's approval, such approval not to be unreasonably conditioned, delayed, or withheld.

Baylor shall provide such other administrative support as it deems in its discretion to be necessary for implementation of the activities assigned to Baylor under the Development Plan. The salary for each Project Manager and such other administrative support shall be funded from the Quarterly R&D Payments to the extent set forth in the Development Budget.

2.4 Use of Baylor Subdivisions. Baylor, at its discretion, may act through its Innovation Development Center and such other subdivision of Baylor as Baylor shall designate to Kuur in the Development Plan or other written notice, to fulfill its obligations under Section 2.2. For the avoidance of doubt, each "subdivision of Baylor" as used in the immediately preceding sentence shall be part of Baylor and not an entity legally distinct from Baylor.

2.5 Compliance. Each Party shall comply with all Applicable Laws in connection with its performance hereunder, including with respect to any Early R&D Activities. Without limiting the generality of the foregoing, (a) Baylor shall (i) conduct its activities under the Development Plan in accordance with GLP, GMP and GCP and other Applicable Laws, as applicable, including establishing and maintaining a trial master file for any FIM Studies and maintaining adequate records of and appropriately reporting any adverse events, and managing materials, data and results in compliance with Privacy Laws and other Applicable Laws; (ii) obtain institutional review board approvals for all animal and FIM Studies conducted under the Development Plan; (iii) obtain appropriate informed consent documents from all subjects participating in any FIM Studies under the Development Plan or that have provided biological samples for use in connection with the Development Plan as required by Applicable Laws and as necessary to fulfill its obligations under this Agreement and the License and Option Agreement; and (b) Kuur shall and shall ensure that its Affiliates (i) conduct their activities under the Development Plan in accordance with GLP, GMP, and GCP, as applicable, including maintaining adequate records of and appropriately reporting any adverse events, and managing materials, data and results in compliance with Privacy Laws and other Applicable Laws; (ii) obtain (and ensure that each Affiliate obtains) institutional review board approvals for all animal and human studies (if any) conducted by Kuur or its Affiliates pursuant to the Development Plan; (iii) obtain (and ensure that each Affiliate obtains) appropriate informed consent documents from all subjects participating in any clinical trials conducted by Kuur or its Affiliates pursuant to the Development Plan or that have provided biological samples for use in connection with any research or development conducted by Kuur or its Affiliates pursuant to the Development Plan as required by Applicable Laws and as necessary to fulfill its obligations under this Agreement.

2.6 Baylor Enabling Technology.

(a) *Presentation*. Baylor may, at its option and without obligation, identify and present Baylor Enabling Technology to the JSC which it recommends be included or used in connection with one or more Products. If the JSC agrees that such Baylor Enabling Technology is appropriate for use in one or more Projects, Baylor and Kuur may negotiate in good faith the commercially reasonable terms for the use of such Baylor Enabling Technology, including the license rights to be granted to Kuur for the use of such Baylor Enabling Technology in the use, development and commercialization of Licensed Products and Licensed Technology; provided that neither Party shall be required to agree to any such terms except in its sole and absolute discretion.

(b) *Incorporation*.

(i) Baylor shall not utilize any Baylor Enabling Technology in connection with any work performed in connection with the Development Plan unless and until the JSC has approved such use and the Parties have agreed on the terms therefor in accordance with Section 2.6(a).

(ii) Notwithstanding the foregoing Section 2.6(b)(i), if Baylor does utilize any Baylor Enabling Technology in connection with such work without such approval and agreement, then Baylor hereby grants to Kuur, a non-exclusive license under Baylor's right, title and interest in such Baylor Enabling Technology Controlled by Baylor in the Field and Outside the Field to the extent necessary for Kuur to exercise (and to the same extent as Kuur has the right to exercise) its license rights under the License and Option Agreement.

(iii) The license set forth in Section 2.6(b)(ii) shall (1) be sublicenseable through multiple tiers of sublicensees and assignable in connection with a permitted assignment of the License and Option Agreement, (2) survive for so long as the license rights to such Licensed Product or Licensed Technology under the License and Option Agreement continue, (3) be royalty-bearing in accordance with Section 5.13 of the License and

Option Agreement if such Baylor Enabling Technology includes the only Valid Claim(s) covering such Licensed Product (but only if Baylor has granted Kuur an exclusive license to such Baylor Enabling Technology that includes the only Valid Claim(s) covering such Licensed Product under the License and Option Agreement), and (4) be royalty-free and fully paid up if such Baylor Enabling Technology does not include the only Valid Claim(s) covering such Licensed Product or is not exclusively licensed to Kuur under the License and Option Agreement. If all Baylor Enabling Technology utilized by Baylor in breach of Section 2.6(b)(i) that is necessary for Kuur to exercise its license rights under the License and Option Agreement is included in the license granted under Section 2.6(b)(ii), then the grant of such license shall be Kuur's sole remedy and relief for any non-compliance with Section 2.6(b)(i). If Kuur seeks any further remedy (including a claim for breach), Kuur shall have the burden of showing that the license granted in Section 2.6(b)(ii) is not sufficient to exercise its license rights under the License and Option Agreement. For the avoidance of doubt, except as otherwise specified above in this Section 2.6(b), nothing in this Section 2.6(b) shall modify or abate any payments otherwise due under the License and Option Agreement.

2.7 Identification of Future Oncology Inventions and Future Non-Oncology Inventions. Baylor shall use Commercially Reasonable Efforts to require that its employees and contractors conducting activities under the Development Plan identify and disclose all inventions or other Technology Rights that would constitute Future Oncology Inventions and Future Non-Oncology Inventions, as such upon or promptly after its discovery, in accordance with Baylor's then-current intellectual property policies or agreements with employees and contractors. Baylor shall notify the Joint Steering Committee of any so identified Future Oncology Inventions and Future Non-Oncology Inventions, upon and after which notice Kuur shall be free to exercise its Option with respect thereto in accordance with Sections 3.1 or 3.2, as applicable, of the License and Option Agreement.

2.8 Work Plans and SICRAs.

(a) *Work Plans*. The JSC shall establish Work Plans, that may include associated budgets, and any modifications or amendments to such Work Plans, that will set out the specific services to be performed by Baylor to carry out the Development Plan. Each Work Plan shall be subject to the terms and conditions of this Agreement and the License and Option Agreement, unless specifically and expressly agreed otherwise by the Parties.

(b) *SICRAs*. The JSC shall establish SICRAs, that may include associated budgets, and any modifications or amendments to such SICRAs that will set out the specific services to be performed by Baylor or its designees under the SICRA to carry out the Development Plan. Each SICRA may be subject to a procurement review process by the JSC whereby Baylor and/or Kuur may submit alternatives for the cost-effective and time-efficient execution of the work to be conducted under any such, as applicable SICRA, at the JSC's discretion. The JSC will be responsible for awarding the work based on the merits of different proposals received for the procurement of such work.

(c) Each SICRA shall be consistent with and subject to the terms and conditions of this Agreement and the License and Option Agreement, unless specifically and expressly agreed otherwise by the Parties. In the event of any conflict between any SICRA, on the one hand, and this Agreement or the License and Option Agreement, on the other hand, such SICRA shall control, provided that such SICRA and all amendments or side agreements thereto have been approved in writing in their respective full and final forms (including all exhibits, appendices and attachments) by Kuur.

(d) Kuur may enter into any SICRA with a Third Party. For each SICRA between Kuur and a Third Party governing clinical Early R&D Activities set forth in the Development Plan approved by the JSC: (i) unless otherwise approved by Baylor in writing, such SICRA shall name Baylor as an intended third party beneficiary thereof; (ii) Kuur shall promptly provide Baylor with a true, accurate and complete copy of each such executed SICRA and any amendment(s) and/or side agreement(s) thereto and all material correspondence relating to each such SICRA, amendment or side agreement; (iii) such SICRA shall require such Third Party to maintain the confidentiality of all data and results generated under such agreement in accordance with Article XVII of the License and Option Agreement (subject to Section 17.5 thereof) and to comply with all Applicable Laws, and (iv) regardless of whether or not Baylor is named as an intended third party beneficiary to a SICRA, Kuur shall require performance measures, including budget and milestones, in such SICRA and, upon Baylor's request, shall use reasonably diligent efforts to enforce the terms and conditions of any such SICRA.

(e) The Parties agree that a Third Party SICRA in the form set forth as Exhibit A-2 hereto shall satisfy the requirements of Sections 2.8(d) and (e).

(f) Prior to any SICRA being entered into pursuant to Sections 2.8(d) or (e), the Parties shall execute a letter setting forth (i) Baylor's consent to such SICRA to the terms thereof (with the agreed form of such SICRA attached as an exhibit), if needed, and (ii) the agreement of the Parties as to any other terms applicable to the Parties' respective rights and obligations with respect to such SICRA, including, if and as applicable, audit and inspection rights, approval of alternate investigators and changes to the research plan and budget, patent prosecution and enforcement, exercise of options to intellectual property, indemnification and survival of sublicenses (provided that with regard to each of the foregoing clauses (i) and (ii), such consent and/or agreement by Baylor shall not to be unreasonably withheld, conditioned or delayed).

(g) A breach under one SICRA will be deemed to be a breach of any other SICRA, but only if and to the extent the acts, omissions, or other circumstances that gave rise to the breach of the one SICRA also gives rise to breach of such other SICRA.

2.9 Baylor Covenants.

(a) Baylor shall not use, during the Development Term, the services of any persons or entities debarred under 21 U.S.C. § 335(a) or 335(b) or any foreign equivalent, nor disqualified as described in 21 CFR 812.119 or foreign equivalent, in any capacity in connection with the performance of its obligations under this Agreement. Baylor shall immediately inform Kuur of any debarment or of the commencement of any debarment or like proceedings against Baylor or any individual or entity performing Early R&D Activities during the Development Term.

(b) Baylor shall permit only Baylor employees (except for any contractor that is a party to a valid agreement with Baylor pursuant to which such contractor irrevocably assigns sole ownership of all Technology and Technology Rights arising from any work conducted under the Development Plan (each, such agreement, a "Baylor Contractor Agreement" and each such contractor that is party to a Baylor Contractor Agreement, a "Baylor Contractor")) to perform any work assigned to or undertaken by Baylor under the Development Plan to which Baylor is a party. Without limiting the generality of the foregoing, Baylor shall not permit any student or visiting personnel to perform any such work unless such student or visiting personnel is also an employee of Baylor or a Baylor Contractor that is a party to a Baylor Contractor Agreement at the time such student or visiting personnel performs such work.

2.10 Academic Freedom. Baylor shall retain, and Kuur acknowledges that Baylor shall retain complete academic freedom including, without limitation, all rights and freedom, in its sole discretion, (i) to direct and control its activities under the Development Plan (provided that nothing in this subclause (i) will release Baylor from those obligations it has expressly accepted under this Agreement, the Development Plan), (ii) to modify or terminate any activity under the Development Plan if, in Baylor's reasonable judgment, (1) continuing the activity would jeopardize the health or safety of any patients, healthcare providers to such patients, or Baylor employees who would otherwise be involved in such activities or (2) Baylor otherwise determines that it is obligated under Applicable Laws to discontinue such activity, (iii) to direct, control, operate, begin, continue, and terminate any and all of its activities outside of the Development Plan and subject to Sections 5.2 and 5.4 of this Agreement and Sections 2.4(b) and 3.6 of the License and Option Agreement, including its educational activities, innovative activities, research and development, (v) subject to Section 5.2 of this Agreement, to hire, retain, dismiss, or compensate its innovators, faculty, staff, students, employees, researchers, and/or other members, and (vi) subject to only Article VIII of this Agreement, to publicly disclose, whether through publications (whether or not peer-reviewed), oral presentations, or any other means, any and all research results, data, findings, conclusions, ideas, theories, discoveries, innovations, and other information.

2.11 Use of Funds.

(a) Baylor shall apply the payments it receives under this Agreement solely to carry out its activities under the Development Plan and in accordance with the Development Plan (including a Work Plan or SICRA contemplated thereby) and the terms and conditions of this Agreement. Baylor covenants that it shall use reasonable

efforts to avoid using any funds obtained from or on behalf of any Third Party that give rights to such Third Party in or to any Licensed Product or Licensed Technology or Future Product or Future Technology (other than a Future Product that has become a Released Product or Future Technology that has become a Released Invention, subject to, but only to the extent permitted in, Section 3.6 of the License and Option Agreement), except to the extent agreed upon by the JSC and/or set forth in a specific line item of the Development Budget approved by the JSC. For clarity, this Section 2.12 will not prevent Baylor from using equipment funded by an unrestricted grant from a Third Party, provided that such Third Party does not acquire any rights, title or interest (including any contingent rights) in or to any Technology or intellectual property or other Technology Rights arising from the use of such equipment.

(b) Baylor acknowledges that if a Third Party were to acquire Technology Rights in the products or technology developed under this Agreement without Kuur's consent, it may be extremely detrimental to Kuur and may impair its ability to effectively develop and commercialize products and technology arising from the Development Plan. Promptly following the Effective Date, Baylor shall establish processes and procedures (including regular training) to be provided by Baylor to its staff conducting the Development Plan to prevent such use of such Third Party funds, and Baylor shall comply with such processes and procedures. Baylor shall conduct regular audits, at least annually, to ensure such processes and procedures are being followed and to determine if any modifications to such processes and procedures are advisable. Baylor shall promptly upon becoming aware report to the JSC (i) any violation of such processes and procedures, and (ii) any instance of Third Party funding of any work conducted in connection with the Development Plan that has not been approved by the JSC and through which such Third Party may acquire rights in or to any product or technology being developed under this Agreement. Nothing in this Section 2.12(b) shall relieve Kuur from any burden of proof it would otherwise bear to demonstrate actual harm to Kuur arising from any use of Third Party funds by Baylor.

ARTICLE III
KUUR SUPPORT

3.1 R&D Payments.

(a) Quarterly R&D Payment. Kuur shall pay Baylor the Quarterly R&D Payment for each Fiscal Year Quarter during the Term not later than 5 PM Central Time on the tenth (10^{th}) Business Day following the commencement of such Fiscal Year Quarter. The Quarterly R&D Payment will be applied against any outstanding Work Plans and SICRAs to which Baylor is a party.

(b) Quarterly R&D Payment True-Up. If at the end of a Fiscal Year, the sum of the Quarterly R&D Payments received by Baylor for such Fiscal Year exceed Baylor's expenditures on Development Plan activities approved by the JSC in accordance with the Development Budget (including activities pursuant to Work Plans and SICRAs to which Baylor is a party), Kuur shall be entitled to deduct such excess amount from the next Quarterly R&D Payment(s) that otherwise would be due for the Fiscal Year Quarter(s) immediately following the discovery of such overage (each a "True-Up Credit"). If at the end of a Fiscal Year, the sum of the Quarterly R&D Payments received by Baylor for such Fiscal Year are less than Baylor's expenditures on Development Plan activities approved by the JSC in accordance with the Development Budget (including activities pursuant to Work Plans and SICRAs to which Baylor is a party), Baylor shall notify Kuur of such shortfall and Kuur shall pay Baylor within thirty (30) days of such notice the full amount of such shortfall (each a "True-Up Payment").

3.2 Payment. Any monetary payment owed by Kuur to Baylor under this Agreement ("Payment") shall be made in accordance with this Section 3.2 and Section 3.3. Kuur shall make any Payment to Baylor at its cost in immediately available indefeasible unconditional funds in U.S. dollar currency without any set-off or deduction (other than as set forth in Section 3.1(b)) in such form or manner as reasonably directed by Baylor. A Payment is owed when due and non-cancelable and non-refundable, except as provided in the next sentence of this Section 3.2 or as set forth in Section 5.2(c), Section 5.4(c) or Section 10.3(a). If Baylor fails to perform its obligations with respect to any portion of the Development Plan, including any Work Plan or SICRA to be supported by a Payment made by Kuur and received by Baylor, the unused portion of the Allocated Amount for such activities shall be (i) credited to Kuur for any other Projects under the Development Plan that remain uncompleted or, (ii) refunded to Kuur if no other Projects remain in progress. Any amount of any Payment that is not received by Baylor when it is due shall accrue interest, from the date it is due until Baylor's receipt of such amount in accordance with this Section 3.2, at the rate of the lower of (a) one-and-one-half percent (1.5%) per full or partial calendar month, or (b) the highest enforceable rate of

interest under applicable law. All such interest shall be paid simultaneously with the unpaid amount on which such interest accrued.

3.3 Taxes. Any Payment shall be made without any deduction, set-off or withholding of any sales, use, excise, value added or other applicable taxes, tariffs or duties, payment of which shall be the sole responsibility of Kuur (excluding any applicable taxes based on Baylor's net income). In the event that such taxes, tariffs or duties are assessed against Baylor, Kuur shall reimburse Baylor for any such amounts paid by Baylor or, prior to the payment of such amounts by Baylor, provide Baylor with valid tax exemption certificates with respect thereto.

3.4 Annual Kuur Commitment. As of the Second Restatement Effective Date, and during the Development Term, Kuur will invest not less than [*] per Fiscal Year to support Early R&D Activities and/or other Product research and development under this Agreement pursuant to the Development Plan and Development Budget, in each case, as determined by the JSC.

3.5 Kuur Modified NKT Technology. Kuur may, at its option and without obligation, identify and present to the JSC, Technology and Technology Rights which (i) are not Third Party Enabling Technology, (ii) are related to Modified NKTs, and (iii) are discovered or acquired by Kuur, and which it recommends be used in connection with, or incorporated into, any Project or Licensed Product or Future Product. If the JSC agrees that such Technology and Technology Rights are appropriate for use in one or more Projects, Baylor and Kuur may negotiate in good faith the commercially reasonable terms for incorporating such Technology into this Agreement; provided that neither Party shall be required to agree to any such terms except in its sole and absolute discretion.

3.6 Early R&D Activities.

(a) Baylor shall have a non-exclusive right to conduct preclinical, IND-enabling Early R&D Activities relating to each Distinct Product (as defined in the License and Option Agreement) that is a Licensed Core Product and/or a Future Product (if any) in accordance with Section 2.6 of the License and Option Agreement and the Development Plan, other than those activities that Kuur undertakes pursuant to Sections 5.2(c) or 5.4(a)(iv) of this Agreement or that Kuur has elected to undertake (including as set forth in Section 2.1(b) of this Agreement), or as otherwise expressly set forth herein or in the License and Option Agreement.

(b) Kuur shall have the right, itself and with its Affiliates and Third Parties to conduct Early R&D Activities (including activities relating to and reasonably likely to contribute to and the filing of an investigational new drug application (IND) (or foreign equivalent), or to the development of a Commercial Manufacturing Process, or to the design and execution of clinical studies) and, if such development is successful, commercialization, and any and all such other activities, including such activities as are assigned to it by the JSC in accordance with this Agreement.

3.7 License to Baylor for Early R&D Activities. Kuur hereby grants to Baylor a non-exclusive (subject to Section 3.6), fully paid-up license to use the Kuur Property solely to conduct Baylor's activities under the Development Plan in accordance with this Agreement and the terms of the applicable Work Plan and Specific Industrial Clinical Research Agreement, in each case, during the Development Term.

ARTICLE IV
JOINT STEERING COMMITTEE

4.1 Purpose. On or promptly after the Effective Date, the Parties shall appoint members to the Joint Steering Committee ("JSC") in accordance with Section 4.2. The JSC shall approve and monitor the work performed in support of the Development Plan, including any approved Work Plans or SICRAs between the Parties, the protocols for each pre-clinical and clinical study to be conducted pursuant to the Development Plan, and coordinate the Parties' co-development efforts, including reviewing and discussing data, information and results arising from such efforts. The JSC shall also periodically review and update the Development Plan and the Development Budget in accordance with this Article IV. The JSC shall only have the authority expressly granted under this Agreement with all other authority reserved to the Parties.

4.2 Composition and Payment.

(a) General. The JSC shall consist of ten members, each a "JSC Member" and collectively, "JSC Members," of which: (i) five members may be appointed by Kuur, and (ii) five members may be appointed by Baylor. The initial members of the JSC are attached as Exhibit B. Each Party shall have sole discretion over the appointment of its JSC Members including choice of appointees and length of service of each. Each Party may change its JSC Members by written notice to the other Party. Each Party shall appoint one of its JSC Members to act as a co-chairperson of the JSC and may change its designated co-chairperson from time to time upon written notice to the other Party. The JSC may change its size from time to time by mutual consent of the Parties, provided that the JSC shall consist at all times of an equal number of JSC Members of each Party.

(b) Consultancy Payments. JSC Members serving on behalf of a Party but who are not employees of that Party may receive consultancy payments for time and reasonable expenses incurred in the exercise of their responsibilities (each, a "Consultancy Payment"), but which payments shall not be part of the Development Budget. All Consultancy Payments shall be consistent with the fair market value of such services, and shall be reviewed through a mutually agreed process to ensure that such payments do not provide an improper inducement to the applicable JSC Member or create a conflict of interest. Neither Party shall directly pay the other Party's current or past JSC Members for the exercise of their responsibilities on the JSC or for any other consultancy arrangement during the Term. Any change to Consultancy Payments approved by the JSC after the Effective Date shall be subject to veto by (i) one senior executive officer of Baylor to be named by Baylor and (ii) one senior executive officer of Kuur to be named by Kuur, such veto to be exercised within thirty (30) days of such JSC approval.

(c) Alternate Members. If a JSC Member cannot attend a JSC Meeting, they may nominate an alternate person (such person, a "JSC Alternate Member") to serve in their capacity at a JSC Meeting via written notice (which notice can be sent by email) to the JSC co-chairpersons prior to the next scheduled JSC Meeting. The JSC Alternate Member's appointment to the JSC shall be limited to the single JSC Meeting for which notice has been given (unless such written notice specified that such JSC Alternate Member's appointment to the JSC will cover more than one JSC Meeting). Upon such person's appointment as a JSC Alternate Member, each such JSC Alternate Member shall execute a written agreement to be bound by the obligations of confidentiality under Article VIII of the Co-Development Agreement.

4.3 Meetings and Voting.

(a) Meetings. The JSC shall meet no less than four times per Fiscal Year on or around April 15, July 15, October 15, and January 15, or such other dates as unanimously agreed by the JSC, each a "JSC Meeting." Each JSC Meeting shall be conducted at a specific location or remotely, including by videoconference, teleconference or any other method as may be agreed by the JSC Members beforehand. Unless otherwise agreed by the Parties in writing, all information disclosed, discussed, and/or exchanged during a JSC Meeting shall be Confidential Information in accordance with Article VIII and each JSC Member, who is not otherwise bound by a confidentiality obligation covering this Agreement, shall execute an agreement to be bound by the obligations of confidentiality under Article VIII, the form of such agreement to be mutually agreed by the Parties. The co-chairpersons shall jointly prepare the agenda for each JSC meeting and shall circulate reasonably detailed minutes for each JSC meeting within fifteen (15) days following such meeting.

(b) Voting. Voting shall occur solely during JSC Meetings or Interim Voting Meetings (Section 4.3 (e)) at which at least one representative for each Party shall be present or actively participating remotely for a meeting of the JSC to take place and for any decision to be submitted to a vote (and all current JSC Members or JSC Alternate Member(s) are present or actively participating remotely, with any vacancies being disregarded for such quorum purposes). Each Party shall have collectively among its JSC Members (including any JSC Alternate Member(s)) one vote per issue upon which a vote is taken by the JSC as required or otherwise permitted under this Agreement, and if a decision of the JSC is required under this Agreement, the unanimous vote of the JSC is required. If a decision of the JSC is required but does not receive the unanimous vote of the JSC, then no action shall be taken.

(c) Resolution of Impasses. If a vote is taken, but is not unanimous (i.e., there is a deadlock), the JSC shall strive in good faith for the next fifteen (15) days to resolve such issue. If, after such fifteen (15)-day period, the JSC cannot reach consensus on such issue, then the JSC, may, if the JSC Members agree to consult within the next

thirty (30) days with an external advisor for non-binding advice related to the issue upon which such vote was taken. The expense for any external advisor shall be born equally by the Parties. If the JSC still cannot reach consensus on such issue after receiving advice from the external advisor, or the JSC cannot agree to seek such advice during such thirty (30) day period, or the JSC elects, in its discretion, to forego acquiring such advice from an external advisor, the JSC shall refer the matter to one senior executive officer of Baylor not serving as a current JSC Member to be named by Baylor and one senior executive officer of Kuur not serving as a current JSC Member to be named by Kuur or its Affiliates (as defined in the License and Option Agreement), who shall meet within thirty (30) days of the referral of such matter to such officers. Together, such senior officers shall have complete and sole authority to resolve the matter; provided, however, if the Parties' respective senior officers have not reached consensus on such matter (i.e., there is a deadlock) and such matter relates to any product that has completed a FIM Study, then Kuur shall have the final decision-making authority with respect to such matter.

(d) Interim Voting Meetings. The JSC may determine to meet via electronic or telephonic correspondence and vote on matters requiring action by the JSC during the interim period between regularly scheduled JSC Meetings (an "Interim Voting Meeting"). Any such Interim Voting Meeting shall take place via emailed notice to all JSC Members. The JSC co-chairpersons shall agree to call any Interim Voting Meeting prior to engaging the remaining JSC Members. Once the need to call an Interim Voting Meeting has been agreed by the JSC co-chairpersons, information on the matter requiring attention and voting by the JSC shall be distributed by emailed notice to the entire JSC Members. JSC Members will be provided with a deadline (which shall be a minimum of five (5) Business Days) by which they must communicate their vote to the JSC co-chairpersons in writing. Each Party shall have collectively among its JSC Members (including any JSC Alternate Member(s)) one vote per issue upon which a vote is taken during an electronic Interim Voting Meeting by the JSC as required or otherwise permitted under this Agreement, and if a decision of the JSC is required under this Agreement, the Parties shall endeavor to reach such decision by consensus. Any and all information disclosed, discussed, or exchanged during the course of such an electronic Interim Voting Meeting shall be Confidential Information in accordance with Article VIII. One of the co-chairpersons shall circulate the outcome of the issue to all JSC Members in writing within twenty-four (24) hours of the voting deadline. The matter requiring an Interim Voting Meeting shall be documented and incorporated into the minutes of the next regularly scheduled JSC meeting.

4.4 Development Plan.

(a) Development Plan Contents. The Development Plan shall detail the activities between Baylor and Kuur, including any ongoing or planned Work Plans or SICRAs involving Baylor, and any other matters deemed pertinent by the Parties.

(b) Development Plan Progress and Results. At least ten (10) Business Days prior to each scheduled JSC meeting, each Party shall provide the other Party with a report of its current and planned activities and results under the Development Plan. Each Party shall provide the other Party's JSC Members with such further information regarding such activities and results as they may reasonably request.

(c) Development Plan Review. The JSC shall review the Development Plan at each JSC Meeting for its scientific, medical, technical, and commercial merit in view of developments over at least the then most recent twelve (12) calendar months. The JSC may modify the Development Plan. It is anticipated that the Development Plan shall be updated in accordance with this subsection (b) to address the integration of Future Products (if any) and Future Technology (if any).

(d) Development Budget.

(i) Review and Modification. The JSC shall review the Development Budget at each JSC Meeting for its commercial and fiscal merit in view of the Development Plan and prior budget amounts, actual prior expenditures, market conditions, and planned future activities and expenditures. The JSC may modify the Development Budget (including the Allocated Amounts and Unallocated Amounts), subject to the Annual Kuur Commitment. For the avoidance of doubt, the JSC has no authority (1) to increase the Annual Kuur Commitment which may only be increased by the written agreement of an authorized officer of Kuur or (2) to decrease the Annual Kuur Commitment which may only be decreased by the written agreement of an authorized officer of Baylor.

(ii) Spending Unallocated Amount. Either Party (through its JSC Members or otherwise) may present to the JSC a proposal for the use of all or a portion of the Unallocated Amount for the conduct of research and development of Licensed Products, Licensed Technology, Future Products or Future Technology. The Development Plan and Budget shall be amended by the JSC to include the approved activities and associated approved budgeted amounts, and such budgeted amounts shall be included in the Allocated Amounts going forward. Any portion of the Unallocated Amount unspent at the end of a Fiscal Year shall be added to the Unallocated Amount for the next Fiscal Year (the "Added Amount").

4.5 Limitations. The JSC shall not, and shall not have the authority to, waive or modify any right or obligation of either Party under this Agreement. Nothing in this Agreement or the License and Option Agreement shall obligate a Party to enter into an agreement with any Third Party and the JSC shall not have the authority to cause, compel or in any way require a Party to enter into an agreement with any Third Party.

4.6 Termination of JSC. The JSC shall terminate at the end of the Development Term.

ARTICLE V
RESEARCH & DEVELOPMENT ACTIVITIES; KEY PERSON

5.1 General. Without, for the avoidance of doubt, limiting Kuur's right to elect to undertake Early R&D Activities as set forth in Section 2.1 of this Agreement, (a) the Parties intend that, to the extent reasonably practicable, all Early R&D Activities shall be conducted pursuant to Work Plans and/or SICRAs, each as described in the Development Plan and funded by the Development Budget; and (b) the Parties intend that all work pursuant to the Development Plan be undertaken in a cost-effective and time-efficient manner, such that, if the JSC agrees that a Third Party is substantially more qualified and equipped to undertake such work, then the work may be outsourced to such Third Party. Either Party shall have right to suggest alternative procurement sources for specific Projects or portions thereof, and the award of such work will be made by the JSC based on an objective review of capabilities and costs for such work.

5.2 Key Person.

(a) Time Commitment and Responsibilities. In recognition of each Key Person's key role in development of Core Subject Technology and Future Technology under the Development Plan, Baylor shall designate such portion of each Key Person's working hours to be spent directly planning, organizing, performing, managing, or directing the Projects or other activities applicable to such Key Person under the Development Plan or enhancements or modifications thereof or otherwise performing research, development, and collaboration activities under this Agreement necessary to timely complete the Projects under the Development Plan. Baylor shall take such commercially reasonable steps as necessary to adapt any of the Key Person's other employment responsibilities to accommodate such designation of working hours. Baylor shall also provide administrative support for each Key Person in accordance with Section 2.3.

(b) Alternate Key Person.

(i) Baylor shall notify Kuur in writing within ten (10) days if a Key Person leaves the employment of Baylor or becomes unwilling or unable to fulfill the role assigned to such Key Person under Section 5.2(a) or the applicable Work Plan.

(ii) At its sole discretion, Baylor may include with any notice under Section 5.2(b)(i) the name and qualifications of another Baylor employee of similar rank and experience to take over the role assigned to such Key Person ("Baylor's Proposed Alternate Key Person").

(iii) Kuur shall have twenty (20) days from its receipt of Baylor's notice under Section 5.2(b)(ii) to notify Baylor in writing of Kuur's decision to either (1) accept Baylor's Proposed Alternate Key Person, whereupon Baylor's Proposed Alternate Key Person shall become the new Key Person, or (2) decline Baylor's Proposed Alternate Key Person.

(c) Transfer of Development Plan Activities. If Baylor does not propose an Alternate Key Person under Section 5.2(b)(ii) or if Kuur declines Baylor's Proposed Alternate Key Person, the Parties shall meet to discuss in good faith what elements of the Development Plan are likely to be impacted by the Key Person's withdrawal substantially and negatively (each such element, a "Key Person Negatively Impacted Development Plan Activity"). Kuur shall have the right, in its sole discretion, to transfer each Key Person Negatively Impacted Development Plan Activity to another research organization of its choice or to itself (upon transfer, a "Key Person Transferred Development Plan Activity"). Kuur may, at its discretion, deduct from the then-current Quarterly R&D Payment(s) the remaining Allocated Amount(s) designated in the Development Budget for each such Key Person Transferred Development Plan Activity, such deduction to be divided equally among the remaining Quarterly R&D Payments for the period over which such Key Person Transferred Development Plan Activity will be conducted. For the avoidance of doubt, Kuur shall retain its Option associated with such Key Person Transferred Development Plan Activity following transfer to itself or another research organization.

5.3 Reporting; Data Package.

(a) Quarterly Reports. Within at least fifteen (15) days before each scheduled JSC Meeting, each Party shall provide the other Party with a detailed written report setting forth all activities under any ongoing Work Plans or SICRAs undertaken by (or overseen by) such Party, pursuant to the Development Plan since the last held JSC Meeting on a Project-by-Project basis, and all data and results therefrom. The reporting Party shall promptly provide such additional information regarding such activities to the other Party as such other Party reasonably requests.

(b) Delivery of Data and Results under Completed Work Plans. For completed Work Plans, Baylor shall provide to Kuur: (i) the experimental information, resultant data and reports agreed to in such Work Plan, and (ii) a final report of all data, results and analyses obtained and performed under such Work Plan within sixty (60) days of the completion of all work under such Work Plan or its earlier termination.

(c) Delivery of Data and Results under SICRAs. For SICRAs to which Baylor is a party, Baylor shall provide to Kuur: within fifteen (15) days from the beginning of each Calendar Quarter, a detailed written report setting forth the activities undertaken by (or overseen by) Baylor during the prior Calendar Quarter in connection with each SICRA, and all data and results therefrom, and including at least all safety, pharmacokinetic, correlative and efficacy data, and formatted to provide both interval and cumulative data, and such additional information regarding such activities undertaken by (or overseen by) Baylor in connection with each SICRA to Kuur, as Kuur reasonably requests) (provided, however, that, unless otherwise requested by Kuur, and other than references thereto in the reports, the SICRA quarterly reports to be provided under this Section do not need to include the actual data or other information that is available for Kuur to access through Baylor's electronic case report form (referred to by Baylor as "OnCore") reporting system (the "Oncore Reporting System") to the extent that Kuur can access, download and obtain copies of all such data and other information at any time and it is available as of the submission date of the report(s). Baylor shall ensure that all patient data arising in connection with each such clinical study shall be entered into the OnCore Reporting System within thirty (30) days of each such patient's visit or Baylor's receipt of the patient data.

(d) Monthly Clinical Trial Updates. Baylor shall provide to Kuur on a monthly basis a short (e.g., less than one page per study) summary for each clinical study that will include an interval and cumulative listing of the number of (1) patients enrolled, (2) products manufactured, (3) patients treated, (4) patients on study, (5) patients withdrawn early, (6) patients completing study, (7) any serious adverse events, (8) any expedited safety reports, and (9) deaths on study (and such additional information regarding such activities undertaken by (or overseen by) Baylor in connection with each such clinical trial, as Kuur reasonably requests). Baylor shall ensure that all patient data arising in connection with each such clinical study shall be entered into the OnCore Reporting System (defined in Section 5.3(b)) within thirty (30) days of each such patient's visit.

(e) Delivery of Data Package. Within thirty (30) days following the Completion of a FIM Study (with respect to which Baylor conducted activities or provided oversight), or such other time period as the Parties may agree in writing with respect to such FIM Study, Baylor shall deliver to Kuur the Data Package for such FIM Study, and shall promptly provide to Kuur such additional information regarding such FIM Study and Data Package as Kuur reasonably requests.

(f) Project Reports, Data and Results Provided to Kuur. Without limiting the generality of the foregoing in this Section 5.3, with respect to the reports, data and results to be provided to Kuur under this Section 5.3 (or elsewhere in this Agreement) with respect to any Early R&D Activities or otherwise, all such reports, and all data and results from such Early R&D Activities, shall be provided by Baylor to Kuur with respect to any Early R&D Activities conducted by Baylor under a Work Plan or a SICRA where Baylor is a party thereto, including on a Project-by-Project basis, in Baylor's standard format which shall include, without limitation, methods, results and conclusion sections and such reports should be signed and dated by the investigator and provide sufficient detail such that a trained person with only superficial knowledge of the Project will be able to interpret the data and results. For the avoidance of doubt, Baylor acknowledges and agrees to provide Kuur with access to, and copies of, all reports, data and results arising from the Early R&D Activities conducted by (or overseen by) Baylor.

(g) Form of Data Packages and Reports. Each of the reports and Data Packages delivered pursuant to this Section 5.3 shall be uploaded via an online portal established by the Parties and prepared in accordance with the format determined by the JSC from time to time.

5.4 Unperformed Early R&D Activities.

(a) *Notice*.

(i) Baylor shall notify Kuur in writing within thirty (30) days if it determines that it expects to be unable to, or has not performed one or more of its assigned material Early R&D Activities under the Development Plan in accordance with the time frame and other performance metrics for such activity set forth agreed to by the JSC.

(ii) Kuur shall provide written notice to Baylor that Baylor has not performed, or appears reasonably likely to be unable to perform one or more of its assigned Early R&D Activities in accordance with the time frame and other performance metrics for such activity agreed to by the JSC.

(iii) For the avoidance of doubt, notice under Section 5.4(a)(i) shall not be required for Baylor's JSC Members to, nor in any way restrict Baylor's JSC Members ability to, request, advocate, and vote for changes to the Development Plan.

(iv) Subject to Section 5.4(b), upon Kuur's receipt of such written notice under Section 5.4(a)(i) or Baylor's receipt of such written notice under Section 5.4(a)(ii) (as applicable), and if Baylor does not cure such failure to Kuur's reasonable satisfaction within 60 days of the earlier of (1) the occurrence of such failure or (2) the date of such notice, Kuur shall have the right to transfer solely such material, non-performed Early R&D Activities to another research organization, or to itself. For clarity, the transfer of any Early R&D Activities under this Section 5.4(a)(iv) will not affect any Option granted to Kuur under the License and Option Agreement associated with such Early R&D Activities or, for clarity, limit Kuur's rights under Section 2.1.

(b) *Experimental Nature*. Kuur acknowledges and agrees that Early R&D Activities are experimental in nature and no specific result or experimental end point can be assured. Accordingly, performance of Early R&D Activities without achieving a desired result or experimental end point shall not alone constitute a failure to perform any material Early R&D Activity and shall not give rise to any right to transfer such Early R&D Activities under Section 5.4(a)(iv).

5.5 Third Party Enabling Technology. Baylor and Kuur each shall notify the JSC of any Third Party Enabling Technology identified by it, and which it recommends be used in connection with, or incorporated into, any Project, Licensed Product or Future Product. If the JSC determines that such Third Party Enabling Technology is appropriate for use in the conduct of the Development Plan with respect to a given Project, Licensed Product or Future Product, then Baylor and Kuur shall discuss such issue, and determine in good faith which of the Parties is best suited to pursue acquiring such Third Party Enabling Technology and, if an agreement is reached, such Party shall use Commercially Reasonable Efforts to acquire an appropriate license to such Third Party Enabling Technology, with the right to sublicense to the other Party as needed for such other Party to perform its rights and obligations under this Agreement and the License and Option Agreement (each, a "Third Party Enabling License"). The costs (other than royalties) of such Third Party Enabling License that are directly attributable to the conduct of the Development Plan shall be paid

from the Annual Oncology Commitment or Annual Non-Oncology Commitment, as applicable. To the extent any royalties are due under such Third Party Enabling License, and such royalties are paid by Kuur, it shall have the right to deduct such royalties from the royalties owed to Baylor for the applicable Licensed Product, as and to the extent set forth in Section 5.13 of the License and Option Agreement. For the avoidance of doubt, it shall be reasonable for Baylor to decline to enter into any agreement that would require Baylor to incur out-of-pocket expenses.

ARTICLE VI
RECORDS AND REGULATORY MATTERS

6.1 Financial Records.

(a) *Records*. Baylor shall use Commercially Reasonable Efforts to maintain complete and accurate records relating to its expenditures under the Development Budget, which records shall contain sufficient information to permit Kuur to confirm the accuracy of any reports delivered to Kuur with respect to the use of such funds and compliance in other respects with this Agreement. Baylor shall retain such records for at least three (3) years following the end of the Fiscal Year to which they pertain.

(b) *Audit by Kuur*. During the Development Term and for a period of two (2) years thereafter, Kuur or its representatives, upon reasonable written notice to Baylor, shall have the right, solely at Kuur's expense, no more than once each twelve (12) month period, and only once after the Development Term to inspect, during Baylor's regular business hours, Baylor's financial books and records relating to its expenditures under the Development Budget.

6.2 Scientific Records.

(a) *Records*. Baylor shall maintain complete, current and accurate records of all Early R&D Activities conducted by it hereunder and all data and other information, including, without limitation, laboratory notebooks, assay results and equipment readings, resulting from such activities in accordance with Applicable Laws. Such records shall reflect all work done and results achieved in the performance of the Early R&D Activities in good scientific manner appropriate for regulatory and patent purposes. Baylor shall maintain separate laboratory notebooks for all work conducted in connection with the Development Plan.

(b) *Audits*. During the Development Term and for a period of two (2) years thereafter, Kuur or its representatives, upon reasonable written notice to Baylor, shall have the right, solely at Kuur's expense, no more than once each twelve (12) month period, and only once after the Development Term to inspect, during Baylor's regular business hours, Baylor's scientific books and records relating to its activities under the Development Plan. During such audit, Baylor will permit Kuur's representatives to audit the work performed pursuant to the Development Plan and the facilities at which such work is conducted, to determine that Baylor is conducting or conducted such work in accordance with the terms and conditions of this Agreement, that the Applicable Laws are being met, and that Baylor is providing adequate facilities and staffing. Kuur's failure to exercise its right to conduct an audit as described in this Section 6.2(b) shall not represent a waiver of any future exercise of this right or of any other rights under this Agreement, nor does it represent acceptance of any conditions past or present that might exist or result from such conditions at Baylor's facilities.

(c) *Access*. During the Development Term and thereafter, Kuur or its representatives shall have the right, upon reasonable written notice and during Baylor's regular business hours, to have access to and make copies of Baylor's books and records relating to its activities under the Development Plan in support of patent prosecution and defense and regulatory activities relating to the Licensed Products, Future Products, Licensed Technology and Future Technology, provided that if Kuur does not exercise its Option with respect to any Future Product or Future Technology, then Kuur's rights under this subsection (c) with respect to such Future Product or Future Technology shall expire contemporaneously with the expiration of such Option.

6.3 Regulatory Authority Inspections. If any Regulatory Authority requests access to Baylor's records, facilities and/or personnel, or conducts an unannounced inspection, in each case relating to the Development Plan or to any Licensed Product, Licensed Technology, Licensed Future Product (if any) or Licensed Future Technology (if

any), then Baylor will promptly notify Kuur by telephone (including voicemail) within twenty-four (24) hours followed by immediate written confirmation. Kuur will have the right to be present at any Regulatory Authority audit or inspection that relates to any Licensed Product, and, if time reasonably permits, to conduct a pre-inspection audit.

6.4 Regulatory Authority Communications. Baylor will provide Kuur with copies of all written communications received by Baylor from any Regulatory Authority relating to the Development Plan or to any Licensed Product, Licensed Technology, Licensed Future Product (if any) or Future Technology (if any) promptly upon Baylor's receipt thereof and, for verbal communications, shall provide Kuur with a written summary thereof promptly after such verbal communication. Baylor shall contemporaneously provide Kuur with a copy of any written communication from Baylor to a Regulatory Authority relating to the Development Plan or to any Licensed Product, Licensed Technology, Future Product or Future Technology. Where Baylor is required or intends to respond to any communication from a Regulatory Authority relating to the Development Plan or to any Licensed Product, Licensed Technology, Future Product or Future Technology, to the extent practicable, Baylor shall provide Kuur with a draft copy of such communication and the proposed response sufficiently in advance of the date that such response is to be submitted, in order to permit Kuur to review and comment upon such response. To the extent permitted by Applicable Laws, Baylor may, in its reasonable judgment, incorporate such Kuur comments into such response prior to submission. Kuur may review any adverse event data or reports for pharmacovigilance as part of its GCP and regulatory compliance.

6.5 Research Misconduct. Baylor shall immediately inform Kuur upon discovery of any potential misconduct by any individual or entity performing Early R&D Activities.

ARTICLE VII
OWNERSHIP AND RESERVATION OF RIGHTS

7.1 Baylor. Baylor shall retain and continue to solely own all rights, title and interest in and to all Technology owned or otherwise Controlled by Baylor existing as of the Effective Date, and any and all improvements, derivative works, and other derivations of any of the foregoing, and all Technology Rights in or to any of the foregoing, and all Marks and other intellectual property rights discovered, developed, invented, conceived of, reduced to practice or created solely by Baylor employees or contractors working on its behalf in the conduct of the Development Plan ("Baylor Property"). Baylor covenants that (a) it shall require all such employees and contractors to assign all right, title and interest in all such Technology Rights and other intellectual property rights to Baylor, and (b) ensure that such right, title and interest in all such Technology Rights and other intellectual property rights vest in Baylor. No right or license is or shall be deemed to be granted, expressly or implicitly, to or under any Baylor Property except solely for the licenses expressly granted in Sections 2.1, 2.2, and 2.3 of the License and Option Agreement. Baylor does not assign, transfer, or convey any right, title, interest, ownership, or co-ownership, or grant any lien or similar right, in or to any Baylor Property, or grant any right, claim, or expectation to Kuur to any such right, title, interest, ownership, co-ownership, lien, or similar right, or any license other than as expressly set forth in Sections 2.1, 2.2, and 2.3 of the License and Option Agreement, whether expressly or implicitly. If Baylor or any employee or contractor of Baylor owns or acquires an ownership interest in or to any Kuur Property in connection with this Agreement, Baylor agrees to assign, transfer, and convey, and Baylor hereby assigns, transfers, and conveys, and Baylor agrees to cause all such employees and contractors to assign, transfer, and convey, to Kuur all such interest, without any payment or right to any payment of any kind. Baylor shall, and shall cause such employees and contractors to, execute any document or take any reasonable action as requested by Kuur to effect any such assignment.

7.2 Kuur. Kuur shall retain and continue to solely own all rights, title and interest in and to all of the Technology owned or Controlled by Kuur existing as of the Effective Date, and any and all improvements, derivative works, and other derivations of any of the foregoing, and all Technology Rights in or to any of the foregoing, and all Marks and other intellectual property rights discovered, developed, invented, conceived of, reduced to practice or created solely by Kuur employees or contractors working on its behalf in the conduct of the Development Plan ("Kuur Property"). No right or license is or shall be deemed to be granted, expressly or implicitly, to or under any Kuur Property except solely for the licenses expressly granted in Section 3.7. Kuur does not assign, transfer, or convey any right, title, interest, ownership, or co-ownership, or grant any lien or similar right, in or to any Kuur Property, or grant any right, claim, or expectation to Baylor to any such right, title, interest, ownership, co-ownership, lien, or similar right, or any license other than as expressly set forth in Section 3.7, whether expressly or implicitly. If Kuur or any employee or contractor of Kuur owns or acquires any ownership interest in or to any Baylor Property in connection

with this Agreement, Kuur agrees to assign, transfer, and convey, and Kuur hereby assigns, transfers, and conveys, and Kuur agrees to cause all such employees and contractors to assign, transfer, and convey, to Baylor all such interest, without any payment or right to any payment of any kind. Kuur shall, and shall cause such employees and contractors to, execute any document or take any reasonable action as requested by Baylor to effect any such assignment.

7.3 Joint Property. The Parties shall jointly own all rights, title and interest in and to any and all improvements, derivative works, and other derivations of any Baylor Technology or Kuur Technology and all Marks and other intellectual property rights discovered, developed, invented, conceived of, reduced to practice or created jointly by Kuur employees or consultants working on its behalf and Baylor employees or consultants working on its behalf, in each case, in the conduct of the Development Plan ("Joint Property"). Except to the extent either Party is restricted by the licenses and options granted to the other Party under the License and Option Agreement, each Party shall be entitled to practice and exploit the Joint Property without the duty of accounting or seeking consent from the other Party, and each Party hereby consents to any further sublicensing of such Joint Property anywhere in the world, subject to the licenses granted under the License and Option Agreement. Kuur shall have the first right, but not the obligation, to file and prosecute patent applications claiming any Joint Property, at its expense and in consultation with Baylor, and Baylor shall cooperate reasonably with Kuur in connection therewith.

7.4 CREATE Act. It is the Parties' intention that this Agreement is a "joint research agreement" as that phrase is defined in 35 U.S.C. §102(c) as amended by the Cooperative Research and Technology Enhancement (CREATE) Act, including the provisions of 35 U.S.C. §102(b)(2)(c). The Parties agree to cooperate and to take reasonable actions to maximize the protections available for the Patent Rights covering the Licensed Technology, Future Oncology Technology or Future Non-Oncology Technology under such safe harbor provisions.

ARTICLE VIII
CONFIDENTIALITY AND NON-DISCLOSURE

8.1 Incorporation of Article XVII of License and Option Agreement. Article XVII of the License and Option Agreement (captioned "Confidentiality and Non-Disclosure") is hereby incorporated by reference *mutatis mutandis* into and made a part of this Agreement.

ARTICLE IX
WARRANTIES AND LIABILITY

9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that it has the authority to enter this Agreement, and the execution, delivery and performance of this Agreement by such Party has been duly and properly authorized by all necessary corporate actions, and this Agreement constitutes the valid and binding obligation of such Party, except as may be subject to applicable bankruptcy, insolvency, reorganization, arrangement or other similar laws relating to or affecting the rights of creditors generally and the availability of equitable remedies.

9.2 Baylor Representations and Warranties. Baylor represents and warrants that, as of the Effective Date:

(a) All Baylor employees and contractors that perform any Early R&D Activities under this Agreement shall be subject to Baylor's IP Policy including its obligation to assign all right, title and interest in any intellectual property arising from such Early R&D Activities to Baylor and to protect Confidential Information of Baylor and Kuur;

(b) Neither it nor any of its officials or employees have been convicted of a felony in any jurisdiction for conduct relating to the development or approval, including the process for development or approval, of any drug, product or medical device or otherwise relating to the regulation of any drug, product or medical device, including, without limitation, under the FD&C Act; and

(c) It has not been debarred under 21 U.S.C. § 335(a) or 335(b) or any foreign equivalent, nor disqualified as described in 21 CFR 812.119 or foreign equivalent.

9.3 Disclaimer. ALL RESULTS OBTAINED UNDER THE DEVELOPMENT PLAN ARE SUPPLIED "AS IS" "WHERE IS," AND OTHER THAN THE FOREGOING REPRESENTATIONS AND WARRANTIES IN SECTIONS 9.1 AND 9.2, BAYLOR MAKES NO, AND HEREBY DISCLAIMS ALL, WARRANTIES AND REPRESENTATIONS, EXPRESS, IMPLIED, AND STATUTORY, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, USEFULNESS, ANY PARTICULAR RESULT, NON-INFRINGEMENT, TITLE, OR WORKMANSHIP, OR THAT ANY ENFORCEABLE PROPRIETARY RIGHTS WILL ARISE FROM SUCH RESULTS.

9.4 EXCLUSION AND LIMITATION OF LIABILITY. EXCEPT FOR ANY OBLIGATION OF INDEMNITY OR BREACH OF, OR DEFAULT UNDER, ANY SUCH OBLIGATION OR ARTICLE VIII, AND EXCEPT FOR OR IN CONNECTION WITH ANY INFRINGEMENT OR MISAPPROPRIATION OF ANY OF THE OTHER PARTY'S INTELLECTUAL PROPERTY RIGHTS: (a) IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, PUNITIVE, SPECIAL, OR LIQUIDATED DAMAGES OF ANY KIND UNDER OR IN CONNECTION WITH ANY ACTION OR DISPUTE UNDER THIS AGREEMENT; AND (b) IF A PARTY IS LIABLE FOR ANY DAMAGES UNDER THIS AGREEMENT, THE TOTAL AND AGGREGATE DAMAGES FOR WHICH SUCH PARTY MAY BE LIABLE UNDER THIS AGREEMENT SHALL BE LIMITED IN THE AGGREGATE TO THE TOTAL AMOUNT OF THE QUARTERLY R&D PAYMENTS PAID BY KUUR TO BAYLOR UNDER ARTICLE III WITHIN TWENTY-FOUR (24) MONTHS PRIOR TO ASSERTING SUCH CLAIM FOR SUCH DAMAGES AND LOSSES. IN NO EVENT SHALL ANY EXCLUSION OR LIMITATION OF LIABILITY EXCLUDE OR LIMIT ANY FEE OR ROYALTY, OR ANY PART THEREOF, THAT IS DUE UNDER THIS AGREEMENT.

9.5 Indemnification.

(a) EACH PARTY SHALL NOTIFY THE OTHER OF ANY THIRD PARTY'S CLAIM, LAWSUIT OR OTHER PROCEEDING RELATED TO ANY EARLY R&D ACTIVITIES AND OTHER PERFORMANCE UNDER THIS AGREEMENT.

(b) KUUR AGREES THAT IT WILL DEFEND, INDEMNIFY AND HOLD HARMLESS BAYLOR AND ITS AFFILIATES AND THEIR RESPECTIVE FACULTY MEMBERS, SCIENTISTS, RESEARCHERS, EMPLOYEES, STUDENTS, OFFICERS, TRUSTEES AND AGENTS AND EACH OF THEM (THE "BAYLOR INDEMNIFIED PARTIES") FROM AND AGAINST, AND SHALL PAY BAYLOR THE MONETARY VALUE OF, ALL LIABILITIES AND LOSSES RELATED TO OR RESULTING FROM, DIRECTLY OR INDIRECTLY, ANY AND ALL THIRD PARTY CLAIMS, CAUSES OF ACTION, LAWSUITS OR OTHER PROCEEDINGS FILED OR OTHERWISE INSTITUTED AGAINST ANY OF THE BAYLOR INDEMNIFIED PARTIES TO THE EXTENT ARISING FROM (I) ANY NEGLIGENCE, RECKLESSNESS OR WILLFUL MISCONDUCT OF KUUR OR ANY OF ITS AFFILIATES, OR ANY OF THEIR OFFICERS, DIRECTORS, EMPLOYEES, OR AGENTS, IN CONNECTION WITH THIS AGREEMENT (REGARDLESS OF THE EXISTENCE OF, BUT NOT TO THE EXTENT OF, ANY CONTRIBUTORY OR COMPARATIVE NEGLIGENCE OF ANY BAYLOR INDEMNIFIED PARTIES), OR (II) ANY BREACH OF THIS AGREEMENT BY KUUR ("BAYLOR CLAIMS"), AND KUUR WILL ASSUME RESPONSIBILITY FOR ALL COSTS AND EXPENSES RELATED TO SUCH BAYLOR CLAIMS FOR WHICH IT IS OBLIGATED TO INDEMNIFY THE BAYLOR INDEMNIFIED PARTIES PURSUANT TO THIS SECTION 9.5(b), INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE; PROVIDED, HOWEVER, THAT THE INDEMNITY UNDER THIS SECTION 9.5(b) DOES NOT APPLY TO THE EXTENT ANY BAYLOR CLAIM ARISES FROM ANY NEGLIGENCE, RECKLESSNESS, OR WILLFUL MISCONDUCT OF A BAYLOR INDEMNIFIED PARTY OR ANY BREACH OF THIS AGREEMENT BY BAYLOR.

(c) BAYLOR AGREES THAT IT WILL DEFEND, INDEMNIFY AND HOLD HARMLESS KUUR AND ITS AFFILIATES AND THEIR RESPECTIVE DIRECTORS, OFFICERS, EMPLOYEES AND AGENTS AND EACH OF THEM (THE "KUUR INDEMNIFIED PARTIES") FROM AND AGAINST, AND SHALL PAY KUUR THE MONETARY VALUE OF, ALL LIABILITIES AND LOSSES RELATED TO OR RESULTING FROM, DIRECTLY OR INDIRECTLY, ANY AND ALL THIRD PARTY CLAIMS, CAUSES OF ACTION, LAWSUITS OR OTHER PROCEEDINGS FILED OR OTHERWISE INSTITUTED AGAINST ANY OF THE KUUR INDEMNIFIED PARTIES ("KUUR CLAIMS") TO THE EXTENT ARISING FROM (I) ANY

NEGLIGENCE, RECKLESSNESS OR WILLFUL MISCONDUCT OF BAYLOR OR ANY OF ITS AFFILIATES, OR ANY OF THEIR OFFICERS, DIRECTORS, EMPLOYEES, OR AGENTS, IN CONNECTION WITH THIS AGREEMENT (REGARDLESS OF THE EXISTENCE OF, BUT NOT TO THE EXTENT OF, ANY CONTRIBUTORY OR COMPARATIVE NEGLIGENCE OF ANY KUUR INDEMNIFIED PARTIES), OR (II) ANY BREACH OF THIS AGREEMENT BY BAYLOR ("KUUR CLAIMS"), AND BAYLOR WILL ASSUME RESPONSIBILITY FOR ALL COSTS AND EXPENSES RELATED TO SUCH KUUR CLAIMS FOR WHICH IT IS OBLIGATED TO INDEMNIFY THE KUUR INDEMNIFIED PARTIES PURSUANT TO THIS SECTION 9.5(c), INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE; PROVIDED, HOWEVER, THAT THE INDEMNITY UNDER THIS SECTION 9.5(c) DOES NOT APPLY TO THE EXTENT ANY KUUR CLAIM ARISES FROM ANY NEGLIGENCE, RECKLESSNESS, OR WILLFUL MISCONDUCT OF A KUUR INDEMNIFIED PARTY OR ANY BREACH OF THIS AGREEMENT BY KUUR.

(d) THE PARTY CLAIMING INDEMNITY UNDER SECTION 9.5(b) (IF BAYLOR OR A BAYLOR INDEMNIFIED PARTY) OR SECTION 9.5(c) (IF KUUR OR A KUUR INDEMNIFIED PARTY) (THE "INDEMNITEE") AGAINST THE OTHER PARTY (KUUR UNDER SECTION 9.5(b) OR BAYLOR UNDER SECTION 9.5(c)) (THE "INDEMNITOR") FOR A BAYLOR CLAIM (IF BAYLOR IS THE INDEMNITEE UNDER SECTION 9.5(b)) OR A KUUR CLAIM (IF KUUR IS THE INDEMNITEE UNDER SECTION 9.5(c)) (THE "INDEMNIFIED CLAIM") SHALL NOTIFY THE INDEMNITOR WITHOUT UNDUE DELAY IN WRITING OF ANY INDEMNIFIED CLAIM FOR WHICH IT SEEKS INDEMNITY HEREUNDER AGAINST THE INDEMNITOR AND COOPERATE REASONABLY WITH THE INDEMNITOR AT THE INDEMNITOR'S SOLE COST AND EXPENSE. THE INDEMNITOR SHALL PROMPTLY, AFTER BEING SO NOTIFIED, ASSUME THE DEFENSE OF SUCH INDEMNIFIED CLAIM WITH COUNSEL OF ITS CHOICE THAT IS REASONABLY SATISFACTORY TO THE INDEMNITEE. THE INDEMNITOR SHALL NOT SETTLE ANY INDEMNIFIED CLAIM WITHOUT THE INDEMNITEE'S PRIOR WRITTEN CONSENT UNLESS THE ONLY OBLIGATION AND LIABILITY OF, AND THE ONLY ADVERSE IMPACT ON, THE INDEMNITEE AND ITS INDEMNIFIED PARTIES IS A PAYMENT OBLIGATION INDEMNIFIED IN FULL BY THE INDEMNITOR. SUBJECT TO THE INDEMNITOR'S RIGHT TO CONTROL THE DEFENSE AND SETTLEMENT THEREOF, THE INDEMNITEE MAY PARTICIPATE IN AND OBSERVE THE PROCEEDINGS AT ITS OWN COST AND EXPENSE WITH COUNSEL OF ITS OWN CHOOSING.

ARTICLE X
TERM AND TERMINATION

10.1 Term. This Agreement shall commence on the Effective Date and shall continue unless and until terminated in accordance with Section 10.2.

10.2 Termination. This Agreement shall terminate in accordance with the following provisions, and with the effects set forth in Section 10.3:

(a) This Agreement continue until the fifth anniversary of the Second Restatement Effective Date ("Initial Termination Date"), unless earlier terminated pursuant to this Section 10.2, and shall automatically renew for additional five year periods unless either party delivers to the other Party written notice at least 365 days prior to the Termination Date stating its desire to terminate this Agreement as of the Termination Date. "Termination Date" shall mean the Initial Termination Date or the final date of any additional five year period pursuant to this Section 10.2(a), as applicable.

(b) This Agreement shall be co-terminus with the License and Option Agreement and shall terminate automatically, without need for any separate notice or action, upon the termination, expiration, or cancellation of the License and Option Agreement (regardless of any continuation or continued effect of any provisions specified therein as surviving the License and Option Agreement's termination, expiration, or cancellation, and further regardless of any continuation or continued effect of any Work Plan or Specific Industrial Clinical Research Agreement), except that to the extent the License and Option Agreement is terminated only in part, with respect to some but not all Licensed Products, this Agreement shall only terminate with respect to such terminated Licensed Products.

(c) Kuur shall have the right to unilaterally terminate this Agreement upon at least twelve (12) months prior notice, with such termination to be effective no earlier than the Initial Termination Date.

(d) In the event that a Party materially breaches this Agreement, the other Party may terminate this Agreement by giving sixty (60) days' advance notice in writing of such termination to such breaching Party identifying therein such material breach, which termination shall be effective at the end of such sixty (60) day period unless: (1) such breaching Party has remedied or cured such material breach before the end of such sixty (60) day period, or (2) such other Party has expressly revoked such notice of termination in a written notice of revocation to such breaching Party dispatched prior to the end of before the end of such sixty (60)-day period. However, and notwithstanding the foregoing, Baylor may terminate this Agreement solely with respect to a Distinct Product in the event of a material default or material failure by Kuur to perform any of the terms, covenants or provisions of this Agreement, including failure to make timely payment, and including a breach of its obligations under Section 2.6(a) of the License and Option Agreement regarding Baylor's Exclusive Academic Partner Early R&D Participation Rights (and provided such failure to comply was not due to the fault of Baylor or its employees or agents), with respect to such Distinct Product (a "Product-Related Breach"), unless Kuur, within sixty (60) days after delivery of written notice of termination by Baylor identifying such Product-Related Breach, cures such alleged Product-Related Breach.

(ii) Notwithstanding Section 10.2(c)(i), if:

(1) the same type of Product-Related Breach has occurred three (3) times or more with regard to such Distinct Product during the immediately preceding twelve (12) months and (B) Baylor has duly notified Kuur in writing of each such Product-Related Breach,

(2) but (A) Baylor has not given written notice of termination therefor, or (B) termination of this Agreement with respect to such Product Related Breach has been avoided by cure thereof , and

(3) Baylor can demonstrate that the pattern of such Product-Related Breaches (as cured by Kuur) is causing Baylor material and on-going harm,

then Kuur shall not have any further right to cure any further Product-Related Breaches.

(iii) The termination of this Agreement with respect to such Distinct Product shall be effective:

(1) at the end of such sixty (60)-day period if Kuur has the right to cure such Product-Related Breach and such Product-Related Breach is not cured within such sixty (60)-day period, provided that if Kuur initiates the dispute resolution proceedings under Article XI during such sixty (60)-day period, then the termination by Baylor shall not be effective unless and until (A) a final determination is made under Article XI that Kuur so committed such Product-Related Breach, and thereafter (B) Kuur then fails to cure such Product-Related Breach within sixty (60) days after such final determination, or

(2) upon written notice by Baylor if Kuur has no right to cure pursuant to Section 10.2(c)(i), provided that if Kuur initiates the dispute resolution proceedings under Article XI within thirty (30) days of receipt of such written notice by Baylor, then the termination by Baylor shall not be effective unless and until a final determination is made under Article XI whether the requirements of Section 10.2(c)(ii) have been met.

(e) Either Party may terminate this Agreement by written notice of termination to the other Party to be effective at the end of sixty (60) days after such other Party's receipt of such notice of termination in any of the following events, which event is identified in such written notice of termination: (i) if such other Party discontinues its business operations (including such portion of its business operations to which this Agreement relates) or takes steps to dissolve or cease to exist, unless such business operations are continued in the ordinary course or such steps cease and such other Party continues to exist in good standing within such sixty (60) day period, or (ii) if such other Party admits its inability to pay its debts as they become due unless such admission is revoked or rescinded within such sixty (60) day period, or (iii) files or is or becomes subject to a petition in bankruptcy (or similar reorganization proceeding) or makes a general assignment for the benefit of its creditors, or becomes subject to the appointment of a

receiver, unless such petition is dismissed, or such assignment or appointment revoked or rescinded, within such sixty (60) day period.

10.3 Effects of Termination.

(a) Within thirty (30) days of the effective date of termination of this Agreement in its entirety, Baylor shall return to Kuur the Unallocated Amounts (if any) in Baylor's possession existing as such effective date. For clarity, any portion of the Development Budget that is necessary for the funding of any Work Plan or Specific Industrial Clinical Research Agreement that will survive such termination pursuant to Section 10.3(c) shall be deemed to be an Allocated Amount.

(b) Upon the termination of this Agreement in its entirety, each Receiving Party shall promptly, with regard to any Confidential Information of the other Disclosing Party in the possession or control of such Receiving Party (other than that related to portions of this Agreement that do not terminate upon any such termination or that Kuur has the right to continue to use pursuant to the License and Option Agreement): (i) return, or cause the return, to the Disclosing Party (or, if and to the extent expressly requested by such Disclosing Party to such Receiving Party, irretrievably destroy or dispose of as directed by such Disclosing Party) all such Confidential Information, and (ii) irretrievably delete any electronic, digital or other copy or manifestation of such Confidential Information that remains in the possession or control of such Receiving Party after such return, destruction, or disposal of such Confidential Information (except for backup copies created in the normal course of such Party's business, but without the right to use any such backup copies). No such termination of this Agreement shall affect any obligations of the Parties, including payment obligations, due and payable prior to such date of termination.

(c) Any Work Plan and/or Specific Industrial Clinical Research Agreement that has been executed as of the effective date of any early termination of this Agreement and has not been terminated or expired in accordance with its terms shall remain in full force and effect, and Sections 2.2, 2.5, 2.6, 2.7, 2.8(c), 2.8(e), 2.9, 2.10, 2.11, 3.1, 3.2, 3.3, 3.7, 4.1, 4.2, 4.3, 4.5, 4.6, 5.3, 5.4, 9.3, 9.4, and 9.5, and Articles VI, VII, VIII and XI of this Agreement shall remain in effect with respect to such Work Plan and/or Specific Industrial Clinical Research Agreement.

10.4 Survival. The following provisions shall survive any expiration of this Agreement: Sections 3.6(b) (but Section 3.6(b) will not survive expiration or termination of the License and Option Agreement), 9.3, 9.4, 9.5, 10.3, and 10.4, and Article VI, Article VII, Article VIII, Article XI, and Article XII, and any other provisions of this Agreement that by their nature are necessary to survive the expiration or other termination of this Agreement shall survive the expiration or other termination of this Agreement.

ARTICLE XI
DISPUTE RESOLUTION

11.1 Amicable Resolution. The Parties shall attempt to settle any controversy between them and arising under this Agreement amicably. To this end, a senior executive from each Party shall consult and negotiate in good faith to reach a solution. The Parties agree that the period of amicable resolution shall toll any otherwise applicable statute of limitations. If the senior executives from each Party fail to meet, or if the matter remains unresolved, for a period of thirty (30) days from the date such controversy first was raised with the other party by notice delivered under Section 12.9, either Party shall have the right to seek to settle the controversy by binding arbitration pursuant to Section 11.2.

11.2 Arbitration.

(a) Subject to Sections 11.3 and 11.4, any dispute, controversy, or claim arising out of or relating to this Agreement, or the breach, termination or invalidity thereof, including claims for tortious interference or other tortious or statutory claims arising before, during or after termination, providing only that such claim touches upon matters covered by this Agreement, shall be finally settled by arbitration administered by the American Arbitration Association pursuant to the Commercial Arbitration Rules in force at the time of the commencement of the arbitration, except as modified by the specific provisions of this Agreement. It is the specific intent of the Parties that this

arbitration provision is intended to be the broadest form allowed by law. This agreement to arbitrate is intended to be binding upon the signatories hereto, their principals, successors, assigns, subsidiaries and Affiliates.

(b) The Parties agree that a final judgment on the arbitration award shall be binding, final and non-appealable other than for grounds to vacate the final award, and may be entered by any court having jurisdiction thereof.

(c) A panel of three arbitrators shall be appointed to conduct the arbitration, with each Party having the right to select one arbitrator, both of whom will agree on a third arbitrator to act as the chair of the panel. All three of such arbitrators shall be neutrals, i.e., having no affiliation with either Party.

(d) Each arbitrator must be an active or retired lawyer, having practiced actively in the field of commercial law and/or the law relevant to the subject matter of the arbitration, in each case, for at least fifteen (15) years.

(e) The law applicable to the validity of the arbitration clause, the conduct of the arbitration, including any resort to a court for provisional remedies, the enforcement of any award and any other question of arbitration law or procedure shall be the Federal Arbitration Act. The New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards of June 10, 1958 shall govern any and all disputes that may be the subject of arbitration pursuant to this Agreement.

(f) The arbitrator(s) shall hear and determine any preliminary issue of law asserted by a Party to be dispositive of any claim, in whole or part, in the manner of a court hearing a motion to dismiss for failure to state a claim or for summary judgment, pursuant to such terms and procedures as the arbitrator(s) deems appropriate.

(g) The Parties and the arbitrator(s) shall treat all aspects of the arbitration proceedings, including without limitation discovery, testimony and other evidence, briefs and the award, as strictly confidential. Further, except as may be required by law, neither Party nor the arbitrator(s) may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties.

(h) The seat of arbitration shall be New York, New York, USA.

(i) The arbitration shall be conducted in the English language. All submissions shall be made in English or with an English translation. Witnesses may provide testimony in a language other than English, provided that a simultaneous English translation is provided. Each Party shall bear its own translation costs.

11.3 Injunctive Relief. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction, at any time, in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the resolution of any dispute hereunder.

11.4 Construction and Jurisdiction. This Agreement shall be deemed to be subject to, and have been made under, and shall be construed and interpreted in accordance with the laws of the State of New York. No conflict-of-laws rule or law that might refer such construction and interpretation to the laws of another state, republic, or country shall be considered.

11.5 JSC Disputes. Disputes among the JSC shall not be subject to Section 11.2, and shall be resolved solely as set forth in Section 4.3(c).

ARTICLE XII
MISCELLANEOUS

12.1 Use of Names.

(a) Kuur agrees that it shall not use in any way the name of "Baylor College of Medicine" or any logotypes or symbols associated with Baylor or any marks confusingly similar thereto or the names of any of the scientists or other researchers at Baylor without the prior written consent of Baylor.

(b) Notwithstanding Section 12.1(a), Kuur shall have the right: (a) as required by applicable Law, to refer to Baylor as its licensor and to this Agreement and its related agreements in a factual manner, it being expressly understood that Kuur shall have the right to so refer to Baylor as its licensor and to this Agreement in connection with its IPO, as required by applicable Law and/or any securities exchange on which it lists its shares in such IPO, or in connection with subsequent public filings as required under applicable Law or such securities exchanges; and (b) to make appropriate attribution to Baylor as a source of data in keeping with good scientific practice. Nothing in this Section 12.1(b) shall relieve Kuur of its obligations under Article VII with respect to the material with which such use of Baylor's name is associated.

(c) Baylor shall have the right, as required by applicable Law, to refer to Kuur as its licensee and to this Agreement and its related agreements in a factual manner, it being expressly understood that, Baylor shall also have the right to so refer to Kuur as its licensee and to this Agreement in connection with connection with its submissions regulatory, tax, and/or grant authorities. Nothing in this subsection (c) shall relieve Baylor of its obligations under Article VIII with respect to the material with which such use of Kuur's name is associated.

12.2 Independent Contractors. The Parties hereby acknowledge and agree that each is an independent contractor and that neither Party shall be considered to be the agent, representative, master or servant of the other Party for any purpose whatsoever, and that neither Party has any authority to enter into a contract, to assume any obligation or to give warranties or representations on behalf of the other Party. Nothing in this relationship shall be construed to create a relationship of joint venture, partnership, fiduciary or other similar relationship between the Parties.

12.3 Assignment; Change of Control. Neither Party may assign or otherwise transfer this Agreement or any of its rights or obligations hereunder (either in whole or in part) to any person without the prior written consent of the other Party, or delegate any of its rights or obligations hereunder. Notwithstanding the foregoing, however, Kuur may delegate any of its rights or obligations hereunder and may assign or otherwise transfer this Agreement and its rights and obligations hereunder, either in whole or in part, without Baylor's consent: (a) in connection with any Change of Control, or the transfer or sale of all or substantially all of the assets, or the business of, Kuur to which this Agreement relates, or (b) to any Affiliate (and, for clarity, to a New Kuur Group Topco); so long as Kuur gives Baylor prompt notice of such action and the assignee or successor entity or Affiliate, as the case may be, acknowledges its consent and agreement to the terms of this Agreement and the License and Option Agreement (and, if and as applicable all Work Plans and SICRAs in effect at such time) in writing before such assignment; and so long as such action is not entered into solely to satisfy creditors of Kuur. This Agreement shall be binding upon and shall inure to the benefit of the Parties and each of their respective successors, legal representatives and assignees. Any attempted assignment or other transfer of this Agreement not effected in accordance with this Article XII shall be null and void.

12.4 Contract Interpretation**.** All references in this Agreement to Articles, Sections, Exhibits, Appendices or Schedules shall, unless otherwise expressly stated herein, mean the relevant sections, articles, exhibits, appendices or schedules to this Agreement, and the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any exhibits, appendices or schedules attached hereto). The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof. Where this Agreement states that a party "shall," "will," or "must" perform in some manner or otherwise act or omit to act, it means that the party is legally obligated to do so in accordance with this Agreement. Unless the context otherwise clearly requires, whenever used in this Agreement: (a) the words "include", "includes" or "including" shall be construed as incorporating also the phrase "but not limited to" or "without limitation"; (b) the word "or" includes the conjunctive and the disjunctive (i.e., "and/or"), (c) the words of any gender

include the other gender, and (d) words using the singular or plural number also include the plural or singular number, respectively. Any reference to a statute is deemed also to refer to any amendments or successor legislation as in effect at the relevant time. All references to dollars, cash or "$" mean U.S. dollars. Any reference to a Contract or other document as of a given date means the Contract or other document as amended, supplemented and modified from time to time through such date. The term "sublicensee" used herein means an Affiliate Sublicensee and/or a Third Party Sublicensee unless otherwise expressly stated herein.

12.5 Entire Agreement. The terms and conditions herein as well as those of the License and Option Agreement, constitute the entire agreement between the Parties and shall supersede all previous agreements, whether electronic, oral or written, between the Parties hereto with respect to the subject matter hereof and thereof. No agreement of understanding bearing on this Agreement shall be binding upon either Party hereto unless it shall be in writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement. Electronic communication between the Parties shall not constitute an agreement of understanding, unless it is subsequently reduced to writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement.

12.6 Non-Waiver. The Parties covenant and agree that if a Party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a Party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such Party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a Party except by its written consent.

12.7 Severability. The Parties hereby agree that neither Party intends to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries, and that if any word, sentence, paragraph or clause or combination thereof of this Agreement is found, by a court or executive body with judicial powers having jurisdiction over this Agreement or any of the Parties hereto, in a final, unappealable order to be in violation of any such provision in any country or community or association of countries, such words, sentences, paragraphs or clauses or combination shall be inoperative in such country or community or association of countries, and the remainder of this Agreement shall remain binding upon the Parties hereto. In lieu of such inoperative words, sentences, paragraphs or clauses, or combination of clauses, there will be added automatically as part of this Agreement, a valid, enforceable and operative provision as close to the original language as may be possible which preserves the economic benefits to the Parties.

12.8 Force Majeure. No liability hereunder shall result to a Party by reason of delay in performance caused by force majeure, that is circumstances beyond the reasonable control of the Party, including, without limitation, acts of God, fire, flood, war, terrorism, civil unrest, labor unrest, or shortage of or inability to obtain material or equipment.

12.9 Notices. All notices, demands or other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given: (a) when delivered personally to the recipient, to the address set forth below, if sent to the recipient by reputable express courier service (charges prepaid), or mailed to the recipient by certified or registered mail, return receipt requested and postage prepaid, or (b) when sent to the recipient by electronic mail to the electronic mail address set forth below and the recipient has confirmed receipt of such electronic mail. Such notices, demands and other communications shall be sent to the Parties at the addresses indicated below:

If to Baylor:

Baylor College of Medicine
One Baylor Plaza
Cullen Building,
Suite 106A
Houston, Texas 77030
United States of America
Attn: Robert F. Corrigan

If to Kuur:

Cell Medica, Inc. (d/b/a Kuur Therapeutics)
6200 Savoy Dr, #1200
Houston, Texas 77036
United States of America
Attn: Daniel Lang, M.D.

With copy (which shall not constitute notice) to:

Norton Rose Fulbright US LLP
1301 McKinney
Suite 5100
Houston, Texas 77010
United States of America
Attn: William Davis, II

With copy (which shall not constitute notice) to:

Hogan Lovells US LLP
609 Main St., Suite 4200
Houston, Texas 77002
Attn: Melinda Lackey
Email: [*]

12.10 Counterparts. The Parties may execute this Agreement in multiple counterparts, each of which constitutes an original as against the Party that signed it, and all of which together constitute one agreement. This Agreement is effective upon delivery of one executed counterpart from each Party to the other Party. The signatures of the Parties need not appear on the same counterpart. The delivery of signed counterparts by facsimile or email transmission that includes a copy of the sending Party's signature is as effective as signing and delivering the counterpart in person.

12.11 Effect of Restatement. The Parties agree that this Second Restated Co-Development Agreement supersedes and replaces the First Restated Co-Development Agreement from and after the Second Restatement Effective Date. Notwithstanding the foregoing, the terms of the First Restated Agreement shall continue to apply with respect to matters that occurred prior to the Second Restatement Effective Date, and the Original Agreement shall continue to apply with respect to matters that occurred prior to the First Restatement Effective Date.

Signature Page Follows

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement in multiple originals by their duly authorized officers and representatives on the respective dates shown below.

CELL MEDICA, INC.	BAYLOR COLLEGE OF MEDICINE
Name: /s/ Daniel Lang Daniel Lang, M.D.	Name: /s/ Michael B. Dilling Michael B. Dilling Ph.D., CLP
Title: President	Title: Director, Baylor Licensing Group
Date: October 13, 2021	Date: October 12, 2021

[*Signature Page to the Second Amended and Restated Co-Development Agreement*]

Exhibit A-1

Intentionally Omitted

Exhibit A-1-1

Exhibit A-2

Form of Third Party Specific Industrial Clinical Research Agreement

The form of the Third Party Specific Industrial Research Agreement is to be provided by the Parties.

*** * * * ***

Exhibit B

JSC Members

The initial JSC Members of the JSC as of the Effective Date are set out below:

Baylor:
[*]

Kuur:

[*]

Each of the individuals named above may attend a meeting of the JSC at the discretion of the nominating party; *provided* that no more than five individuals designated by a party may attend any individual JSC meeting.

*** * * * ***

Exhibit 10.72

Certain information in this exhibit is marked [*] has been excluded from the exhibit because it is both (i) not material, (ii) is the type that the company treats as private or confidential, and (iii) would be competitively harmful if publicly disclosed.

EXECUTION VERSION CONFIDENTIAL

SECOND AMENDED AND RESTATED

EXCLUSIVE LICENSE AND OPTION AGREEMENT

BY AND BETWEEN

BAYLOR COLLEGE OF MEDICINE

AND

CELL MEDICA, INC.

(d/b/a KUUR THERAPEUTICS)

Original Effective Date: APRIL 29, 2016

First Restatement Effective Date: FEBRUARY 28, 2020

Second Restatement Effective Date: October 12, 2021

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SECOND AMENDED AND RESTATED
EXCLUSIVE LICENSE AND OPTION AGREEMENT

This Second Amended and Restated Exclusive License and Option Agreement (the "Second Restated Agreement" or "Agreement" herein), effective as of **October 12, 2021** (the "Second Restatement Effective Date"), is by and between Baylor College of Medicine ("Baylor"), a Texas nonprofit corporation having its principal place of business at One Baylor Plaza, Houston, Texas 77030, and Cell Medica Inc., doing business as Kuur Therapeutics, a Texas corporation with its principal place of business at 6200 Savoy Dr., #1200, Houston TX 77036 ("Kuur", collectively the "Parties", individually, a "Party.") As of the Second Restatement Effective Date, this Second Restated Agreement amends and restates that certain Amended and Restated Exclusive License and Option Agreement (the "First Restated Agreement"), entered into on February 28, 2020, (the "First Restatement Effective Date") by Baylor and Kuur Therapeutics Ltd. (formerly known as Cell Medica Ltd.), and as assigned by Kuur Therapeutics Ltd. to Cell Medica Inc. on August 26, 2020, which First Restated Agreement amended and restated that certain Exclusive License and Option Agreement dated April 29, 2016, (the "Original Effective Date"), as amended by that certain First Amendment dated May 26, 2017, that certain Second Amendment dated December 5, 2017, that certain Third Amendment dated May 17, 2018, that certain Fourth Amendment dated December 19, 2018, and that certain Fifth Amendment dated September 27, 2019 (collectively, the "Original Agreement").

WHEREAS, Baylor's mission is to advance human health through the integration of education, research, patient care and community service;

WHEREAS, Baylor owns or controls Core Subject Technology and Core Patent Rights in the Field;

WHEREAS, pursuant to the First Restated Agreement, Baylor has granted and Kuur has received from Baylor a royalty bearing, worldwide, exclusive license under the Core Subject Technology and Core Patent Rights in the Field, with certain options to extend the scope of the license under the terms set forth herein;

WHEREAS, Baylor owns or controls Future Oncology Technology and Patent Rights thereto in the Field;

WHEREAS, Future Oncology Products may be discovered, developed or otherwise arise under and/or embody Future Oncology Technology;

WHEREAS, pursuant to the First Restated Agreement, Baylor has granted and Kuur has received from Baylor an exclusive option to obtain a royalty bearing, worldwide, exclusive license under the Future Oncology Technology and Patent Rights thereto in the Field to research, develop, commercialize, and manufacture such Future Oncology Products;

WHEREAS, Baylor owns or controls Future Non-Oncology Technology and Patent Rights thereto Outside the Field;

WHEREAS, Future Non-Oncology Products may be discovered, developed or otherwise arise under and/or embody Future Non-Oncology Technology;

WHEREAS, pursuant to the First Restated Agreement, Baylor has granted and Kuur has received from Baylor an exclusive option to obtain a royalty bearing, worldwide, exclusive license under the Future Non-Oncology Technology and Patent Rights thereto Outside the Field to research, develop, commercialize, and manufacture such Future Non-Oncology Products;

WHEREAS, Baylor and Kuur Therapeutics Ltd. have also entered into the that certain Co-Development Agreement dated April 29, 2016, as amended by that certain First Amendment dated July 12, 2017 and that certain Second Amendment dated February 28, 2019 (collectively, the "Original Co-Development Agreement"), as amended and restated on February 28, 2020, and as assigned from Kuur Therapeutics Ltd. to Cell Medica Inc. on August 26, 2020 (the "First Restated Co-Development Agreement"), for the collaborative development of Core Subject Technology, Future Oncology Technology and Future Non-Oncology Technology, and such Future Oncology

Products and Future Non-Oncology Products as Kuur may opt to license under the terms set forth herein, such collaborative development subject to the terms set forth in the First Restated Co-Development Agreement; and

WHEREAS, Baylor and Kuur have also, concurrent with the execution of this Second Restated Agreement, amended and restated certain terms of the First Restated Co-Development Agreement in its entirety as set forth in the first restated Original Co-Development Agreement which was executed on an even date with the First Restated Agreement (the "Second Restated Co-Development Agreement" or the "Co-Development Agreement" herein); and

WHEREAS, Baylor and Kuur desire to amend and restate certain terms of the First Restated Agreement in its entirety as set forth in this Second Restated Agreement.

NOW, THEREFORE, for and in consideration of the promises and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto expressly agree as follows:

ARTICLE I
DEFINITIONS AND CONSTRUCTION

1.1 General Definitions. As used in this Agreement the following capitalized terms (whether used in the singular or plural) not defined elsewhere in this Agreement shall have their respective meanings as set forth in this Section 1.1. Additional terms are defined in Section 1.2. Capitalized terms not otherwise defined in this Agreement shall have the meaning provided in the Co-Development Agreement.

"Affiliate" means, with respect to a Party, any corporation, partnership, joint venture or other entity which, directly or indirectly, controls such Party, is controlled by such Party or is under common control with such Party. For the purpose of this definition of "Affiliate," the terms "controls," "controlled by," and "under common control with" means (a) having the actual, present capacity to elect a majority of the directors or other governing body of an entity; or (b) having the power to direct at least fifty percent (50%) of the voting rights entitled to elect directors or other governing body.

1.1 "Affiliate Sublicensee" means any Affiliate of Kuur to which Kuur grants a sublicense under any of the licenses granted to Kuur by Baylor under this Agreement to one or more of any of the Licensed Products pursuant to a sublicense agreement to which such Affiliate sublicensee of Kuur and/or Kuur and/or any other Affiliate of Kuur is a party, in accordance with Article VIII.

"Antigen Option" has the meaning given in Section 4.1.

"Applicable Laws" means all applicable federal, state and local laws, rules, and regulations. Applicable Laws include, without limitation, relevant provisions of the U.S. FD&C Act, GCP, GLP, GMP and Privacy Laws.

"Calendar Year" means a period of one year beginning on January 1 and ending on the next December 31.

"CAR" means a chimeric antigen receptor.

"Kuur Successor" means the surviving entity under the definition of Change of Control clause (a), the acquiring party or group under the definition of Change of Control clause (b) and/or the Third Party buyer under the definition of Change of Control clause (c).

"Change of Control" means the occurrence of any of the following events: (a) any consolidation or merger of Kuur with or into any other entity in which the holders of Kuur's outstanding voting securities immediately before such consolidation or merger do not, immediately after such consolidation or merger, retain securities representing a majority of the voting power of the surviving entity or stock representing a majority of the voting power of an entity that wholly owns, directly or indirectly, the surviving entity; (b) the sale, transfer or assignment of securities of Kuur representing a majority of the voting power of all of Kuur's outstanding voting securities to an acquiring party or group which is not (i) an Affiliate or (ii) a New Kuur Group Topco; or (c) the sale of all or substantially all of Kuur's assets or business to which this Agreement relates to a Third Party (i.e., not to a Kuur Affiliate or a New Kuur Group

Topco). A "New Kuur Group Topco" means a body corporate whose shareholders will, immediately following the relevant sale, transfer or assignment, (i) comprise substantially the same persons as the shareholders of Kuur and (ii) have substantially the same proportionate interests in shares in such body corporate as the shareholders of Kuur had in Kuur, in each case immediately prior to such acquisition.

"COC Closing" means the date of the closing of the first Change of Control of Kuur during the Term.

"Confidential Information" means and includes, individually and collectively, any proprietary or confidential Know-How or other proprietary and/or secret information (scientific, technical or commercial) of or, directly or indirectly, originating with, provided, disclosed, or made available or accessible by, or obtained from, a Party (the "Disclosing Party"), in each case, to or for the other Party (the "Receiving Party"), in connection with this Agreement or the Co-Development Agreement, whether in written, electronic, digital, visual, aural, verbal, or oral or other tangible or intangible form, whether provided, disclosed, made accessible or available or obtained, and whether or not labeled or otherwise identified as confidential, subject to Section 17.2.

"Control" means, with respect to any material, information, or intellectual property right or any other Technology or Technology Right, that a Party (a) owns such material, information, or intellectual property right or other Technology or Technology Right, or (b) has a license or a sublicense (as applicable) to, or a right to use such material, information, or intellectual property right or other Technology or Technology Right, in each case of (a) or (b), with, as applicable, a right to access, use, or license or sublicense (as applicable), such material, Information, or intellectual property right or other Technology or Technology Right on the terms and conditions set forth herein, without violating the terms of any agreement with or obligation to any Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use or license or sublicense (as applicable); except that, in each case, if (i) Baylor would "Control" any material, information, or intellectual property right or any other Technology or Technology Right but solely for a payment obligation in connection with a grant of the right to access, use, or license, or sublicense (as applicable), such material, Information, or intellectual property right or other Technology or Technology Right to Kuur, and (ii) Kuur agrees, to reimburse Baylor, or assume such payment obligation from Baylor, then such material, information, intellectual property rights or other Technology or Technology Rights shall be deemed to be Controlled by Baylor, provided that any such agreement to reimburse Baylor shall be set forth in a separate written agreement between Baylor and Kuur governing the terms of a license of said intellectual property right, material, or information; and/or (ii) where a license or sublicense (as applicable) shall be exclusive hereunder, if Baylor does not have the right to grant an exclusive license but has the right to grant a non-exclusive license under an agreement that is in existence as of the time Baylor would first be required hereunder to grant Kuur an exclusive license or sublicense (as applicable), such license or sublicense (as applicable) shall be non-exclusive until such time as Baylor has the right to grant, and grants, such exclusive license to Kuur. Baylor shall be under no obligation to seek the right to grant exclusive licenses, and makes no representations or warranties that it shall acquire the right to grant said license on an exclusive basis. This "Control" definition includes all other correlative meanings, including "Controlled," "Controlling," and "Controls".

"Data Package" shall have the meaning given in the Co-Development Agreement.

"Developers" means the individuals listed under Schedule A, who were employees of Baylor at the time of Disclosure of the applicable Core Subject Technology.

"Development Budget" shall have the meaning given in the Co-Development Agreement.

"Development Plan" shall have the meaning given in the Co-Development Agreement.

"Disclosure" means a disclosure that contains sufficient detail to enable one skilled in the art to comprehend, replicate and use the disclosed invention.

"Distinct Product" has the meaning given in Section 2.6(a)(ii).

"Early R&D Activities" means, with respect to each Distinct Product, both (a) all pre-clinical studies required to be conducted to obtain the allowance of the initial IND with respect to such Distinct Product, and (b) the first clinical study of such Distinct Product in a human subject, whether healthy normal or patient (the "FIM Study").

"Effective Date" means April 29, 2016 the effective date of the Original Agreement, also referred to herein as the Original Effective Date.

"Field" means the prevention, treatment and/or modulation of cancer in humans. For the avoidance of doubt, Field does not include the prevention, treatment and/or modulation of cancer in non-human animals.

"Future Oncology Option" has the meaning set forth in Section 3.1(a). "Future Non-Oncology Option" has the meaning set forth in Section 3.2(a).

"IND" means any investigational new drug application, clinical trial application, clinical trial exemption or similar or equivalent application or submission for approval to conduct initial human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

"Know-How" means and includes, individually and collectively, any analyses, assays, conclusions, experiments, results, tests, candidates, prototypes, test versions, works-in-process, concepts, discoveries, technology, ideas, improvements, inventions, contracts, controls, metrics, properties, standards, data (financial, clinical, personnel, scientific, technical, or other data), designs, drawings, documents, files, records, forecasts, proposals, plans (research, commercialization, business), formulas, information, interfaces, know-how, lists (customer lists, prospect lists), materials, mechanisms, modes of action, methods, processes, procedures, protocols, techniques, specifications, systems, technologies, trade secrets in each case, whether proprietary or not, whether patentable or not, and whether in written, electronic, digital or other form (whether tangible or intangible).

"Legal Costs" means all attorneys' fees and other legal fees and expenses, filing or maintenance fees, assessments and all other costs and expenses related to prosecuting, obtaining and maintaining patent protection on the Patent Rights in the United States and foreign countries, in each case incurred in accordance with this Agreement.

"Mark" means any trademark, service mark, trade name, corporate name, business name, domain name, logos, slogans, trade dress, packaging design, and other designations of source or origin of any kind, and any translation, transliteration, adaptation, derivation and combination thereof, and all intellectual or proprietary rights to or arising from any of the foregoing, including, without limitation, any common law rights, registration, application for registration, extension, and renewal thereof or related thereto, and all goodwill symbolized by any of the foregoing or associated therewith.

"Modified NKT" means a [*].

"Modified NKT Product" means any pharmaceutical product for administration to humans comprising a Modified NKT as the active agent and/or any combination pharmaceutical product for administration to humans comprising a Modified NKT as one of the active agents. A Modified NKT Product may [*] other than Modified NKTs produced in the manufacture of such product so long as such other [*] are not represented to Baylor or any Third Party (including any Regulatory Authority) as having any therapeutic effect, and such product is developed and commercialized as a product in which the Modified NKT component is represented to be the primary active therapeutic ingredient in such product as reflected, for example, in the Development Plan and regulatory filings for such product. For clarity, a product based on a [*], will not be deemed to be a Modified NKT Product so long as such Modified NKTs are not represented to Baylor or any Third Party (including any Regulatory Authority) as having any therapeutic effect, and such product is not developed and commercialized as a Modified NKT product (i.e., [*] [*]Modified NKT is intended to be the primary active therapeutic ingredient in such product as reflected in the development plans and regulatory filings for such product).

"Natural Killer Cell" or "NK Cell" means an innate lymphocyte that (a) displays rapid effector responses on encounter with an infected, allogeneic, or transformed cell, (b) does not express a T-cell receptor, and (c) recognizes target cells through a balance of signals from activating receptors, which recognize stress-induced ligands, and

inhibitory receptors, which predominantly engage MHC class I molecules. For the avoidance of doubt, NK Cells do not include T Cells and do not include Natural Killer T Cells.

"Natural Killer T Cell" or "NKT" means a cell characterized by the expression of a T cell receptor that (a) (i) recognizes glycolipid antigens presented by the CD1d molecule, and (ii) is unable to recognize any specific peptide antigens presented by major histocompatibility complex antigens, or (b)(i) in the case of NKT-like MAIT cells, recognizes metabolites of vitamin B2 or vitamin B9 presented by the MR1 molecule, and (ii) is unable to recognize any specific peptide antigens presented by major histocompatibility complex antigens. For the avoidance of doubt, "Natural Killer T Cells" and "NKTs" do not include T Cells and do not include Natural Killer Cells.

"Net Sales" means, with respect to a particular Licensed Product in a particular period, the gross amount of monies or cash equivalent or other consideration that is billed, invoiced or received (whichever occurs first) for sales, leases, or other modes of transfer of Licensed Products by Kuur and its Affiliates or sublicensee(s) (the "Selling Party") to independent, unrelated wholesaler(s), distributor(s) or end users (each a "Buyer" and collectively "Buyers"), during such period (a "Sale"), less:

(a) reasonably and customary trade, quantity, physician samples, or cash discounts and rebates to the extent actually allowed and taken;

(b) amounts repaid or credited to customers by reason of rejections or returns;

(c) to the extent separately stated on purchase orders, invoices or other documents of sale, taxes and/or other governmental charges (except regulatory filing fees) which are actually paid by or on behalf of the Selling Party for the production, sale, transportation, delivery or use of a Licensed Product; and

(d) reasonable charges borne by the Selling Party for handling, delivery or transportation of Licensed Products to customers through the use of Third Party delivery or transportation services, if separately stated.

The term "Net Sales" in the case of non-cash sales in a given country received by Selling Party for the sale, leases, sublicenses, or other modes of transfer of Licensed Products to end users means the greater of the average Net Sale price charged to Buyers for cash sales of such Licensed Product in such country and the fair market value based on pricing in comparable markets as determined by a Third Party appointed by mutual agreement of the Parties.

For clarity, if Kuur sells or transfers Licensed Products to a distributor or wholesaler, Net Sales with respect to such Licensed Products are to be calculated on that wholesaler's or distributor's sale to an end user NOT on Kuur's sale or transfer price to that party. Licensed Products sold to any Affiliate, sublicensee or Third Party solely for use in clinical trials shall not be included in Net Sales.

"New Modified NKT Product" means [*].

"Option Exercise Payment" has the meaning given in Section 3.5.

"Outside the Field" means solely the prevention, treatment and/or modulation of human diseases and disorders other than cancer in humans. For the avoidance of doubt, Outside the Field does not include the prevention, treatment and/or modulation of cancer in non-human animals.

"Party" means either Kuur or Baylor, and "Parties" means Kuur and Baylor.

"Patent Rights" means any of the following, anywhere in the world and under any law or legal system: rights in inventions, patents, patent applications, and patent disclosures (including, without limitation, any provisional, utility, and design models and patent applications, continuation, continuation-in-part, divisional, reissue, re-examination, revision, substitution, and extension, and foreign, international, national, and other counterparts and equivalents thereof), including the rights to claim priority from any patent application therein (including the right to claim priority from the priority chain of any such patent application). With regard to a specific product or technology, such product or technology is "covered by" a Patent Right if making, using, selling, or offering to sell such product

or practicing such technology, without authorization of the holder of such Patent Right would infringe at least one Valid Claim of such Patent Right.

"Pivotal Clinical Trial" means a clinical study of an investigational product in patients with the primary objective of confirming with statistical significance the efficacy and safety with the aim to obtain regulatory approval in any country as described in 21 C.F.R. 312.21(c), or a comparable clinical study prescribed by the relevant regulatory authority in a country other than the United States.

"Project" has the meaning given in the Co-Development Agreement.

"Progressed Distinct Product" has the meaning given in Section 2.6(c).

"Regulatory Authority" means any governmental or regulatory authority with jurisdiction over the research, development, manufacture, use, marketing or sale or other distribution of any Licensed Product, Licensed Technology, Future Product or Future Technology, including, without limitation, the U.S. Food & Drug Administration and any applicable foreign, state, or local equivalent. "Regulatory Authority" shall also include any non-governmental group licensed or otherwise authorized by an entity described in the preceding sentence to perform inspections, audits and/or product marketing, product study or other reviews.

"ROFN Product" means solely (a) a Modified NKT Product; (b) for use in the Field and/or Outside the Field, (c) conceived, created, made, and/or developed (i) outside the Development Plan, outside the Co-Development Agreement, and outside any Specific Industrial Research Agreement, Work Plan or Specific Industrial Clinical Research Agreement, and (ii) without material support or contribution from the Development Budget or from any Third Party (other than where such support or contribution is received by Baylor from a governmental agency that does not limit, restrict, or qualify Baylor's rights, title, and/or interest in resulting inventions), and (d) owned solely by Baylor and the subject of Technology Rights owned solely by Baylor.

"ROFN Product Rights" means, with respect to a discrete ROFN Product, solely Technology Rights (a) covering any method, procedure, or process for manufacturing or using such ROFN Product, or feature or component of such ROFN Product; (b) conceived, created, made, and/or developed outside the Development Plan, outside the Co-Development Agreement, and outside any Specific Industrial Research Agreement, Work Plan or Specific Industrial Clinical Research Agreement, solely by Baylor employees in the scope of their employment, and without material support or contribution from the Development Budget or from any Third Party (other than where such support or contribution is received by Baylor from a governmental agency that does not limit, restrict, or qualify Baylor's rights, title, and/or interest in resulting inventions), and (c) owned by Baylor.

"Royalties" has the meaning set forth in Section 5.13(b).

"Specific Industrial Clinical Research Agreement" or "SICRA" shall have the meaning given in the Co-Development Agreement.

"Specific Industrial Research Agreement" or "SIRA" means an agreement between Kuur (and/or its Affiliate) and a Third Party to conduct all or a specific non-clinical trial portion of a Project.

"Sublicensing Revenue" means all (i) cash upfront payments, (ii) sublicensing fees and (iii) all sublicense maintenance fees that are paid to Kuur by any sublicensee in consideration for the grant of a sublicense of Kuur's rights under this Agreement, but, in each case, (1) only during the Sublicensing Revenue Period, and (2) excluding the following payments:

(a) payments made in consideration for the issuance of equity or debt securities of Kuur or any of its Affiliates to the extent not exceeding the fair market value thereof;

(b) that portion of payments for direct or fully burdened expenses (collectively not to exceed one hundred fifty percent (150%) of direct expenses) associated with research or development as calculated in accordance with GAAP, to the extent that such expenses are separately listed and part of the sublicense;

(c) royalties or other payments based on sales of Licensed Products by the sublicensee (payment for which has been otherwise provided in Section 5.13 herein);

(d) milestone payments associated with the development and/or commercialization of Licensed Products by the sublicensee (payment for which has been otherwise provided in Section 5.14 herein); and

(e) payments for supply of Licensed Products for use in clinical trials by or on behalf of, or for resale by, any sublicensee.

"Sublicensing Revenue Period" means the period commencing on the First Restatement Effective Date and continuing thereafter for five (5) years immediately following the First Restatement Effective Date, unless this Agreement is terminated earlier.

"T Cell" means any of the lymphocytes that mature in the thymus and have the ability to recognize specific peptide antigens presented by major histocompatibility complex antigens through the receptors on their cell surface.

"TCR" means a T Cell receptor.

"Technology" means, collectively and individually, Know-How, apparatuses, developments, research and development information, test information, engineering, diagrams, blueprints, schematics, show-how, works, software (object code and source code), computer programs, computer applications, and documentation.

"Technology Right" means any of the following, anywhere in the world and under any law or legal system: (i) rights in inventions and Patent Rights, (ii) copyrights, database rights, mask work rights, industrial design rights, registered designs, unregistered design rights, Community design rights, and any rights similar thereto, whether arising from statute, regulation, common or judicial law, treaty or otherwise, and any registration, application for registration, and renewal thereof or related thereto, any right of attribution and integrity and other moral right, (iii) right in or arising from any trade secret, Know-How, and confidential or proprietary or other information, material, items or things, and (iv) other intellectual or industrial property rights, priority rights, prior user rights and all other rights of a like nature; in each case whether registered or unregistered, and whether or not capable of registration, whether existing now or being recognized or created in the future, anywhere in the world and under any law or legal system, including without limitation the right to apply for the protection of the foregoing, in any part of the world, and the right to take, defend, or appeal proceedings, and recover and retain damages, and obtain all other relief and remedies in respect of infringements thereof and rights of protection of an interest therein under the laws of all jurisdictions; but "Technology Right" shall not include any Mark or any right to or arising from any Mark.

"Term" means the term of this Agreement commencing on the Effective Date and ending on the earlier of the expiration under Article X or the termination of this Agreement under Article XI.

"Third Party" means any person or entity who is not Kuur or any of its Affiliates, or Baylor or any of its Affiliates, or any employee thereof.

"Third Party Sublicensee" means any Third Party sublicensee to which Kuur (or an Affiliate Sublicensee) grants a sublicense under any of the licenses granted to Kuur by Baylor under this Agreement to one or more of any of the Licensed Products pursuant to a sublicense agreement to which such Third Party sublicensee and Kuur and/or any Affiliate of Kuur is a party.

"Trigger Oncology Product" has the meaning set forth in Section 3.1(a).

"Trigger Non-Oncology Product" has the meaning set forth in Section 3.2(b)(i).

"Valid Claim" means any claim: (a) in an unexpired issued Patent Right which has not been held unenforceable, unpatentable or invalid by a decision of a court or other government agency of competent jurisdiction following exhaustion of all possible appeal processes, and which has not been admitted to be invalid or unenforceable through reissue, reexamination or disclaimer; or (b) in a pending patent application in the Patent Rights.

"Work Plan" shall have the meaning given in the Co-Development Agreement.

1.2 Definitions Related to Technologies and Products. As used in this Agreement, the following capitalized terms (whether used in the singular or plural) shall have their respective meanings as set forth in this Section 1.2.

"Baylor Target Antigen" means each of GD2 and GPC3.

"Construct" means the specific [*] included or expressed by a modified cell (e.g., by a Modified NKT). Where a modified cell includes expresses one or more [*], "Construct" means the specific combination of such [*].

"Licensed Antigen" means each Baylor Target Antigen for which Kuur has exercised its option pursuant to Section 4.1.

"New Antigen" has the meaning given in the Co-Development Agreement. In addition, solely for purposes of Section 5.14(a)(i), the antigen to which the New Modified NKT Product is directed shall also be deemed to be a New Antigen.

"Replacement Antigen" means a New Antigen selected to replace a Baylor Target Antigen in the Development Plan in accordance with Section 4.4(d) of the Co-Development Agreement.

"Baylor Target Patent Rights" means the following Patent Rights:

(a) the patents and patent applications listed under the heading "Baylor Target Patent Rights" in Schedule C,

(b) any divisions and continuations of the applications of clause (a),

(c) any continuations-in-part of the applications of clauses (a) through (b) solely to the extent the claims thereof are directed to subject matter specifically described in the patent applications of clauses (a) through (b) and are dominated by the claims of such patent applications of clauses (a) through (b),

(d) any non-U.S. applications corresponding to the applications of clauses (a) through (c) counterpart, pending or issued patents in all other countries, and

(e) any patent which issues in any jurisdiction from any of the applications of clauses (a) through (d) and any oppositions, reissues, re-examinations, or renewals of such patents.

"Core Platform Patent Rights" means the following Patent Rights:

(e) the patents and patent applications listed under the heading "Core Platform Patent Rights" in Schedule C,

(f) any patent application, or any claim thereof, owned or co-owned by Baylor and filed after the Effective Date claiming Core Subject Technology or the use of Core Subject Technology, or materials developed with the use of Core Subject Technology,

(g) any divisions and continuations of the applications of clauses (a) through (b),

(h) any continuations-in-part of the applications of clauses (a) through (c) solely to the extent the claims thereof are directed to subject matter specifically described in the patent applications of clauses (a) through (c) and are dominated by the claims of such patent applications of clauses (a) through (c),

(i) any non-U.S. applications corresponding to the applications of clauses (a) through (e) counterpart, pending or issued patents in all other countries

(j) any patent which issues in any jurisdiction from any of the applications of clauses (a) through (f) and any oppositions, reissues, re-examinations, or renewals of such patents. Schedule C shall be updated on an annual basis, or as needed via mutual agreement of the Parties.

"Core Subject Technology" means and includes Licensed Core Products and Licensed Core Technology.

"Licensed Core Product(s)" means:

(a) with respect to the Core Platform Patent Rights, the NKT Platform Subject Technology, or the NKT Process Subject Technology: any product that incorporates, utilizes or is made through use of the NKT Platform Subject Technology, and/or the NKT Process Subject Technology, and/or is covered by the Core Platform Patent Rights; and

(b) with respect to the NKT CAR Subject Technology, the following products, to the extent covered by the Core Target Patent Rights or incorporating, utilizing, or made through the use of, the NKT CAR Subject Technology or the Core Platform Patent Rights:

(i) any Modified NKT Product consisting of a Modified NKT expressing a CAR targeting any Licensed Antigen; and

(ii) any New Modified NKT Product.

A Licensed Core Product shall be determined to be a Distinct Product in accordance with Section 2.6(a). For clarity, any Construct created pursuant to the Development Plan that meets the requirements of clause (a) or (b) of this definition of the term "Licensed Core Product(s)" will be deemed to be a Licensed Core Product (rather than a Future Product) and the Technology Rights therein and thereto shall be deemed to be part of the Licensed Core Technology Rights (rather than part of the Future Oncology Technology Rights or Future Non-Oncology Technology Rights).

"Licensed Core Technology" means and includes NKT CAR Subject Technology, NKT Platform Subject Technology, and NKT Process Subject Technology.

"Licensed Core Technology Rights" means and includes Technology Rights (a) covering Licensed Core Technology (including, without limitation, the Core Platform Patent Rights), and (b) Controlled by Baylor.

"NKT CAR Subject Technology" means solely Modified NKT biological materials, Technology and Know-How, in each case,

(i) useful in the Field,

(ii) developed, discovered, invented, conceived of, reduced to practice or created by

(A) any of Developers of the subject matter described in clause (a), (b) or (c) of this definition of the term "NKT CAR Subject Technology", or

(B) any employees or contractors of Baylor working on the subject matter described in clause (a), (b) or (c) of this definition of the term "NKT CAR Subject Technology" and under the supervision of any of such Developers in Baylor's facilities, and

(iii) Controlled by Baylor as of the Effective Date, including, without limitation, any of the foregoing that are covered by or disclosed in the Baylor Target Patent Rights, and/or described in any of the following disclosures:

(a) BLG 11-059, "Immunotherapy of Metastatic Melanoma and Other Tumors Using Genetically Engineered GD2-Specific T Cells"; and

(b) BLG 15-055, “Glypican-3 Specific Chimeric Antigen Receptors for Adoptive Immunotherapy”;

but, in each case, excluding any biological materials, Technology, and Know-How to the extent not Controlled by Baylor.

“NKT Platform Subject Technology” means solely biological materials, Technology and Know-How, in each case,

(i) useful in the Field for discovering, identifying, characterizing, and producing new Modified NKTs,

(ii) developed, discovered, invented, conceived of, reduced to practice or created by

(A) any of Developers of the subject matter described in clause (a) or (b) of this definition of the term “NKT Platform Subject Technology”, or

(B) any employees or contractors of Baylor working on the subject matter described in clause (a) or (b) of this definition of the term “NKT Platform Subject Technology” and under the supervision of any of such Developers in Baylor’s facilities, and

(iii) Controlled by Baylor as of the Effective Date, including, without limitation, any of the foregoing that are covered by or disclosed in the Core Platform Patent Rights, and/or described in any of the following disclosures:

(a) BLG 12-005, “Targeting the Tumor Microenvironment Using Manipulated NKT Cells”; and

(b) BLG 15-093, “The identification of the NKT-cell subset that is responsible for in-vivo persistence and therapeutic activity and defining the conditions required for propagation of this subset in culture,”

(c) BLG 18-020, “CD1d-restricted NKT cells as a platform for off-the-shelf cancer immunotherapy,”

(d) BLG 21-059, “Therapeutic implications of LEF1-mediated functional fitness in human NKT cells,” and

(e) BLG 21-061, “CAR NKTs expressing artificial micro RNA-embedded shRNA for down-regulation of MHC Class I and II expression,” but, in each case, excluding any biological materials, Technology, and Know-How to the extent not Controlled by Baylor.

“NKT Process Subject Technology” means solely biological materials, Technology and Know-How, in each case,

(i) useful for producing NKTs, Modified NKTs, or Modified NKT Products in the Field,

(ii) (A) developed, discovered, invented, conceived of, reduced to practice, created or used by (1) Dr. Metelitsa or (2) any employees or contractors of Baylor working in Dr. Metelitsa’s laboratory and under his direct supervision, in each case, within the scope of his or their position with Baylor, or (B) covered by the Core Platform Patent Rights, and

(iii) Controlled by Baylor as of the Effective Date, but, in each case, excluding any biological materials, Technology, and Know-How to the extent not Controlled by Baylor.

“Future Products” means Future Oncology Products and Future Non-Oncology Products, as applicable.

"Future Technology" means and includes Future Oncology Technology and/or Future Non-Oncology Technology, as applicable.

"Future Oncology Technology" means solely biological materials, Technology and Know-How, including improvements or enhancements to the Core Subject Technology, in each case, Controlled by Baylor and:

(a) (i) developed, discovered, conceived, or created by employees or contractors of Baylor, in each case, within the scope of their position with Baylor, and (ii) arising from activities (1) under the Development Plan and (2) materially supported by payments from Kuur under the Development Budget; or

(b) (i) developed, discovered, invented, conceived of, reduced to practice or created for use in the Field, (ii) by (1) Dr. Metelitsa or (2) any employees or contractors of Baylor working in his laboratory and under his direct supervision, in each case, within the scope of his or their position with Baylor, and (iii) outside of the Development Plan, outside of the Development Budget, and outside the Co-Development Agreement, but expiring on the date upon which the both Parties acknowledge that there are no longer any Kuur-funded activities in the Metelitsa Lab under the Development Plan or in the Development Budget (the "Future Metelitsa Lab Oncology Technology"); or

(c) (i) developed, discovered, invented, conceived of, reduced to practice or created by employees or contractors of a Third Party if such Third Party has executed a SIRA or SICRA with Baylor and/or Kuur that is in effect at the time of such development, discovery, invention, conception, reduction to practice or creation, and (ii) arising from activities (1) within the scope of such, as applicable, SIRA or SICRA, (2) under the Development Plan, and (3) materially supported by payments from Kuur under the Development Budget.

"Future Oncology Patent Rights" means Patent Rights covering Future Oncology Technology Controlled by Baylor.

"Future Oncology Technology Rights" means and includes Technology Rights, including any Future Oncology Patent Rights (a) related to Future Oncology Technology, and (b) Controlled by Baylor.

"Licensed Future Oncology Product" has the meaning given in Section 3.1.

"Future Oncology Product" means, as to a particular Future Oncology Invention, any product developed for use in the Field, including the Trigger Oncology Product, that (a) constitutes, incorporates, or utilizes, or is created or made using, such Future Oncology Invention, and/or (b) is covered by any Future Oncology Patent Rights, or is covered by other Future Oncology Technology Rights. A Future Oncology Product shall be deemed to be a Distinct Product in accordance with Section 2.6(a).

"Future Oncology Invention" means either (a) a patentable invention, or (b) a separate and distinct method, biological material, product, feature or component of a product, process, technique or trade secret, in each case, within the Future Oncology Technology, and in each case, as disclosed by one or more employees or contractors of Baylor in accordance with its normal invention disclosure requirements and policies.

"Future Non-Oncology Technology" means solely biological materials, Technology and Know-How, including improvements or enhancements to the Core Subject Technology, in each case:

(a) developed, discovered, invented, conceived of, reduced to practice or created for use Outside the Field;

(b) Controlled by Baylor;

(c) developed, discovered, invented, conceived of, reduced to practice or created after the Effective Date;

(d) developed, discovered, invented, conceived of, reduced to practice or created by (i) Dr. Metelitsa, (ii) any employees or contractors of Baylor working in his laboratory and under his direct supervision, in each case, within the scope of his or their position with Baylor, or (iii) employees or contractors of a Third Party within the scope of a SIRA or SICRA executed by such Third Party with Baylor or Kuur that is in effect at the time of such development, discovery, invention, conception, reduction to practice or creation; and

(e) arising from activities (i) under the Development Plan and (ii) materially supported by payments made by Kuur under the Development Budget.

"Future Non-Oncology Patent Rights" means Patent Rights (a) covering Future Non-Oncology Technology, and (b) Controlled by Baylor.

"Future Non-Oncology Technology Rights" means and includes Technology Rights, including any Future Non-Oncology Patent Rights (a) covering Future Oncology Technology, and (b) Controlled by Baylor.

"Licensed Future Non-Oncology Product" has the meaning given in Section 3.2.

"Future Non-Oncology Product" means, as to a particular Future Non-Oncology Invention, any product intended for use Outside the Field, including the Trigger Non-Oncology Product, that (a) constitutes, incorporates, or utilizes, or is created or made using, such Future Non-Oncology Invention, and/or (b) is covered by any Future Non-Oncology Patent Rights or covered by other Future Non-Oncology Technology Rights. A Future Non-Oncology Product will be deemed to be a Distinct Product in accordance with Section 2.6(a).

"Future Non-Oncology Invention" means either (a) a patentable invention, or (b) a separate and distinct method, biological material, product, feature or component of a product, process, technique or trade secret, in each case, within the Future Non-Oncology Technology, and in each case, as disclosed by one or more employees or contractors of Baylor in accordance with its normal invention disclosure requirements and policies.

"Licensed Product" means a Licensed Core Product, a Licensed Future Oncology Product, and/or a Licensed Future Non-Oncology Product, as applicable.

"Licensed Technology" means Core Subject Technology, Licensed Products, Future Oncology Inventions to which Kuur exercises its option pursuant to Section 3.1 and Future Non-Oncology Inventions to which Kuur exercises its option pursuant to Section 3.2.

1.3 Definitions Related to Financial Provisions. As used in this Agreement, the following capitalized terms (whether used in the singular or plural) shall have their respective meanings as set forth in this Section 1.3.

"Baylor's Account" shall mean:

[*]

"Business Day" means a day (other than a Saturday or Sunday) on which banks in New York and Texas are open for the transaction of normal banking business.

"Group Company" or "Group Companies" has the meaning given to this term in the Articles of Association.

"Initial Public Offering" or "IPO" means the admission of any ordinary shares of Kuur or of a new holding company of Kuur to trading, or the granting of permission for any ordinary shares of Kuur or of a new holding company of Kuur to be dealt in, on a Recognized Investment Exchange or other internationally recognized investment exchange.

"License Execution Fee" has the meaning given to this term in Section 5.1.

"Liquidation Event" means a return of all or substantially all of the assets of Kuur on a liquidation, dissolution, winding up or similar event.

"Ordinary Shares" has the meaning given to this term in the Articles of Association.

"Recognized Investment Exchange" means a recognized investment exchange as defined by section 286 of the United Kingdom's Financial Services and Markets Act 2000, as amended, together with (whether or not falling within such definition) the Main Market of the London Stock Exchange plc, the AIM market of the London Stock Exchange plc, NASDAQ, NYSE, and Euronext.

1.4 Contract Interpretation. All references in this Agreement to Articles, Sections, Exhibits, Appendices or Schedules shall, unless otherwise expressly stated herein, mean the relevant sections, articles, exhibits, appendices or schedules to this Agreement, and the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any exhibits, appendices or schedules attached hereto). The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof. Where this Agreement states that a party "shall," "will," or "must" perform in some manner or otherwise act or omit to act, it means that the party is legally obligated to do so in accordance with this Agreement. Unless the context otherwise clearly requires, whenever used in this Agreement: (a) the words "include", "includes" or "including" shall be construed as incorporating also the phrase "but not limited to" or "without limitation"; (b) the word "or" includes the conjunctive and the disjunctive (i.e., "and/or"), (c) the words of any gender include the other gender, and (d) words using the singular or plural number also include the plural or singular number, respectively. Any reference to a statute is deemed also to refer to any amendments or successor legislation as in effect at the relevant time. All references to dollars, cash or "$" mean U.S. dollars. Any reference to a Contract or other document as of a given date means the Contract or other document as amended, supplemented and modified from time to time through such date. The term "sublicensee" used herein means an Affiliate Sublicensee and/or a Third Party Sublicensee unless otherwise expressly stated herein.

ARTICLE II
LICENSE GRANTS

2.1 License Grant: Licensed Core Technology & Licensed Core Products; Baylor Target Antigens.

(a) Subject to (i) the reservations of rights set forth in Sections 2.4 and 2.5, and (ii) Baylor's rights set forth in Section 2.6, Baylor hereby grants to Kuur an exclusive, worldwide, sublicensable (with the right to further sublicense through multiple tiers of sublicensees, all in accordance with Article VIII) license under the Licensed Core Technology Rights, including the Core Platform Patent Rights, to research, develop, make, have made, use, market, sell, offer to sell, lease and import Licensed Core Products in the Field (subject to expansion under Section 3.8), all under and in accordance with the terms and conditions of this Agreement and subject to the payment of Royalties and other payments applicable to such Licensed Core Products.

(b) [Intentionally Omitted.]

2.2 License Grant: Future Oncology Technology & Licensed Future Oncology Products. Subject to (a) the reservations of rights set forth in Sections 2.4 and 2.5 and (b) Baylor's rights set forth in Section 2.6, (c) completion of the Option Exercise Procedure (Section 3.4), and (d) payment of the Option Exercise Payment (Section 3.5) by Kuur to and receipt by Baylor, Baylor hereby grants to Kuur an exclusive, worldwide, sublicensable (with the right to further sublicense through multiple tiers of sublicensees, all in accordance with Article VIII) right and license under the Future Oncology Technology Rights, including the Future Oncology Patent Rights, to research, develop, make, have made, use, market, sell, offer to sell, lease and import (x) Licensed Future Oncology Products in the Field and Licensed Core Products in the Field (subject in each case to expansion under Section 3.8), and (y) any Licensed Future Non-Oncology Products both in the Field and Outside the Field (if the expansion under Section 3.8 is completed), all under and in accordance with the terms and conditions of this Agreement and subject to the payment of Royalties and other payments applicable to such Licensed Future Oncology Products and such Licensed Core Products.

2.3 License Grant: Future Non-Oncology Technology and Future Non-Oncology Products. Subject to (a) the reservations of rights set forth in Sections 2.4 and 2.5 and (b) Baylor's rights set forth in Section 2.6, (c) completion of the Option Exercise Procedure (Section 3.4), (d) completion of the Future Non-Oncology Product Option payment obligations (Section 3.2(c)), (e) payment of the Option Exercise Payment (Section 3.5), by Kuur to and receipt by Baylor, Baylor hereby grants to Kuur an exclusive, worldwide, sublicensable (with the right to further sublicense through multiple tiers of sublicensees, all in accordance with Article VIII) right and license under the Future Non-Oncology Technology Rights, including the Future Non-Oncology Patent Rights, to research, develop, make, have made, use, market, sell, offer to sell, lease and import (x) Licensed Future Non-Oncology Products Outside the Field (subject to expansion under Section 3.8) and (y) Licensed Core Products in the Field, and Licensed Future Oncology Products in the Field (subject in each case to expansion under Section 3.8), all under and in accordance with the terms and conditions of this Agreement and subject to the payment of Royalties and other payments applicable to such Licensed Future Non-Oncology Products and such Licensed Core Products.

2.4 Qualification and Restrictions on Licenses.

(a) *Ownership of Licensed Rights*. Any license granted by Baylor under this Agreement under or to or regarding any Patent Right is granted by Baylor only to the extent that Baylor Controls such Patent Right. Any license granted by Baylor under this Agreement to or regarding any Technology and Technology Rights is granted by Baylor only to the extent that Baylor Controls such Technology and the Technology Rights in such Technology.

(b) *License Restrictions*. The grants in Sections 2.1, 2.2, and 2.3 shall be further subject to, restricted by and non-exclusive with respect to:

(i) making or using the Core Subject Technology, Future Oncology Technology, Future Non-Oncology Technology, and/or inventions claimed in the Core Platform Patent Rights, Baylor Target Patent Rights, Future Oncology Patent Rights, and Future Non-Oncology Patent Rights, as applicable, by Baylor for research, patient care, teaching and other educational activities for non-commercial purposes;

(ii) any non-exclusive licenses of the Core Subject Technology, Future Oncology Technology, Future Non-Oncology Technology, and/or inventions claimed in the Core Platform Patent Rights, Baylor Target Patent Rights, Future Oncology Patent Rights, and Future Non-Oncology Patent Rights, as applicable, that Baylor may grant to other academic or non-profit research institutions for non-commercial research purposes, provided that Baylor shall notify Kuur in advance of any such grant made with respect to the Future Oncology Technology and Future Non-Oncology and any Core Subject Technology made after the Effective Date, but only to the extent that Baylor is permitted under its agreement(s) related to such grant (provided that Baylor uses reasonable efforts to obtain the right to so notify Kuur);

(iii) making or using the Core Subject Technology, Future Oncology Technology, Future Non-Oncology Technology, and/or inventions claimed in the Core Platform Patent Rights, Baylor Target Patent Rights, Future Oncology Patent Rights, and Future Non-Oncology Patent Rights, as applicable, by academic and nonprofit research institutions for non-commercial research purposes, pursuant to a nonexclusive license granted by Baylor as described above in Section 2.4(b)(ii), including Baylor's provision of notice to Kuur; and

(iv) any non-exclusive license of the Core Subject Technology, Future Oncology Technology, Future Non-Oncology Technology, and/or inventions claimed in the Core Platform Patent Rights, Baylor Target Patent Rights, Future Oncology Patent Rights, and Future Non-Oncology Patent Rights, as applicable, that Baylor is required by law or regulation to grant to the United States of America or to a foreign state pursuant to an existing or future treaty with the United States of America.

With respect to subclauses (i), (ii), (iii) and (iv) of this Section 2.4(c), (A) Baylor shall not conduct any clinical trial of any Progressed Distinct Product (regardless of whether or not Kuur has provided Baylor with written notice of Kuur's intent to initiate Phase 2 clinical trials), nor grant to any Third Party the right to do so, without the written approval of Kuur in its sole discretion; and (B) with respect to any Progressed Distinct Product that is not subject to the immediately preceding subclause (A), Baylor and its grantees under subclause (ii), (iii) or (iv) may conduct additional phase 1 clinical trials for such Progressed Distinct Product, provided that Baylor provides Kuur (1) written notice prior to the conduct of any such trial(s) so that appropriate safety data exchange reporting procedures

can be established, (2) the opportunity to comment on the trial design and protocol and reasonable updates on such trial(s), and (3) the results of such trial(s), including data, promptly following their conclusion. Baylor shall promptly provide Kuur with any information of which it becomes aware in connection with any activity performed pursuant to this Section 2.4(b) that relates to a potential safety issue with any Licensed Product or Future Product.

(c) *Present Interest in Future Technology*. Nothing in this Agreement shall give or be deemed to give Kuur any present license, right, title, or interest in or to any Future Technology other than the options set forth in Article III (but, for clarity, without limiting the provisions of Article III, including Section 3.1(f)), and then only if and to the extent (i) Future Technology is created in accordance with this Agreement, any applicable SIRA, Work Plan or SICRA, and the Co-Development Agreement, or in Dr. Metelitsa's lab during the Term, and (ii) Kuur fully complies with the requirements set forth in Article III to exercise its option(s) under Article III.

(d) *Academic Freedom*. Baylor shall retain, and Kuur acknowledges that Baylor shall retain complete academic freedom including, without limitation, all rights and freedom, in its sole discretion, (i) to direct and control its activities under the Development Plan (provided that nothing in this subclause (i) will release Baylor from those obligations it has expressly accepted under the Co-Development Agreement, the Development Plan or any Work Plan or SICRA), (ii) to modify or terminate any activity under the Development Plan if, in Baylor's reasonable judgment, (1) continuing the activity would jeopardize the health or safety of any patients, healthcare providers to such patients, or Baylor employees who would otherwise be involved in such activities or (2) Baylor otherwise determines that it is obligated under Applicable Laws to discontinue such activity, (iii) to direct, control, operate, begin, continue, and terminate any and all of its activities outside of the Development Plan and subject to Sections 5.2 and 5.4 of the Co-Development Agreement and Sections 2.4(b) and 3.6 of this Agreement, including its educational activities, innovative activities, research and development, (v) subject to Section 5.2 of the Co-Development Agreement, to hire, retain, dismiss, or compensate its innovators, faculty, staff, students, employees, researchers, and/or other members, and (vi) subject to only Article XVII of this Agreement, to publicly disclose, whether through publications (whether or not peer-reviewed), oral presentations, or any other means, any and all research results, data, findings, conclusions, ideas, theories, discoveries, innovations, and other information.

2.5 Government Reservation. Rights under this Agreement are or may be subject to rights required to be granted to the Government of the United States of America pursuant to 35 USC Sections 200-212, 42 USC 241, 37 CFR 401, and 42 CFR 52, including a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject inventions throughout the world. Rights under this Agreement are further subject to the terms of those certain Cancer Research Grant Contracts between Baylor and the Cancer Prevention and Research Institute of Texas with effective dates of April 1, 2010, December 10, 2010, and June 1, 2011 (each a "CPRIT Grant Agreement" and collectively, the "CPRIT Grant Agreements"; Exhibits A1, A2, and A3, respectively). To the extent that there is a conflict between the terms of this Agreement and the terms of the CPRIT Grant Agreements or any applicable law or regulation, (a) the terms of the law or regulation shall prevail over this Agreement and the CPRIT Grant Agreements, and (b) the CPRIT Grant Agreements shall prevail over this Agreement. Kuur shall use reasonable efforts to disclose sufficient information to Baylor so that Baylor can satisfy its reporting obligations to CPRIT set forth in the CPRIT Grant Agreements.

2.6 Baylor's Early R&D Participation Rights.

(a) *Grant*. Subject to the terms and conditions of this Agreement, Kuur hereby agrees that Baylor shall have the worldwide right to be Kuur's exclusive academic partner to conduct all preclinical, IND-enabling Early R&D Activities with respect to each Licensed Core Product, Future Oncology Product, and Future Non-Oncology Product ("Baylor's Exclusive Academic Partner Early R&D Participation Rights"). Without limiting Baylor's Exclusive Academic Partner Early R&D Participation Rights set out in the foregoing sentence, Kuur shall have the right (either itself or through any of its Affiliates or sublicensees or any other Third Parties) to conduct Early R&D Activities, including to prepare IND applications and subsequent services and other activities as required to support clinical development with respect to each Licensed Core Product, Future Oncology Product and Future Non-Oncology Product which is a Distinct Product. If Kuur conducts Phase I clinical trial activities, Baylor will be (unless Baylor notifies Kuur that it does not want to be) the lead clinical center, chief (lead) investigator and will be entitled to first and last authorship academic credit with respect to such Early R&D Activities, subject to the terms and conditions of this Agreement (including Section 17.5) and the Co-Development Agreement. Baylor's rights under this Section 2.1 may be waived or amended by the JSC upon prior written request by Kuur and after such request is approved in writing

by the JSC. For the avoidance of doubt, references in this Agreement to Section 2.6(a) include the following clauses (i), (ii) and (iii) set out below in this Section 2.6(a).

(i) Kuur hereby grants to Baylor the worldwide, non-exclusive right to conduct Early R&D Activities with respect to each Licensed Core Product, Future Oncology Product and Future Non-Oncology Product which is a Distinct Product, such Early R&D Activities to be funded under the Development Budget.

(ii) Each Licensed Core Product and, subject to Section 2.6(a)(iii) below, each Future Oncology Product and Future Non-Oncology Product shall be a deemed a "Distinct Product" if and to the extent a Regulatory Authority (A) requires that a separate and distinct Investigational New Drug Application (IND) or Biologics License Application (BLA), or their equivalents outside the United States, be filed with respect thereto to clinically develop in humans and obtain approval to market such product or (B) if no such authorization has yet been sought, would be reasonably expected to require such separate and distinct application if or when such authorization is sought. For the avoidance of doubt, any combination product comprising a Licensed Core Product, Future Oncology Product and Future Non-Oncology Product on the one hand, and another active agent (whether or not another Licensed Core Product, Future Oncology Product or Future Non-Oncology Product) (a "Combination Product") shall be deemed to be a Distinct Product separate from any such Licensed Core Product, Future Oncology Product, and Future Non-Oncology Product if the combination product is subject to a separate and distinct IND or BLA, or their non-US equivalents. For further avoidance of doubt, (x) a Licensed Core Product, Future Oncology Product, or Future Non-Oncology Product which is administered as a concurrent therapy (and not a combination product) along with another product which contains a different active agent, wherein each product is subject to a separate IND or BLA (or their non-US equivalents), shall not be considered a different Distinct Product from the Licensed Core Product, Future Oncology Product, or Future Non-Oncology Product when administered alone.

(iii) Notwithstanding anything to the contrary in this Agreement or the Co-Development Agreement, a Future Oncology Product or Future Non-Oncology Product that otherwise meets the requirements of Section 2.6(a)(ii) for a Distinct Product will only be deemed to be a Distinct Product if: (A) such product is a Modified NKT Product, or (B) such product is not a Modified NKT Product and such product contains a specific Construct or other component covered by Technology Rights owned by Baylor, is produced by a process covered by Technology Rights owned by Baylor, or is otherwise covered by Technology Rights owned by Baylor that is exclusively licensed to Kuur pursuant to this Agreement.

(b) [*Intentionally Omitted*.]

(c) *Fulfillment on a Product by Product Basis*. It is understood and agreed that a Distinct Product shall be deemed a "Progressed Distinct Product" once:

(i) the Early R&D Activities have been completed by Baylor and/or Kuur for such Distinct Product;

(ii) the Data Package for such Distinct Product has been delivered to Kuur;

(iii) the Early R&D Activities have been fully funded (as between the Parties) by Kuur as provided in the Development Plan and Development Budget, or in the applicable Work Plan or SICRA and its corresponding budget; and

(iv) if such Distinct Product is a Future Oncology Product or a Future Non-Oncology Product, Kuur has exercised its option with respect to such Distinct Product in accordance with Sections 3.1, 3.2, and 3.3 (as applicable) and in accordance with Section 3.4 and Section 3.5.

Kuur's obligations under Section 2.6(a) shall be deemed to be completed, fulfilled, and concluded with respect to each Progressed Distinct Product and, thereafter, the rights granted under Sections 2.1, 2.2, and 2.3, solely with respect to each such Progressed Distinct Product, shall not be subject to this Section 2.6. In addition, it is understood and agreed that with respect to each Progressed Distinct Product (for so long as it remains the same Distinct Product), Kuur shall

have all rights, without an obligation to involve Baylor, to conduct all further human clinical or nonclinical studies of such Progressed Distinct Product, in other patient populations and in other indications.

(d) In the event that Kuur or any of its Affiliates conducts or has conducted any preclinical, IND-enabling Early R&D Activities with respect to any Distinct Product, alone or with a Third Party independent of the Co-Development Agreement (while the Co-Development Agreement is in effect) in contravention of Baylor's Exclusive Academic Partner Early R&D Participation Rights set forth above in Section 2.6(a), Baylor shall have the right to terminate this Agreement solely with respect to such Distinct Product, in accordance with Section 11.1, except solely if and to the extent that:

(i) the Work Plan for such Distinct Product permits any such preclinical, IND-enabling Early R&D Activities by Kuur without participation of Baylor;

(ii) Kuur provides Baylor a written proposal for preclinical, IND-enabling Early R&D Activities for such Distinct Product, but the Parties do not reach agreement on a Work Plan for the conduct of such preclinical, IND-enabling Early R&D Activities for such Distinct Product as a result of Baylor's demanding material terms to be included in such Work Plan, which Kuur shows to be objectively unreasonable;

(iii) Baylor agrees in advance in writing to such preclinical, IND-enabling Early R&D Activities by Kuur without participation of Baylor;

(iv) Baylor fails to perform its obligations under the Co-Development Agreement or the Development Plan or applicable Work Plan, as set forth in the Co-Development Agreement or such Work Plan with respect to such Distinct Product or New Antigen Product;

(v) Kuur has terminated the Co-Development Agreement for
Baylor's material breach in accordance with Article X of the Co-Development Agreement; or xxx

(vi) Baylor cannot perform such preclinical, IND-enabling Early R&D Activities due to its contractual obligations to a Third Party.

The effects of any such termination of rights to a Distinct Product are set forth in Section 11.5.

2.7 Change of Control of Kuur. Upon the COC Closing during the Term, the following shall apply:

(a) Early R&D Rights.

(i) *Licensed Core Products*. With respect to any Licensed Core Products, the conditions set forth in clause (b) of Section 2.2 and clause (b) of Section 2.3, and the license granted to Baylor under Section 2.6(a) shall continue with full force and effect as though no Change of Control had occurred.

(ii) *Future Technology Products*. The Kuur Successor may elect, upon written notice to Baylor within one hundred eighty (180) days of COC Closing, to terminate the Co-Development Agreement and, concomitantly, the conditions set forth in clause (b) of Section 2.2 and clause (b) of Section 2.3 and the license granted to Baylor under Section 2.6(a) and the rights granted to Baylor under Section 2.6(d) (the "Early R&D Rights Termination"), such termination effective only upon the later to occur of (i) the last day of the second full Calendar Year after Baylor's receipt of such notice of termination, or (ii) the third anniversary of the Effective Date, whichever is later (the "Wind Down Period"). Upon expiration of the Wind Down Period, the conditions set forth in clause (b) of Section 2.2 and clause (b) of Section 2.3 and the license granted to Baylor under Section 2.6(a) and the rights granted to Baylor under Section 2.6(d) shall be deemed terminated with respect to any and all Licensed Future Oncology Products and Licensed Future Non-Oncology Products licensed to Kuur as of the last day of the Wind Down Period or thereafter, including all Future Oncology Products or Future Non-Oncology Products as to which Kuur exercises its options under Section 3.1 and Section 3.2, respectively, during the Wind Down Period or pursuant to Section 2.7(c) below.

(iii) For the avoidance of doubt, effective upon any Early R&D Rights Termination, with respect to one or more Future Technology Products which include, incorporate, or utilize or are made with, any Future Oncology Invention or Future Non-Oncology Invention that is not licensed to Kuur or the Kuur Successor as of the last day of the Wind Down Period, or thereafter, pursuant to, but only to the extent of, any then-ongoing options under any then-existing Work Plan or SICRA that continues past the last day of the Wind Down Period (each, an "Independent Product"), Baylor has and shall retain the right to conduct, at its own expense, Early R&D Activities related to such Independent Products, provided that the Kuur Successor shall have a right of first negotiation solely during such Wind Down Period with respect to any such Independent Product in the event Baylor seeks to license rights to such Independent Product.

(b) *Obligations during the Wind Down Period*. During the Wind Down Period, the Kuur Successor shall:

(i) Cause its designated members to participate fully and in good faith in the JSC including appointing its allotted JSC members in accordance with Section 4.2 of the Co-Development Agreement promptly after the COC Closing, and participating in drafting, adopting, and revising the Development Plan and the Development Budget. Baylor shall also cause its designated JSC members to participate fully and in good faith in the JSC, including participating in drafting, adopting, and revising the Development Plan and the Development Budget during the Wind Down Period;

(ii) pay (A) any unpaid portion of the Allocated Amounts (as defined in the Co-Development Agreement) for the remainder of the year in which the COC Closing occurs and (B) the Allocated Amounts for each of the two full Fiscal Years (as defined in the Co-Development Agreement) of the Wind Down Period, which amount, in aggregate for such two full Fiscal Years of the Wind Down Period, shall be, subject to clause (iv) of this Section 2.7(b), either:

(x) $[*] _____, inclusive of the amounts paid for any funding of preclinical and FIM Studies required to be funded as noted in clauses (iii) and (iv) of this Section 2.7(b) (the "Ceiling Amount"); or

(y) the Budgeted Amount (as defined below), if the Ceiling Amount is greater than the amount equal to [*]% _____of sum of the Allocated Amounts for each of such remaining two full Fiscal Years of the Wind Down Period, to the extent agreed upon in the Development Plan existing as of the date of such termination notice (the "Budgeted Amount"); by way of example:, if the Allocated Amounts for the first of the two Fiscal Years was $[*] and for the second of the two Fiscal Years was $[*], the amount owed would be $[*] (i.e., [*]% of the aggregate Budgeted Amount of $[*]);

(iii) fund any preclinical studies under any Work Plan or Specific Industrial Clinical Research Agreement or other documented plan and in progress at the time of the Change of Control, through the end of the Wind Down Period; and

(iv) fund to completion and complete (subject to any technical failure of the relevant product) any FIM Studies in progress at the time of the Change of Control, even if such FIM Studies extend beyond the Wind Down Period (such period extending beyond the Wind Down Period, the "Tail Period").

(c) *Retention of Option Rights During Wind Down*. The Kuur Successor shall have the options provided under Sections 3.1 and 3.2 (i) during the Wind Down Period with respect to any Future Oncology Products and Future Oncology Inventions or Future Non-Oncology Products and Future Non-Oncology Inventions arising under the Development Plan and funded by the Development Budget, and (ii) during the Tail Period with respect to any Future Oncology Products and Future Oncology Inventions or Future Non-Oncology Products and Future Non-Oncology Inventions arising during the Tail Period under specific Work Plans or SICRAs as provided in Section 2.7(b)(iv).

(d) *Other Termination of the Co-Development Agreement during Wind Down*. During the Wind Down Period, each Party shall retain its rights under Article X of the Co-Development Agreement.

2.8 Right of First Negotiation. Subject to the last sentence of this Section 2.8, Kuur shall have a right of first negotiation with respect to any ROFN Product and associated ROFN Product Rights as and to the extent provided under this Section 2.8. Following the disclosure to Baylor of any ROFN Product and associated ROFN Product Rights (whether or not patentable) by Baylor employees, and prior to offering a license to any Third Party with respect thereto, Baylor shall inform Kuur of such disclosure and provide a written summary of such ROFN Products and associated ROFN Product Rights. Kuur shall have a period of [*] days to elect to exercise such right of first negotiation, and upon written notice thereof in such time period, Baylor shall negotiate with Kuur, in good faith, for a period of [*] days , the commercially reasonable terms of a license agreement for such ROFN Product that is the subject of such invention disclosure and the associated ROFN Product Rights. In the event the Parties are unable to agree on such license agreement in such time period, Baylor shall not have the right to license such ROFN Product or such associated ROFN Product Rights to a Third Party on terms that are less favorable to Baylor than the terms last offered by Kuur for a period of [*] days . The right of first negotiation under this Section 2.8 shall terminate upon termination or expiration of the later of: (i) the Co-Development Agreement or (ii) the Tail Period. Notwithstanding the foregoing, with respect to any ROFN Product which is directed to the same target as to which any Licensed Core Product is directed, Baylor's sole obligation with respect thereto shall be to so inform Kuur of such ROFN Product and provide to Kuur a written summary of such ROFN Product and its associated ROFN Product Rights.

ARTICLE III
OPTION GRANTS

3.1 Grant of Exclusive Future Oncology Option.

(a) Effective upon payment of the License Execution Fee in Section 5.1, and subject to Section 3.3, Baylor hereby grants to Kuur an exclusive option (the "Future Oncology Option") to obtain the license set forth in Section 2.2 with respect to each Future Oncology Invention, as all further described in this Section 3.1. The option period for a given Future Oncology Invention shall commence upon Disclosure of such Future Oncology Invention to the JSC under the Co-Development Agreement (or in the case of any Future Oncology Invention which constitutes Future Metelitsa Lab Oncology Technology, following the Disclosure to Baylor of such Future Oncology Invention, Baylor shall so provide Kuur such Disclosure in writing, and the option period with respect thereto shall commence as of the date of such Disclosure), in each case, a "Future Oncology Invention Disclosure Date," and shall expire [*] after the delivery to Kuur of the Data Package for the FIM Study with respect to the first Future Oncology Product which embodies, includes or incorporates, or is made using, such Future Oncology Invention (the "Trigger Oncology Product"), subject to Section 3.1(b). If Kuur exercises such option prior to the conduct of the FIM Study for such Trigger Oncology Product, Baylor shall retain the right to continue to conduct the FIM Study for such Trigger Oncology Product under and in accordance with the terms of the Co-Development Agreement and Section 2.6.

(b) Notwithstanding Section 3.1(a), the option period for a Future Oncology Invention shall expire (i) [*] months after the Future Oncology Invention Disclosure Date if such Future Oncology Invention has not been incorporated into the Development Plan within such [*] period (provided that (A) the option period shall not so expire if such Future Oncology Invention is not incorporated into the Development Plan due to Baylor's JSC members not agreeing to incorporate such Future Oncology Invention into the Development Plan or Baylor's lack of resources or capacity to perform Early R&D Activities for such Future Oncology Invention, or (B) if any part of the FIM Study is conducted by Baylor, then such option shall not expire until [*] after the delivery to Kuur of the Data Package for such FIM Study with respect to such Future Oncology Invention; or (ii) if such Future Oncology Invention is dropped from the Development Plan, twelve (12) months after such Future Oncology Invention is dropped from the Development Plan, provided that such Future Oncology Invention is not dropped from the Development Plan due to Baylor's lack of resources or capacity to perform Early R&D Activities for such Future Oncology Invention.

(c) When exercising its option with respect to a particular Future Oncology Invention (and its associated Future Oncology Patent Rights), Kuur shall have the right to exercise such option:

(i) solely with respect to, and as embodied in, or used to manufacture or create, the relevant Trigger Oncology Product, and not as to all other Future Oncology Products (an "Oncology Product-Only Exercise"),

in which event the license granted in Section 2.2 with respect to such Future Oncology Invention shall be restricted to only such Trigger Oncology Product, and only one Option Exercise Payment shall be due to Baylor;

(ii) solely with respect to such Future Oncology Invention (and its associated Future Oncology Patent Rights), but not the specific Trigger Oncology Product (an "Oncology Invention-Only Exercise"), in which event the license granted in Section 2.2 with respect to such Future Oncology Invention shall include all Future Oncology Products other than the Trigger Oncology Product, and only one Option Exercise Payment shall be due to Baylor with respect to such Future Oncology Invention (or more than one such payment, if the option is being exercised to more than one Future Oncology Invention embodied in, or used to manufacture or create the Trigger Oncology Product at such time); or

(iii) both (A) with respect to the particular Trigger Oncology Product, as well as (B) with respect to one or more Future Oncology Inventions embodied in, or used to manufacture or create, such Trigger Oncology Product (an "Oncology Product and Invention Exercise"), in which event the license granted in Section 2.2 with respect to such Future Oncology Invention shall include both the Trigger Oncology Product and all other Future Oncology Products, and an Option Exercise Payment shall be due to Baylor for the exercise with respect to the Trigger Oncology Product as well as to each of the Future Oncology Inventions. (For the purpose of exemplary illustration of such Option Exercise Payment only, and without implying any cap on the Option Exercise Payment: [*] in total would be owed upon an Oncology Product and Invention Exercise for only one Future Oncology Invention or a total of [*] in total would be owed upon an Oncology Product and Invention Exercise for two separate Future Oncology Inventions.)

(d) It is expressly understood that a particular Trigger Oncology Product as to which Baylor conducts a FIM Study may include, incorporate, or embody, or have been made using, more than one Future Oncology Invention, one or more of which Kuur has not yet exercised its option with respect to as of the time of delivery to Kuur of the Data Package. In such event, Kuur may exercise some or all of such options to the separate Future Oncology Inventions, all as provided in Section 3.1(c) and in accordance with Section 3.5, and each exercise would be subject to a separate Option Exercise Payment. It is also understood that a particular Trigger Oncology Product as to which Baylor conducts a FIM Study may include, incorporate, or embody, or have been made using either (i) one or more Future Oncology Inventions as to which Kuur has already exercised its option, as of the time of delivery to Kuur of the Data Package therefor, or (ii) one or more inventions or aspects of the Core Subject Technology, in each of which event, Kuur would be required to make a separate Option Exercise Payment only for the Future Oncology Invention as to which it had not yet exercised its option, and not with respect to those Future Oncology Inventions as to which it had previously exercised its option or to any Core Subject Technology already licensed to Kuur under Section 2.1.

(e) For clarity, the exclusive license granted by Baylor to Kuur under Section 2.2 upon an Oncology Invention-Only Exercise or an Oncology Product and Invention Exercise with respect to a particular Future Oncology Invention pursuant to Sections 3.1(c)(ii) or (iii) respectively, and in accordance with Sections 3.4 and 3.5, shall not include a license to research, develop, make, have made, use, market, sell, offer to sell, lease and import Licensed Core Products and Future Oncology Products in the Field that incorporate or utilize any Future Oncology Invention as to which Kuur has not yet exercised its license option.

(f) Notwithstanding anything contained herein to the contrary in this Agreement or the Co-Development Agreement, the Parties hereby acknowledge and agree that: (i) as of or prior to the First Restatement Effective Date, Kuur has exercised, or has been deemed to have exercised, any option hereunder that applies to the New Modified NKT Product, and (ii) no option or other payments are required or owed by Kuur in connection with any such exercised, or deemed exercised, option hereunder that applies to the New Modified NKT Product.

3.2 Grant of Exclusive Future Non-Oncology Option.

(a) Option Grant. Effective upon Kuur fulfilling the payment obligations set forth in clauses (i) and (ii) of Section 3.2(c), and subject to the conditions and restrictions below and Section 3.3, Baylor hereby grants to Kuur an exclusive option (the "Future Non-Oncology Option") to obtain the license set forth in Section 2.3 with respect to each Future Non-Oncology Invention.

(b) Option Period.

(i) The option period for a given Future Non-Oncology Invention shall be in effect only following receipt of payment of the Future Non-Oncology Technology Research & Development Payment under Section 3.2(c)(ii), and shall commence upon Disclosure of such Future Non-Oncology Invention to the JSC under the Co-Development Agreement, and expire [*] months after the delivery to Kuur of the Data Package for the FIM Study with respect to the first Future Non-Oncology Product which embodies, includes or incorporates, or is made using, such Future Oncology Invention (the "Trigger Non-Oncology Product"), subject to Section 3.2(b)(ii). If Kuur exercises such option prior to the conduct of the FIM Study for such Trigger Non-Oncology Product, Baylor shall retain the right to continue to conduct the FIM Study for such Trigger Non-Oncology Product under and in accordance with the terms of, the Co-Development Agreement and Section 2.6.

(ii) Notwithstanding Section 3.2(b)(i), the option period for a Future Non-Oncology Invention shall expire (A) [*] after the Future Non Oncology Invention Disclosure Date if such Future Non-Oncology Invention has not been incorporated into the Development Plan within such [*] period (provided that (1) the option period shall not so expire if such Future Non-Oncology Invention is not incorporated into the Development Plan due to Baylor's JSC members not agreeing to incorporate such Future Non-Oncology Invention into the Development Plan or Baylor's lack of resources or capacity to perform Early R&D Activities for such Future Non-Oncology Invention), or (2) if any part of the FIM Study is conducted by Baylor, then such option shall not expire until [*] after the delivery to Kuur of the Data Package for such FIM Study with respect to such Future Non-Oncology Invention; or (B) if such Future Non-Oncology Invention is dropped from the Development Plan, [*] after such Future Non-Oncology Invention is dropped from the Development Plan, provided that such Future Non-Oncology Invention is not dropped from the Development Plan due to Baylor's lack of resources or capacity to perform Early R&D Activities for such Future Non-Oncology Invention.

(iii) When exercising its option with respect to a particular Future Non-Oncology Invention (and its associated Future Non-Oncology Patent Rights), Kuur shall have the right to exercise such option:

(1) solely with respect to, and as embodied in, or used to manufacture or create, the relevant Trigger Non-Oncology Product, and not as to all other Future Non-Oncology Products (a "Non-Oncology Product-Only Exercise"), in which event the license granted in Section 2.3 with respect to such Future Oncology Invention shall be restricted to only such Trigger Non-Oncology Product, and only one Option Exercise Payment shall be due to Baylor;

(2) solely with respect to such Future Non-Oncology Invention (and its associated Future Non-Oncology Patent Rights), but not the specific Trigger Non-Oncology Product (a "Non-Oncology Invention-Only Exercise"), in which event the license granted in Section 2.3 with respect to such Future Non-Oncology Invention shall include all Future Non-Oncology Products other than the Trigger Oncology Product, and only one Option Exercise Payment shall be due to Baylor with respect to such Future Non-Oncology Invention (or more than one such payment, if the option is being exercised to more than one Future Oncology Invention embodied in, or used to manufacture or create the Trigger Oncology Product at such time); or

(3) both (x) with respect to the particular Trigger Non-Oncology Product, as well as (y) with respect to one or more Future Non-Oncology Inventions embodied in, or used to manufacture or create, such Trigger Non-Oncology Product (a "Non-Oncology Product and Invention Exercise"), in which event the license granted in Section 2.3 with respect to such Future Non-Oncology Invention shall include both the Trigger Non-Oncology Product and all other Future Non-Oncology Products, and an Option Exercise Payment shall be due to Baylor for the exercise with respect to the Trigger Oncology Product as well as to each of the Future Oncology Inventions with respect to which it exercised such option (e.g. $[*] in total would be owed upon a Non-Oncology Product and Invention Exercise for only one Future Non-Oncology Invention or a total of [*] in total would be owed upon a Non-Oncology Product and Invention Exercise for two separate Future Non -Oncology Inventions).

(iv) It is expressly understood that a particular Trigger Non- Oncology Product as to which Baylor conducts a FIM Study may include, incorporate, or embody, or have been made using, more than one Future Non-Oncology Inventions, one or more of which Kuur may have not yet exercised its option with respect to as of the time of delivery to Kuur of the Data Package. In such event, Kuur may exercise some or all of such options to each of

the separate Future Non-Oncology Inventions, all as provided in Section 3.2(b)(iii) and in accordance with Sections 3.4 and 3.5 and during the Option Period for such Trigger Non-Oncology Product, and each exercise would be subject to a separate Option Exercise Payment. It is also understood that a particular Trigger Non-Oncology Product as to which Baylor conducts a FIM Study may include, incorporate, or embody, or have been made using either (A) one or more Future Non-Oncology Inventions as to which Kuur has already exercised its option, as of the time of delivery to Kuur of the Data Package therefor, or (B) one or more inventions or aspects of the Core Subject Technology, in each of which event, Kuur would be required to make a separate Option Exercise Payment only for the Future Oncology Invention as to which it had not yet exercised its option, and not with respect to those Future Oncology Inventions as to which it had previously exercised its option, or to any Core Subject Technology already licensed to Kuur under Section 2.1.

(c) Conditions. The grant of the Future Non-Oncology Option in Section 3.2(a) is conditioned on, subject to, and restricted by the following terms:

(i) Future Non-Oncology Product Option Payment. Kuur shall pay, and does pay, Baylor a one-time, non-refundable, payment of [*] on or before the earlier of (A) the date on which Kuur first exercises its option under Section 3.2 or (B) December 31, 2020 (the "Future Non-Oncology Product Option Payment"). If Kuur fails to make said Future Non-Oncology Product Option Payment, Baylor shall be free to commercialize the Future Non-Oncology Technology with Third Parties without any further obligation to Kuur or any limitation under this Agreement, other than as set forth in Article XVII.

(ii) Future Non-Oncology Technology Research & Development Payment. In addition to the Future Non-Oncology Product Option Payment, Kuur shall also pay, and does pay, [*] in addition to and at the same time as the [*] Quarterly R&D Payment (as defined under and in accordance with conditions set forth in the Co-Development Agreement) to support the research and development of Future Non-Oncology Technology as set forth in the proposed Development Plan and Budget therefor (the "Future Non-Oncology Technology Research & Development Payment"). Notwithstanding the foregoing, Kuur shall not be obligated to make the Future Non-Oncology Technology Research & Development Payment until Baylor has provided Kuur with an acceptable work plan for use of such funds, and Kuur has agreed that such work plan is acceptable.

3.3 Option Maintenance Terms. The Future Oncology Option (Section 3.1) and the Future Non-Oncology Option (Section 3.2) will continue in force until the termination of the Co-Development Agreement (such period, the "Option Maintenance Period"), subject to Section 2.7. Upon termination under this Section 3.3 of the Future Oncology Option and/or the Future Non-Oncology Option (other than as provided in Section 2.7), all rights in Future Oncology Inventions and the Future Non-Oncology Inventions as to which Kuur has not, as of such time, exercised its option will remain with Baylor, and all contingent future interests shall automatically, without need for any notice or other action, terminate, and Kuur shall not have any right to any license under this Agreement for such Future Technology; provided, however that the following shall apply in such event:

(a) if such termination occurs within the six-month period after delivery of the Data Package referred to in Section 3.1, or Section 3.2(b) for any particular Future Oncology Product and/or Future Non-Oncology Product, the option to the Future Oncology Invention(s) relevant to such particular Future Oncology Option or Future Non-Oncology Invention(s) relevant to such Future Non-Oncology Option shall survive to the end of the Option Period under Section 3.1 or Section 3.2(b), and solely with respect to such invention(s); and

(b) such termination of the Co-Development Agreement shall not affect any then-ongoing Work Plans or Specific Industrial Clinical Research Agreement, which shall continue in accordance with its terms, all as further provided in the Co-Development Agreement, and Kuur shall retain the option rights set forth in Section 3.1 or Section 3.2, as applicable, with respect to any Future Technology and/or Future Oncology Products or Future Non-Oncology Products arising from such continuing Work Plan(s) or Specific Industrial Clinical Research Agreement(s).

(c) For the avoidance of doubt, ROFN Products are not subject to the options under Section 3.1 and Section 3.2.

3.4 Option Exercise Procedure.

(a) Future Oncology Products. For each distinct Future Oncology Invention, and for each Trigger Oncology Product in which any such invention is embodied, included or incorporated, or used to make, if Kuur elects to exercise its option set forth in Section 3.1 it shall deliver to Baylor during the Option Period written notice of such election to exercise its option under Section 3.1 identifying each such distinct Future Oncology Invention and/or Trigger Oncology Product elected, accompanied by payment of the appropriate Option Exercise Payment. With respect to a distinct Future Oncology Invention or Oncology Trigger Product, the Future Oncology Option under Section 3.1 shall be deemed exercised solely upon receipt by Baylor of such Option Exercise Payment by Kuur.

(b) Future Non-Oncology Products. For each distinct Future Non-Oncology Invention, and for each Trigger Non-Oncology Product in which any such invention is embodied, included or incorporated, or used to make, if Kuur elects to exercise its option set forth in Section 3.2 it shall deliver to Baylor during the Option Period written notice of such election to exercise its option under Section 3.2 identifying each to such distinct Future Non-Oncology Invention and/or Trigger Non-Oncology Product elected, accompanied by payment of the appropriate Option Exercise Payment. With respect to a distinct Future Non-Oncology Invention or Non-Oncology Trigger Product, the Future Non-Oncology Option under Section 3.2 shall be deemed exercised solely upon (i) receipt by Baylor of such Option Exercise Payment by Kuur and (ii) satisfaction of the other conditions set forth in Section 3.2(c).

3.5 Option Exercise Payment. A payment of $[*] ("Option Exercise Payment") shall be paid by Kuur to Baylor for the exercise of the Future Oncology Option as to each Future Oncology Invention or Trigger Oncology Product, as the case may be, or for the exercise of the Future Non-Oncology Option with respect to each Future Non-Oncology Invention or Trigger Non-Oncology Product, as the case may be, in each case for which Kuur exercises the applicable option, in accordance with Sections 3.1, 3.2 and 3.4.

3.6 Released Products and Released Technology Inventions.

(a) Release of Option. If Kuur does not exercise its option with regard to a distinct Future Oncology Invention or Trigger Oncology Product during the option period under Section 3.1 or with regard to a distinct Future Non-Oncology Invention or Trigger Non-Oncology Product during the option period under Section 3.2(b), (each, a "Released Invention" or "Released Product" as the case may be), Baylor shall thereafter have the right to assign, sell, license, or otherwise transfer any rights including any Technology Rights owned by Baylor covering such Released Invention or such Released Product (but no other invention already licensed to Kuur and subject to any existing license rights of Kuur in and to any such Released Invention as it may relate to a Trigger Oncology Product or Trigger Non-Oncology Product, as the case may be, for which it has exercised its option), to any Third Party without the written consent of Kuur, if:

(i) Kuur (collectively with Kuur and its Affiliates and sublicensees) has fewer than three (3) Licensed Core Products and/or Future Oncology Products or Future Non-Oncology Products in development or commercialization; except where the JSC terminated the Early R&D Activities for a Licensed Core Product or a Future Oncology Product or a Future Non-Oncology Product less than 90 days prior to the expiration of the Option Period and has not yet determined a replacement product therefor;

(ii) Such Released Invention is not subject to further use under the Development Plan in connection with other Future Products, as the Development Plan exists as of the time such invention becomes a Released Invention (provided this Section 3.6(a)(ii) shall not prevent Baylor from granting a license to a Released Product, so long as the license granted for such Released Invention extends solely to the use of such Released Invention for the use, manufacture and sale of such Released Product); and

(iii) the license agreement with such Third Party with respect to any such Released Invention and/or Released Product requires that such Third Party pay to Baylor economic terms equivalent to or better than the lesser of (i) the upfront, milestones and royalties set forth in this Agreement with respect thereto, as of such time, or (ii) those last offered by Kuur within the preceding 180 days with respect to such Released Invention and Released Product.

Notwithstanding the foregoing, at no time shall Baylor have the right (even if the conditions in clauses (i), (ii) and (iii) of this Section 3.6(a) are met) to so license its rights to a Released Product or to a Released Invention to a Third Party if such Released Product or any product incorporating or utilizing, or made using such Released Invention has the same molecular target as (A) any Licensed Product, or (B) any Future Product being developed under the Development Plan or a SIRA or Work Plan or SICRA that has not become a Released Product.

(b) Sharing of Proceeds. If Baylor licenses rights to a Released Product as and to the extent permitted under this Section 3.6, Kuur and Baylor shall share the amounts received by Baylor under such license: (i) with [*]_____ to Kuur and [*]_____ to Baylor until the amounts received by Kuur under this Section 3.6 equal Kuur's payments under the Development Plan and disbursed in accordance with the Development Budget for such Released Product, and (ii) thereafter, with [*]_____ to Baylor and [*]_____ to Kuur.

(c) Third Party Components. In the event that a Released Product incorporates Technology that has been licensed to Kuur from a Third Party for use by both Kuur and Baylor, Kuur shall use reasonable good-faith efforts to arrange for a product-specific sublicense to Baylor which can be further sublicensed to a Third Party, where Baylor is permitted to grant such a license to a Third Party under Section 3.6(a). In such cases, however, Kuur will not be required to sublicense any such technologies if such an arrangement results in Kuur being required to pay any amount to its Third Party licensor, or is not justified by reasonable business terms and conditions and in particular if the cash flow implications of extending such a sublicense to Baylor and/or to such Third Party would negatively impact Kuur.

(d) Exclusivity. From the Effective Date until such time as Baylor is permitted to grant a license to any Released Product or Released Invention under Section 3.6(a), Baylor shall not offer to any Third Party any rights, or options to obtain rights, to the Future Oncology Technology or the Future Non-Oncology Technology or any product associated therewith, except as and solely to the extent required under the Existing Third Party Agreement as in effect on the Effective Date.

3.7 Technology Transfer. Upon completion of the FIM Study and exercise by Kuur of its option under Sections 3.1 or 3.2, Baylor shall transfer to Kuur all Technology in Baylor's possession or control, to the extent not already in Kuur's possession, relating to the Future Oncology Invention or Future Non-Oncology Invention (each, an "Invention") and/or Trigger Oncology Product or Trigger Non-Oncology Product, as the case may be (each, a "Trigger Product") for which such option was exercised, including all Technology relating to the Trigger Product (if the option is so exercised) and any Future Product which embodies, includes or incorporates, or is made using, such Invention (if the option to such Invention is exercised). In addition, Baylor will provide (a) reasonable assistance and cooperation in order to enable Kuur or its designee to implement and utilize such transferred Technology, (b) provide Kuur with access to Baylor's employees and contractors with appropriate expertise to answer Kuur's questions related to such transfer; and (c) to Kuur or its designee its inventory of such Future Product and in-process materials (if any) if applicable.

3.8 Expansion of Fields.

(a) Expansion Outside the Field. Kuur is hereby granted the exclusive option to expand the field of use of the license granted to any and all Licensed Core Products, subject to any and all conditions set forth in Section 2.1, and Licensed Future Oncology Products, subject to any and all conditions set forth in Section 2.2, to any indication or applications Outside the Field. Such option shall be exercisable at any time after the payment to Baylor of the Future Non-Oncology Product Option Payment under Section 3.2(c), by written notice to Baylor thereof. Following such exercise, (i) the license grant in Sections 2.1 and 2.2 to Licensed Core Products shall be automatically deemed to be both for uses in the Field and Outside the Field; and (ii) the license grant in Section 2.2 to Licensed Future Oncology Products shall be automatically deemed to be both for uses in the Field and Outside the Field.

(b) Expansion to the Field. Kuur is hereby granted, subject to any and all conditions set forth in Section 2.3, the exclusive option to expand the field of use of the license granted to any and all Licensed Future Non-Oncology Products to any indication or applications in the Field. Such option shall be exercisable at any time after the payment to Baylor of the Future Non-Oncology Product Option Payment under Section 3.2(c), by written notice to Baylor thereof. Following such exercise, the license grant in Section 2.3 to Licensed Future Non-Oncology Products shall be automatically deemed to include both uses in the Field and Outside the Field, and the license grant in Section

2.2 under Future Oncology Technology shall include the right to research, develop, make, have made, use, market, sell, offer to sell, lease and import Licensed Future Non-Oncology Products.

3.9 Requirement for Co-Development Agreement Execution. The licenses to the Core Subject Technology under Section 2.1 and the Future Oncology Option under Section 3.1 are being granted by Baylor to Kuur with the requirement for the contemporaneous execution of the Co-Development Agreement, subject to the terms and conditions of the Co-Development Agreement. For the avoidance of doubt, Kuur will not be entitled to exercise its Future Technology Option unless it also executes the Co-Development Agreement.

3.10 Ownership of Optioned Rights. Any option granted by Baylor under this Agreement to receive any license under or to or regarding any Patent Right or other Technology Right is granted by Baylor only to the extent that Baylor Controls such Patent Right or other Technology Right. Any option granted by Baylor under this Agreement to receive any license under or to or regarding any Technology or Technology Right is granted by Baylor only to the extent that Baylor Controls such Technology and the Technology Rights in such Technology.

ARTICLE IV
OPTION FOR BAYLOR TARGET ANTIGENS; NEW ANTIGENS

4.1 Option for Baylor Target Antigens.

(a) Pursuant to the Original Agreement, Baylor granted to Kuur, for each Baylor Target Antigen (solely to the extent that Baylor Controls Technology Rights relating to such Baylor Target Antigen), an exclusive option to obtain the exclusive license set forth in Section 2.1(a) with respect to each Baylor Target Antigen (with respect to each Baylor Target Antigen, an "Antigen Option").

(b) The Parties hereby acknowledge and agree that: (i) as of or prior to the First Restatement Effective Date, Kuur has exercised, or has been deemed to have exercised, the Antigen Option with respect to the following two Baylor Target Antigens: (A) GD2, and (B) GPC3 (each, an "Exercised Baylor Target Antigen"), and (ii) no option or other payments are required or owed by Kuur in connection with any such exercised, or deemed exercised, Antigen Options for GD2 and GPC3. Accordingly, each of the Exercised Baylor Target Antigens are deemed a Licensed Antigen and (ii) all Baylor Target Patent Rights covering or disclosing any Modified NKT Product directed to an Exercised Baylor Target Antigen are included in the Licensed Core Technology Rights. The Parties further acknowledge and agree that Kuur did not exercise the Antigen Option with respect to the Baylor Target Antigen CSPG4 and such option for CSPG4 has expired.

ARTICLE V
PAYMENTS; CLOSING

5.1 License Execution Fee. As consideration for the rights conveyed by Baylor under this Agreement, Kuur paid Baylor a non-refundable total license fee (the "License Execution Fee") comprising: (a) [*]_____ in cash in immediately available funds by wire transfer to Baylor's Account; and (b) certain shares in Kuur Therapeutics Ltd.

5.2 5.2 through 5.12 [Intentionally Omitted].

5.13 Royalty on Net Sales. Kuur shall pay Baylor the following royalties on a Licensed Product by Licensed Product, country by country, Calendar Year by Calendar Year, basis as set forth herein, subject to the terms and conditions of this Agreement:

(a) For Net Sales by Kuur or its Affiliates or sublicensees:

(i) up to [*]_____of Net Sales if such Licensed Product is covered by a Valid Claim in the country in which it is sold. Notwithstanding the foregoing, Kuur shall have the right to credit against such royalty amount owed under this Section 5.13(a)(i) for a particular Licensed Product any and each amount of royalties owed to Third Parties in consideration for a license to (1) any invention claimed in any

Patent Rights controlled by such Third Party that has been incorporated, with the approval of the JSC under the Co-Development Agreement, or with the approval of Baylor after the expiration or termination of the Co-Development Agreement, into any such Licensed Product; and (2) any other Patent Rights necessary for the manufacture, use or sale or other commercialization of such Licensed Product (clauses (1) and (2), collectively, the "Third Party IP"), to the extent actually paid by Kuur or such Affiliate or by any sublicensee for such Licensed Product; provided, however that the Royalties paid to Baylor for the Net Sales of such Licensed Product shall not be less than one and three quarters of a percent (1.75%) of such Net Sales. Such reduction of Royalties allowed hereunder shall apply on an annual basis with no carryover of Third Party royalty balance from one calendar year to the following calendar year; or

(ii) greater than [*]_____ of Net Sales if such Licensed Product is covered by a Valid Claim in the country in which it is sold. Notwithstanding the foregoing, Kuur shall have the right to credit against such royalty amount owed under this Section 5.13(a)(ii) for a particular Licensed Product any and each amount of royalties owed to Third Parties in consideration for a license to any and all Third Party IP to the extent actually paid by Kuur or such Affiliate or by any sublicensee for such Licensed Product; provided, however that the Royalties paid to Baylor for the Net Sales of such Licensed Product shall not be less than [*]_____ of such Net Sales. Such reduction of Royalties allowed hereunder shall apply on an annual basis with no carryover of Third Party royalty balance from one calendar year to the following calendar year; or

(iii) a royalty of [*]_____ of Net Sales if such Licensed Product is not covered by a Valid Claim in the country in which it is sold, without any credit for royalties or other payments paid by Kuur or such Affiliate or such sublicensee to a Third Party. Notwithstanding the foregoing, Kuur shall have the right to credit against such royalty amount owed under this Section 5.13(a)(iii) for a particular Licensed Product any and each amount of royalties owed to Third Parties in consideration for a license to any and all Third Party IP to the extent actually paid by Kuur or such Affiliate or such sublicensee for such Licensed Product; provided, however that the Royalties paid to Baylor for the Net Sales of such Licensed Product shall not be less than [*]_____ of such Net Sales. Such reduction of Royalties allowed hereunder shall apply on an annual basis with no carryover of Third Party royalty balance from one calendar year to the following calendar year. For clarity, if a Licensed Product is not covered by a Valid Claim in the country in which it is sold (and no such patents included within the Patent Rights issue in such country), then (unless sooner terminated as otherwise provided in Article XI) the day immediately following the tenth (10th) anniversary of the first commercial sale of such Licensed Product on behalf of or otherwise by Kuur in such country, [*]_____shall be owed thereafter to Baylor under this Section 5.13(a)(iv) for such Licensed Product in such country.

(iv) Royalties on Combination Products. If any Licensed Products are contained in any Combination Product, Royalties for such Combination Product shall be prorated as follows:

(1) If the Licensed Product and other active agent are available separately, the Net Sales for purposes of Royalties for the Combination Product will be calculated by multiplying the Net Sales of the combination by the fraction A/(A+B), where A is the separately available gross invoice price of the Licensed Products in the combination, and B is the separately available gross invoice price for all other active agents in the combination.

(2) If the Combination Product includes other active agents for which a public or list price cannot be determined, the Net Sales for purposes of royalty payments will be calculated by multiplying the Net Sales of the combination by A/C, where A is as defined above and C is the gross invoice price of the combination.

(3) If the Licensed Products contained in the combination are not Sold separately, the Parties agree to negotiate in good faith a reduction in the royalty rate to reflect the fair value that the Licensed Product attributed to the overall product sold. If the Parties are unable to reach such an agreement prior to the end of the applicable accounting period, the Parties will refer such matter to a jointly selected third party, in accordance with the provisions of Article XIV, with expertise in the pricing of pharmaceutical products that is not, and has not in the past 5 years been, an employee, consultant, legal advisor, officer, director or stockholder of, and does not have any conflict of interest with respect to, either Party, for resolution.

(b) Collectively the royalty payments that are the subject of this Section 5.13 are termed "Royalties" for purposes of this Agreement and shall be due and payable as provided in Article VI and delivered to Baylor in accordance with Section 5.16.

5.14 Milestone Payments.

(a) *Amounts Owed*.

(i) Kuur shall also pay Baylor a one-time milestone payment on each Licensed Product which is a Distinct Product, within the period of time specified in Section 5.14(d) after the achievement of the corresponding milestone event achieved as set forth in the chart below in this Section 5.14(a)(i) (such chart, the "Milestone Chart" and each such milestone event set out in the Milestone Chart, a "Milestone Event"), the amount of such milestone payment is specified in accordance with the Milestone Chart for such Milestone Event achieved, as of the time of achievement of such Milestone Event in, as applicable, the country or the supra-national jurisdiction, if applicable, where, the IND, BLA or corresponding non-U.S. regulatory application, as applicable, has been allowed or approved for such Distinct Product as of the time of achievement of such Milestone Event (each such milestone payment, a "Milestone Payment"). Notwithstanding anything contained herein to the contrary, each Milestone Payment shall only (A) apply to the first Distinct Product to achieve (if any) each Milestone Event specified in the Milestone Chart, and (B) be payable once regardless of the number of Distinct Products to achieve such Milestone Event.

Milestone Event #	Milestone Event	Milestone Payment (for a Distinct Product)
1	Dosing of first patient in first Pivotal Clinical Trial of such a Distinct Product	$[*]
2	Approval by the FDA or EMA of the first Biological License Application (BLA) or Marketing Authorization Application (MM) for such a Distinct Product (whichever occurs first, but not both)	$ [*] but notwithstanding anything to the contrary herein, such Milestone Payment for the achievement of this Milestone Event 2 for such Distinct Product shall be paid within six (6) months after the First Commercial Sale (as defined below) of such Distinct Product to a Third Party: (A) in the U.S. (if this Milestone Event 2 was achieved by approval by the FDA), or (B) in France, Germany, the United Kingdom, Italy or Spain (*if this Milestone Event 2 was achieved by approval by the EMA*). "First Commercial Sale" means, with respect to a Distinct Product and country, the first sale to a Third Party of such Distinct Product in such country after marketing authorization and pricing approval has been obtained in such country.
3	Completion of the first Calendar Year in which Net Sales by Kuur, its Affiliates and sublicensees, of such a Distinct Product exceed $[*]	$ [*]
4	Completion of the first Calendar Year in which Net Sales by Kuur, its Affiliates and sublicensees, of such a Distinct Product exceed $ [*]	$ [*]
5	Completion of the first Calendar Year in which Net Sales by Kuur, its Affiliates and sublicensees of such a Distinct Product exceed $.[*]	$ [*]
6	Completion of the first Calendar Year in which Net Sales by Kuur, its Affiliates and sublicensees, of such a Distinct Product exceed $.[*]	$[*]

(ii) For the avoidance of doubt, once a Milestone Payment listed in the Milestone Chart above (for Milestone Events 1 through 6) has been paid on a given Distinct Product, should the same Milestone Event (e.g., a second Pivotal Trial for another indication) be achieved, no additional Milestone Payment would be owed), subject solely to Section 5.14(c) with respect to SPP Indications.

(b) *Adjustments for Small Patient Populations*:

(i) As used herein, an "SPP Indication" means an indication for which the patient population for both the U.S. and the E.U., collectively, is estimated (by FDA, EMA, World Health Organization, Centers for Disease Control, or other similarly reputable medical authority) at less than 5,000 patients. If the Parties disagree with respect to the size of such patient population and cannot resolve such issue within thirty (30) days of undertaking to do so, then they shall engage a mutually agreeable Third Party expert to substantiate the estimated patient population. The costs of such expert shall be shared equally by the Parties, and such expert's decision shall be binding upon the Parties.

(ii) If a Distinct Product that is being developed pursuant to this Agreement achieves Milestone Event 1 (Dosing of first patient in first Pivotal Clinical Trial) where such Pivotal Clinical Trial is being conducted for an SPP Indication (an "SPP Pivotal Clinical Trial"), then the Milestone Payment payable under Section 5.14(a) above for the achievement of Milestone Event 1 (the "Original Milestone 1 Payment Amount") shall be reduced by [*] %_____ (such reduced amount, the "SPP Pivotal Trial Milestone Amount"). In such event, (A) if one or more SPP Pivotal Clinical Trials are subsequently initiated pursuant to this Agreement for such Distinct Product for different SPP Indications, then Kuur shall again pay Baylor the SPP Pivotal Trial Milestone Amount upon the dosing of the first patient in the first SPP Pivotal Clinical Trial for such different SPP Indication for up to three (3) such subsequent SPP Pivotal Clinical Trials; and (B) if a Pivotal Clinical Trial is subsequently initiated pursuant to this Agreement for such Distinct Product for an indication other than an SPP Indication, then Kuur shall pay Baylor an amount equal to (1) the Original Milestone 1 Payment Amount minus (2) the total of all other payments made by Kuur for such Distinct Product pursuant to this Section 5.14(b)(ii) (such amount, the "Milestone 1 Differential Amount"). For clarity, for each Distinct Product: (X) the payments made under this Section 5.14(b)(ii) (if any) are in lieu of any other payment to be made to Baylor for the achievement of Milestone Event 1 for such Distinct Product, subject to Section 5.14(b)(iv); (Y) in no event shall the total payments owed by Kuur to Baylor under this Section 5.14(b)(ii) exceed the Original Milestone 1 Payment Amount for such Distinct Product; and (Z) if Kuur makes the Milestone Differential Payment to Baylor under Section 5.14(b)(iv) below for such Distinct Product, then no further payments shall be due to Baylor under this Section 5.14(b)(ii) with respect to such Distinct Product.

(iii) If a Distinct Product that is being developed pursuant to this Agreement achieves Milestone Event 2 (Approval of a BLA or MAA), where such approval is for an SPP Indication, then the Milestone Payment payable under Section 5.14(a) for the achievement of Milestone Event 2 (the "Original Milestone 2 Payment Amount") shall be reduced by [*] %_____ (such reduced amount, the "SPP Approval Milestone Amount"). In such Milestone Event, (A) if such Distinct Product subsequently receives BLA or MAA approval for a different SPP Indication, then Kuur shall again pay Baylor the SPP Approval Milestone Amount upon the receipt of BLA approval from the FDA or MAA approval from the EMA (whichever occurs first, but not both) for such Distinct Product for such SPP Indication for each of up to three (3) subsequent SPP Indications; and (B) if such Distinct Product receives BLA approval from the FDA or MAA approval from the EMA (whichever occurs first, but not both) for an indication other than an SPP Indication, then Kuur shall pay Baylor an amount equal to (1) the Original Milestone 2 Payment Amount minus (2) the total of all other payments made by Kuur for such Distinct Product pursuant to this Section 5.14(b)(iii) (the "Milestone 2 Differential Amount"). For clarity, for each Distinct Product: (X) the payments made under this Section 5.14(b)(iii) are in lieu of any other payment to be made to Baylor for the achievement of Milestone Event 2 for such Distinct Product, subject to Section 5.14(b)(iv); (Y) in no Milestone Event shall the total payments owed by Kuur to Baylor under this Section 5.14(b)(iii) exceed the Original Milestone 2 Payment Amount for such Distinct Product; and (Z) if Kuur makes the Milestone Differential Payment to Baylor under Section 5.14(b)(iv) for such Distinct Product, then no further payments shall be due to Baylor under this Section 5.14(b)(iii) with respect to such Distinct Product.

(iv) If a Distinct Product that has received BLA or MAA approval for an SPP Indication achieves Milestone Event 3 (annual Net Sales in excess of $[*]_____), and Kuur has made payments to Baylor under either or both of Section 5.14(b)(ii) and Section 5.14(b)(iii) for such Distinct Product, then in addition to the Milestone Payment to be made upon such achievement pursuant to Section 5.14(a) above, Kuur shall make a "Milestone Differential Payment" for such Distinct Product equal to the sum of (A) the Milestone 1 Differential Amount for such Distinct Product (if any), plus (B) the Milestone 2 Differential Amount for such Distinct Product (if any). The Milestone Differential Payment shall be made contemporaneously with Milestone Payment for Milestone Event 3.

(v) For purposes of this Section 5.14, the United Kingdom shall not be deemed to be a member state of the E.U.

(c) [*Intentionally Omitted*.]

(d) *Limitations*. For the avoidance of doubt, the maximum amount of Milestone Payments that could potentially be payable by Kuur to Baylor under Section 5.14(a) or 5.14(b) if all of the Milestone Events (i.e., all of Milestone Events 1 through 6 set out in the Milestone Chart) are achieved (if any) is [*]

(e) Notification. Kuur shall notify Baylor in writing within thirty (30) days following the achievement of each Milestone Event (except with respect to Milestone Event 2 which shall be a longer period of time as set out in the Milestone Chart), such notice to be accompanied by payment of the appropriate Milestone Payment, where achieved by Kuur, and within ninety (90) days where such Milestone Event is achieved by any sublicensees of Kuur (except with respect to Milestone Event 2 which shall be a longer period of time as set out in the Milestone Chart). Each Milestone Event is to be paid regardless of whether Kuur or Kuur's Affiliate or Kuur's or its Affiliate's sublicensee is the party achieving such Milestone Event, as provided above.

5.15 Sublicensing Revenue Payments. In the event Kuur (or an Affiliate Sublicensee) grants any sublicenses its license to one or more of the Licensed Products under the Core Platform Patent Rights under this Agreement, Kuur (itself or through its Affiliate) agrees to pay to Baylor the following percentages of Sublicensing Revenue received by Kuur during the Sublicensing Revenue Period (each such share, the "Revenue Share"):

(a) [*] _____ of all Sublicensing Revenue received by Kuur or an Affiliate Sublicensee from a Third Party Sublicensee of any Licensed Product(s) if such sublicense agreement is executed on or before the eighteenth (18th) month period immediately following the First Restatement Effective Date (the "Initial 18-month Period"), provided that Kuur may credit against such Revenue Share (but only up to the amount of such Revenue Share) solely (and not more than) the amount equal to the sum of (i) [*] _____ for each separate Licensed Core Product, if any, sublicensed to such Third Party Sublicensee in such transaction, plus (ii) that portion of any payments of Kuur to Baylor under the Co-Development Agreement (including, for the avoidance of doubt, under any Work Plan or Specific Industrial Clinical Research Agreement) allocable to the research and development of such sublicensed Licensed Product, if made between the First Restatement Effective Date and such Initial 18-month Period;

(b) [*] _____ all Sublicensing Revenue received by Kuur or an Affiliate Sublicensee from a Third Party Sublicensee of a Licensed Product(s) if such sublicense agreement is executed after the Initial 18-month Period but within the three (3) year period immediately following the First Restatement Effective Date, provided that Kuur may credit against such Revenue Share (but only up to the amount of such Revenue Share) solely (and not more than) the amount equal to the sum of (i) [*] for each separate Licensed Core Product, if any, sublicensed to such Third Party Sublicensee in such transaction, plus (ii) that portion of any payments of Kuur to Baylor under the Co-Development Agreement (including, for the avoidance of doubt, under any Work Plan or Specific Industrial Clinical Research Agreement) allocable to the research and development of such sublicensed Licensed Product, if made between such period after the Initial 18-month Period but within the three (3) year period immediately following the First Restatement Effective Date; and

(c) [*] _____ all Sublicensing Revenue received by Kuur or an Affiliate Sublicensee from a Third Party Sublicensee of a Licensed Product(s) if such sublicense agreement is executed after the third (3rd) anniversary of First Restatement Effective Date but within the five (5) year period immediately following the First Restatement Effective Date, provided that Kuur may credit against such Revenue Share (but only up to the amount of such Revenue Share) solely (and not more than) the amount equal to the sum of (i) [*] _____ for each separate Licensed Core Product, if any, sublicensed to such Third Party Sublicensee in such transaction, plus (ii) that portion of any payments of Kuur to Baylor under the Co-Development Agreement (including, for the avoidance of doubt, under any Work Plan or Specific Industrial Clinical Research Agreement) allocable to the research and development of such sublicensed Licensed Product, if made between such period after the third (3rd) anniversary of the Restatement First Effective Date but within the five (5) year period immediately following the First Restatement Effective Date;

(d) In the event that Kuur or an Affiliate Sublicensee receives Sublicensing Revenue in a non-cash form, Kuur shall disclose the fair market value of the non-cash Sublicensing Revenue to Baylor. Baylor will not be entitled to receive any payments before Kuur has converted the non-cash consideration into a cash equivalent form. Kuur shall exercise good-faith efforts to convert the non-cash Sublicensing Revenue to a cash equivalent form as soon as reasonably possible.

5.16 Payment Addresses. Payments shall be made by wire transfer at Kuur's cost using wiring instructions provided in Schedule D. All payments shall reference the corresponding BLG number(s) listed under Article I or under Schedule D as updated.

Baylor Tax ID #: [*]
Baylor College of Medicine
Licensing Group
[*]

Telephone No. [*]
Facsimile No. [*]
-Email: [*]

Payments shall be deemed received only upon confirmation that all funds have been received by the Licensing Group as referenced above, which such confirmation shall be due immediately. Kuur hereby accepts responsibility for ensuring that payment is addressed correctly.

Kuur Payment Contact. For questions about payments, Baylor can contact kuur at the address below:

Title [*]
Name: [*]
Address [*]

Telephone No. [*]
E-Mail [*]

Each Party may update the contact information by written notice.

5.17 Payment Conditions. All payments due hereunder are payable in United States dollars. Kuur is responsible for, and shall not deduct from any payment or impose on Baylor any transfer, exchange, collection or other charges related to any payment, including any wire transfer fees, and other than as expressly provided herein. For sales of Licensed Products in currencies other than the United States Dollar, Kuur shall use an exchange rate based upon the weighted average rate over the relevant time period, as such rates are published in The Wall Street Journal during the period that such payment is due.

5.18 Late Payments. Late payments shall be subject to a charge of [*] _____ per month, the interest being compounded annually, or [*] _____ U.S. dollars ($[*] _____) per month, whichever is greater. Kuur shall calculate the correct late payment charge, and shall add it to each such late payment. Such late payment charge and the payment and acceptance thereof shall not negate or waive the right of Baylor to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment. Kuur shall indemnify Baylor for all attorneys' fees and costs Baylor incurs in obtaining a full payment of that which is owed to Baylor.

5.19 No Precedent. The Parties agree that the amount or rate of any fee, royalty, payment, or consideration under this Agreement is based on the particular circumstances of this transaction, shall not be deemed to be a precedent for any other transaction, whether between the Parties or of any Third Party, or in connection with any rights or remedies asserted by Baylor, and shall not be deemed to be an indication of what constitutes or may constitute, or be used in the determination of, a maximum reasonable royalty regarding any Patent Right or Licensed Technology.

5.20 No Double Payment. To the extent any Distinct Product for which a given Milestone Payment or Royalties on the Net Sales of such Distinct Product hereunder is owed is both a Licensed Core Product and a Licensed Future Oncology Product and/or Licensed Future Non-Oncology Product, such Milestone Payment shall be owed only once, and a Royalty for any Net Sales of such Distinct Product shall be owed only once for the same Net Sales, provided that such Milestone Payment and such Royalty owed for such Distinct Product is at the highest rate for which such Distinct Product qualifies. For the avoidance of doubt, a separate Milestone Payment and separate Royalties shall be owed for a different Distinct Product even if such Distinct Product and one or more other Distinct Products utilize, or are covered by the same Technology Rights.

ARTICLE VI
REPORTING

6.1 Annual Progress Report. No later than sixty (60) days after December 31 of each Calendar Year, for each Licensed Product following completion of its FIM Study, Kuur shall provide to Baylor a written annual progress report describing progress on all research and development and commercial activities with respect to such Licensed Product, during the most recent twelve (12) month period ending December 31 and plans for the forthcoming year ("Annual Progress Report"). If multiple Licensed Products are covered by the license granted under this Agreement, the progress report shall provide the information set forth above for each Licensed Product. At Baylor's request, Kuur shall also provide and shall cause its Affiliates and sublicensees to provide any reasonable additional data Baylor requires to evaluate Kuur's performance of its obligations hereunder.

6.2 Notification of First Sale. For each Licensed Product, Kuur shall notify Baylor of the date on which Kuur, its Affiliates, and/or its sublicensees makes the first sale of such Licensed Product within thirty (30) days of occurrence. Thereafter, with respect to such Licensed Product, Kuur shall notify Baylor of the date of the first sale of such Licensed Product in each country in which it occurs within (a) thirty (30) days of occurrence where such first sale is made by Kuur or its Affiliates, or (b) thirty (30) days of Kuur's being notified of such first sale, where such first sale is made by a sublicensee.

6.3 Royalty Reports. Following the first commercial sale of a Licensed Product, Kuur shall submit to Baylor within sixty (60) days after March 31, June 30, September 30 and December 31, a written report with respect to such Licensed Product on a form provided by Baylor (a current version of which is attached as Schedule E) setting forth for such calendar quarter at least the following information, to the extent Kuur, its Affiliates, and/or sublicensees possesses or can obtain such information:

(i) the number of units such Licensed Product sold by Kuur, its Affiliates, and sublicensees in each country;

(ii) total billings for such Licensed Product sold by Kuur, its Affiliates, and sublicensees in each country;

(iii) the gross amount of monies or cash equivalent or other consideration which is received for sales, leases, licenses or other modes of transfer of Licensed Products by Kuur, its Affiliates, and sublicensees;

(iv) the identity of that consideration which is received instead of money for sales, leases, licenses or other modes of transfer of Licensed Products by Kuur, its Affiliates, and sublicensees;

(v) deductions from the gross amount as expressly permitted herein to determine the Net Sales thereof;

(b) the Third Party royalty, milestone or other payments for which Kuur is seeking a credit under Section 5.13;

(c) the amount of Royalties due thereon, or, if no Royalties are due to Baylor for any reporting period, the statement that no Royalties are due;

(d) the amount of Sublicensing Revenue received by each of Kuur and any Affiliate Sublicensee from its sublicensee(s); and

(e) the amount of other payments due Baylor, including milestone payments.

The royalty report shall be certified as correct by an officer of Kuur. After termination or expiration of this Agreement, Kuur will continue to submit royalty reports and Royalty (and if the Sublicensing Revenue Period has not yet expired, Sublicensing Revenue) payments to Baylor until all Licensed Products made, used, marketed, leased or imported under this Agreement have been sold. In the event a Released Product is licensed to a Third Party, Baylor shall provide to Kuur a report on the sales of such product and royalties or other payments due thereon to Kuur, in nature and substance as set forth in this Section 6.3.

6.4 Payment to Accompany Royalty Reports. Kuur shall pay to Baylor with each such royalty report the amount of Royalties and other payments due with respect to such calendar quarter. If multiple technologies are covered by the license granted hereunder, Kuur shall specify which Licensed Product and Patent Rights are utilized for each Licensed Product included in the royalty report by citing the applicable BLG number listed under Article I of this Agreement or under Schedule C as updated from time to time by Baylor.

6.5 Notification of Merger or Acquisition. In the event of any acquisition, merger, consolidation, change of corporate name, or Change of Control, Kuur shall notify Baylor in writing within ten (10) days of the COC Closing or closing of the event otherwise.

6.6 Entity Status. If Kuur, its Affiliate, or a sublicensee does not qualify as a “small business entity” as provided by the United States Patent and Trademark Office, Kuur must notify Baylor immediately.

ARTICLE VII
RECORDS AND INSPECTION

7.1 Accounting Records. Kuur shall maintain, and shall cause its sublicensees to maintain, complete and accurate records relating to the rights and obligations under this Agreement and any amounts payable to Baylor in relation to this Agreement, which records shall contain sufficient information to permit Baylor to confirm the accuracy of any reports delivered to Baylor and compliance in other respects with this Agreement. The relevant party shall retain such records for at least three (3) years following the end of the Calendar Year to which they pertain.

7.2 Audit by Baylor. During the Term and for a period of two (2) years thereafter, Baylor or its representatives shall have the right to inspect the books and records of Kuur in conjunction with the performance of Kuur’s obligations under the terms and conditions of this Agreement, such right to inspect exercisable, absent cause for more frequent inspection, no more than once each twelve (12) month period and upon reasonable notice. The scope of such audit and inspection activities may include the review of records supporting activities performed by Kuur in conjunction with its obligations under this Agreement, as well as processes and related process internal controls and support systems, the quality and accuracy of which are directly related to the performance of Kuur’s obligations under the terms and conditions of this Agreement. Kuur agrees to provide representatives of Baylor reasonable access to books, records, systems and processes, and shall cooperate fully with Baylor’s representatives in support of their inspection and audit activities during Kuur’s normal business hours.

7.3 Payment Deficiency. If a payment deficiency is determined, Kuur its Affiliate Sublicensee(s), and its Third Party Sublicensee(s), as applicable, shall pay the outstanding amounts within thirty (30) days of receiving written notice thereof, plus interest on such outstanding amounts as described in Article V.

7.4 Responsibility for Audit Costs. Baylor will pay for any audit done under Section 7.2. However, in the event that the audit reveals an underpayment of Royalties or fees by more than five percent (5%) for the period being audited, the cost of the audit shall be paid by Kuur. If the underpayment is less than five percent (5%) but more than two percent (2%) for the period being audited, Kuur and Baylor shall each pay fifty percent (50%) of the cost of the audit. Kuur shall reimburse Baylor for all attorneys’ fees and costs Baylor incurs in obtaining access to conduct the audit and collecting, when applicable, for the cost of the audit and any underpaid amounts and interest.

ARTICLE VIII
SUBLICENSES

8.1 Kuur Sublicensees.

(a) All sublicenses granted by Kuur (or any Affiliate Sublicensee) of its rights hereunder shall be subject to the terms of this Agreement. Kuur shall be responsible for its sublicensees' compliance with this Agreement and shall not grant any rights which are inconsistent with the rights granted to and obligations of Kuur hereunder. Any act or omission of a sublicensee of Kuur which would be a breach of this Agreement if performed by Kuur shall be deemed to be a breach by Kuur of this Agreement (a "Sublicensee Breach"), but notwithstanding anything to the contrary contained in this Agreement, a Sublicensee Breach shall not trigger any right for Baylor to terminate this Agreement (in part or whole) or any other termination right under this Agreement. In the event of any uncured Sublicensee Breach, Kuur shall notify Baylor (promptly after it has actual knowledge) of such Sublicensee Breach and shall act in good faith and in its reasonable business judgment to enforce its rights under its agreement with such sublicensee with respect to such Sublicensee Breach. If (i) such Sublicensee Breach remains uncured after any applicable notice and cure period in Kuur's sublicense agreement with a sublicensee and (ii) such Sublicensee Breach causes or is reasonably likely to cause material harm to Baylor or its reputation, Kuur shall terminate such sublicense agreement.

8.2 Baylor Audit Right. Each sublicense agreement granted by Kuur (and/or its Affiliate Sublicensee) shall include an audit right by Baylor of the same scope as provided in this Article VIII hereof with respect to Kuur and provide that Baylor is an intended Third Party beneficiary regarding such audit right. Each sublicense agreement shall expressly state that it and the sublicenses granted thereunder terminate automatically upon the expiration (but not the early termination) of, and no sublicense agreement shall contain any provision which would cause it to extend beyond the Term of this Agreement as defined below (except with respect to those terms and conditions which are specifically identified as surviving the termination or expiration of the Agreement). Kuur shall give Baylor prompt notification of the identity and address of each sublicensee with whom it concludes a sublicense agreement and shall supply Baylor with a copy of each such sublicense agreement (redacted solely to the extent necessary to withhold confidential information of such sublicensee).

8.3 Service Provider Sublicensees. For clarity, agreements in which Kuur, its Affiliates or its sublicensees granted limited sublicenses to service providers (including, without limitation, CROs, contract manufacturers and clinical sites) solely for the purpose of providing services to Kuur, Affiliates or its sublicensees in furtherance of the purposes of this Agreement, and which do not grant the service provider any right to use any Technology Right licensed by Baylor hereunder for any other purpose, shall not be subject to Section 8.2, but shall be subject to Sections 8.1 and 8.4. Kuur shall use reasonable efforts to maintain an accurate list of all such sublicensees described in this Section 8.3, and shall provide such list to Baylor at least annually.

8.4 Enforcement. Kuur shall enforce or assist Baylor with enforcing any of the provisions mentioned above in this Article VIII against a sublicensee.

ARTICLE IX
PATENTS AND INFRINGEMENT

9.1 Patent Prosecution Responsibility.

(a) *Core Platform Patent Rights; Baylor Target Patent Rights; Other Licensed Technology Patent Rights*. Kuur shall have the right to file, prosecute, and maintain, shall be responsible for filing, prosecuting and maintaining, and shall file, prosecute, and maintain all patent applications and patents included in the Core Platform Patent Rights and, (i) if Kuur exercises its option under Section 3.1 with respect to a Future Oncology Invention, the Future Oncology Patent Rights covering such Future Oncology Invention, (ii) if Kuur exercises its option under Section 3.2 with respect to a Future Non-Oncology Invention, the Future Non-Oncology Patent Rights covering such Future Non-Oncology Invention, and (iii) if Kuur exercises its option pursuant to Section 4.1 with respect to a Baylor Target Antigen, the Baylor Target Patent Rights disclosing or covering such Baylor Target Antigen, and Kuur agrees to pay all Legal Costs associated therewith, except as set forth below in Section 9.2. Kuur shall select

all outside counsel for prosecution of such Patent Rights, which such counsel shall be reasonably acceptable to Baylor. Such patent counsel shall invoice Kuur directly for all such Legal Costs.

(b) Future Patent Rights. Baylor shall have the right of, and be responsible for filing, prosecuting and maintaining all patent applications and patents included in the Future Oncology Patent Rights and Future Non-Oncology Patent Rights and Kuur agrees to pay and shall pay all Legal Costs associated therewith, except as set forth below in this Section 9.1(b). Baylor shall select all outside counsel for prosecution of such Patent Rights, which counsel shall be reasonably acceptable to Kuur. Such patent counsel shall invoice Kuur directly for all such Legal Costs, provided that Kuur's responsibility for such Legal Costs shall be reduced on a pro-rata basis should Baylor license such Patent Rights for fields of use not licensed to Kuur to one or more Third Parties, to the extent permitted hereunder. Upon exercise by Kuur of its option under Section 3.1 or 3.2 with respect to a Future Oncology Invention or Future Non-Oncology Invention, Baylor's rights under this Section 9.1(b) shall cease with respect to such Future Oncology Invention or Future Non-Oncology Invention, and the continued prosecution and maintenance of any Patent Rights claiming such product or invention, shall be Kuur's right, pursuant to Section 9.1(a), provided that for any Patent Rights covering more subject matter than the optioned Future Oncology Invention or Future Non-Oncology Invention, Baylor shall be given sufficient time to arrange for a separate filing for such non-optioned subject matter, provided that the prosecution of such separate filing shall be conducted in a manner that will not adversely affect the validity, scope or enforceability of the patent filings for the optioned subject matter.

(c) Prosecution Diligence. With regard to any patent application or patent that Kuur shall or may file, prosecute, or maintain under this Section 9.1, Kuur

(i) shall file, prosecute, or maintain such patent application or patent diligently and in good faith,

(ii) shall not unreasonably or in bad faith delay the filing of such patent application,

(iii) shall not fail to meet any deadlines or payment obligations required for the continued prosecution of such patent application, and

(iv) shall in good faith and using its diligent efforts file, prosecute, and maintain at least one Valid Claim in at least one patent application or patent covering each Distinct Product.

Any delay or failure to file or prosecute any patent application or to maintain any patent to avoid the coming into existence of a Valid Claim for purposes of avoiding the payment of a Milestone Payment or Royalty shall be deemed to be unreasonable and in bad faith.

9.2 Notification of Intent Not to Pursue. In the event that Kuur decides not to pay for the Legal Costs associated with either: (i) the prosecution to issuance of the Core Platform Patent Rights, Baylor Target Patent Rights, Future Oncology Patent Rights and/or Future Non-Oncology Patent Rights or (ii) the maintenance of any United States or foreign application or issued patent within such Patent Rights, Kuur shall timely notify Baylor in writing thereof. Kuur's right under this Agreement to practice the invention under such Patent Right under Article II and/or Article IV and to prosecute such Patent Right under Section 9.1 shall immediately terminate upon the giving of such notice. If Kuur fails to notify Baylor in sufficient time for Baylor to assume said costs prior to the abandonment or expiration of any such Patent Rights by Kuur in a country, Kuur shall be considered in material breach of this Agreement with respect to the Licensed Products affected by such Patent Rights in such country.

9.3 Notification of Patent Prosecution Action. Each Party agrees to keep the other Party fully informed of all prosecutions and other actions for which it is responsible pursuant to this Article IX, including submitting to such other Party copies of all official actions and responses thereto, and agrees to take into consideration, in good faith, all reasonable comments of such other Party with respect thereto. The Party responsible for prosecution of any Patent Rights under this Article IX shall use all reasonable efforts to amend any patent application to include claims reasonably requested by such other to protect the products to be sold and technologies to be used under this Agreement and to file and prosecute patents in foreign countries indicated by and paid for by Kuur.

9.4 Cooperation. Baylor agrees to reasonably cooperate with Kuur to whatever extent is reasonably necessary and in compliance with applicable law to provide Kuur the full benefit of the license granted herein.

9.5 Infringement Action Procedures. During the Term of this Agreement as defined below, each Party shall promptly inform the other of any suspected infringement of any claims in the Core Platform Patent Rights, Baylor Target Patent Rights (to the extent included in Kuur's licenses hereunder), Future Oncology Patent Rights, or Future Non-Oncology Patent Rights (the "Implicated Patent Rights") or the misuse, misappropriation, theft or breach of confidence of other proprietary rights in the Licensed Technology and/or the Implicated Patent Rights by a Third Party, and with respect to such activities as are suspected. Any action or proceeding against such Third Party shall be instituted as following:

(a) Baylor and Kuur shall discuss in good faith whether to jointly institute an action for infringement, misuse, misappropriation, theft or breach of confidence of the proprietary rights against such Third Party. Such joint action shall be brought in the names of both Baylor and Kuur. If Baylor or Kuur decides to jointly prosecute an action or proceeding after it has been instituted by the other Party, the action shall be continued in the name or names they both agree is expedient for efficient prosecution of such action. Kuur and Baylor shall agree to the manner in which they shall exercise control over any joint action or proceeding against such Third Party. If the Parties cannot agree after a period of 10 days, then Kuur may proceed under Section 9.5(b) below against such Third Party (but not any other Third Party). In such joint action or proceeding, the out-of-pocket costs and any recovery or settlement shall be shared equally.

(b) If the Parties do not agree to participate in a joint action or proceeding as contemplated under Section 9.5(a) against a Third Party, then Kuur shall have the first right, but not the obligation, solely to institute such an action for infringement of the Implicated Patent Rights, or misuse, misappropriation, theft or breach of confidence of the proprietary rights against such Third Party. If Kuur fails to bring such an action or proceeding within a period of three (3) months after receiving notice or otherwise having knowledge of such infringement, then Baylor shall have the right, but not the obligation, solely to prosecute the same at its own expense; and the other Party will reasonably cooperate with such Party prosecuting such action in prosecuting such action. Baylor's cooperation in an action brought by Kuur under this Section 9.5(b) in accordance with Section 9.4 shall be at Kuur's sole expense. Should either Baylor or Kuur commence action under the provisions of this Section 9.5 and thereafter elect to abandon the same, it shall give timely notice to the other Party who may, if it so desires, continue prosecution of such action or proceeding. All recoveries, whether by judgment, award, decree or settlement, from infringement or misuse of Licensed Technology and/or any Implicated Patent Rights by a Party under Section 9.5(a) and this Section 9.5(b) shall be apportioned as follows: (i) the Party bringing the action or proceeding (the "Prosecuting Party") shall first recover an amount equal to the costs and expenses incurred by such Prosecuting Party directly related to the prosecution of such action or proceeding, including any amounts actually paid by the Prosecuting Party to the other Party (the "Non-Prosecuting Party") to the extent such amount reimburses the Non-Prosecuting Party for its costs and expenses incurred in the prosecution of such action or proceeding; (ii) the Non-Prosecuting Party in such action or proceeding shall then recover costs and expenses incurred by the Non-Prosecuting Party, if any, directly related to its cooperation in the prosecution of such action or proceeding and not otherwise previously reimbursed by the Prosecuting Party to the Non-Prosecuting Party and deducted under clause (i); and (the remainder, if any, shall be shared as follows: (x) seventy-five percent (75%) the Prosecuting Party, and twenty-five percent (25%)the Non-Prosecuting Party.

(c) Neither Baylor nor Kuur will notify a possible infringer of infringement or put such infringer on notice of the existence of any Implicated Patent Rights without first obtaining consent of the other, not to be unreasonably withheld or delayed.

9.6 Consent to Settle. Neither Baylor nor Kuur shall settle any action covered by Section 9.5 without first obtaining the consent of the other Party, which consent will not be unreasonably withheld or delayed.

9.7 Liability for Losses. Baylor shall not be liable for any losses incurred as the result of an action for infringement brought against Kuur as the result of Kuur's exercise of any right granted under this Agreement.

9.8 Patent Term Extension. Kuur shall apply for an extension of the term of any patent included within the Implicated Patent Rights if appropriate under the Drug Price Competition and Patent Term Restoration Act of 1984

and/or European, Japanese and other foreign counterparts of such law. Kuur shall prepare all documents, and Baylor agrees to execute the documents and to take additional action as Kuur reasonably requests in connection therewith.

ARTICLE X
TERM

Unless sooner terminated as otherwise provided in Article XI: (a) the licenses to Patent Rights and other licensed Technology Rights granted herein under the respective grants in Article II shall expire on a country-by-country basis, on the later of (i) the date of expiration of the last of such Patent Rights issued in such country licensed to Kuur under this Agreement to expire or (ii) in the event that no patents included within the Patent Rights issue in such country, the day immediately following the tenth (10th) anniversary of the first commercial sale of Licensed Products by Kuur in such country; and (b) after such expiration, but not any early termination by Baylor pursuant to Article XI of this Agreement, Kuur shall have a perpetual, irrevocable, paid-in-full (i.e., royalty free) licenses in such country under the licenses granted by Baylor to Kuur hereunder, including as set out in Sections 2.1, 2.2 and 2.3.

ARTICLE XI
AGREEMENT TERMINATION

11.1 Termination by Baylor for Default.

(a) *On Product by Product Basis*

(i) This Agreement shall immediately terminate solely with respect to a Distinct Product upon the written notification by Kuur that it is discontinuing funding to support Baylor's Exclusive Academic Partner Early R&D Participation Rights with respect to said Distinct Product.

(ii) Baylor may terminate this Agreement solely with respect to a Distinct Product in the event of a material default or material failure by Kuur to perform any of the terms, covenants or provisions of this Agreement, including failure to make timely payment, and including a breach of its obligations under Section 2.6(a) regarding Baylor's Exclusive Academic Partner Early R&D Participation Rights (and provided such failure to comply was not due to the fault of Baylor or its employees or agents), with respect to such Distinct Product (a "Product-Related Breach"), unless Kuur, within sixty (60) days after delivery of written notice of termination by Baylor identifying such Product-Related Breach, cures such alleged Product-Related Breach.

(iii) Notwithstanding Section 11.1(a)(i), if:

(1) (A) the same type of Product-Related Breach has occurred three (3) times or more with regard to such Distinct Product during the immediately preceding twelve (12) months and (B) Baylor has duly notified Kuur in writing of each such Product-Related Breach,

(2) but (A) Baylor has not given written notice of termination therefor or (B) termination of this Agreement with respect to such Product-Related Breach has been avoided by cure thereof, and

(3) Baylor can demonstrate that the pattern of such Product-Related Breaches (as cured by Kuur) is causing Baylor material and on-going harm, then Kuur shall not have any further right to cure any further Product-Related Breaches.

(iv) Termination of this Agreement with respect to such Distinct Product shall be effective

(1) at the end of such sixty (60)-day period if Kuur has the right to cure such Product-Related Breach and such Product-Related Breach is not cured within such sixty (60)-day period, provided that if Kuur initiates the dispute resolution proceedings under Article XIV during such sixty (60)-day period, then the termination by Baylor shall not be effective unless and until (A) a final determination is made under Article XIV that Kuur so committed such Product-Related Breach, and thereafter (B) Kuur then fails to cure such Product-Related Breach within sixty (60) days after such final determination, or

(2) upon written notice by Baylor if Kuur has no right to cure pursuant to Section 11.1(a)(ii), provided that if Kuur initiates the dispute resolution proceedings under Article XIV within thirty (30) days of receipt of such written notice by Baylor, then the termination by Baylor shall not be effective unless and until a final determination is made under Article XIV whether the requirements of Section 11.(a)(ii) have been met.

(b) *Entire Agreement*. This Agreement shall immediately terminate in its entirety upon the written notification by Kuur that it is discontinuing all funding to support Baylor's Exclusive Academic Partner Early R&D Participation Rights. Baylor may terminate this Agreement in its entirety in the event that, at any time during the period from the Effective Date until the end of the sixth anniversary of the Effective Date: Kuur fails to pay at least ninety percent (90%) of all of the amounts due to Baylor; or (ii) Kuur fails to comply with its obligations under Section 2.6 regarding Baylor's Exclusive Academic Partner Early R&D Participation Rights (provided such failure to comply was not caused by the fault of Baylor or its employees or agents to comply with Baylor's obligations under this Agreement or the Co-Development Agreement or any Work Plan or Specific Industrial Clinical Research Agreement) with respect to eighty percent (80%) of the Licensed Core Products or Future Products as to which Early R&D Activities applied (each, an "Essential Breach"), unless Kuur, within sixty (60) days after Baylor giving written notice of termination identifying such Essential Breach, cures such alleged Essential Breach (an "Essential Breach Cure"). The termination of this Agreement in its entirety shall be effective at the end of such sixty (60)-day period if such Essential Breach is not cured within such sixty (60)-day period; provided that if Kuur initiates the dispute resolution proceedings under Article XIV during such sixty (60)-day period, then the termination by Baylor shall not be effective unless and until a final determination is made under Article XIV that Kuur so committed such Essential Breach and Kuur fails to cure such Essential Breach within sixty (60) days after such decision.

(c) For the avoidance of doubt, Kuur shall remain liable for any and all amounts due under this Agreement until such amounts are paid and this obligation shall survive termination date of this Agreement. The failure of Baylor to exercise such right of termination, for non-payment of Royalties, fees or otherwise, shall not be deemed to be a waiver of any right Baylor might have, nor shall such failure preclude Baylor from exercising or enforcing said right upon any subsequent failure by Kuur.

11.2 Termination by Baylor for Kuur Insolvency. Baylor shall have the right, at its option, to cancel and terminate this Agreement in the event that Kuur shall (i) become the defendant in insolvency, dissolution, bankruptcy or receivership proceedings affecting the operation of its business or (ii) make an assignment of all or substantially all of its assets for the benefit of creditors, or in the event that (iii) a receiver or trustee is appointed for Kuur and Kuur shall, after the expiration of thirty (30) days following any of the events enumerated above, have been unable to secure a dismissal, stay or other suspension of such proceedings.

11.3 [Intentionally Omitted].

11.4 Termination by Kuur. Kuur shall have the right in its sole discretion to terminate this Agreement, on a Distinct Product by Distinct Product and/or country by country basis, upon sixty (60) days' written notice to Baylor (it being understood that a termination of its license to an individual Distinct Product shall not be a termination in its entirety to the applicable Licensed Technology employed or utilized in connection therewith except to extent that no other Distinct Product also employs or utilizes such Licensed Technology). For the avoidance of doubt, if Kuur terminates its rights to all Distinct Products in all countries in the Territory, this Agreement shall terminate in its entirety, subject to the survival provisions of Section 11.8.

11.5 Effects of Agreement Termination.

(a) Termination of a Distinct Product or Country. In the event of early termination of this Agreement (i) by Baylor with respect to a Distinct Product pursuant to Section 11.1(a) or in its entirety pursuant to Section 11.1(b), 11.2 or 11.3, or (ii) by Kuur pursuant to Section 11.4 with respect to a Distinct Product or country or in its entirety, the following shall apply:

(i) where such termination is as to this Agreement in its entirety, all options and all licenses granted hereunder shall end and terminate, and all rights to the Licensed Products and related Technology Rights licensed to Kuur shall revert to Baylor, and, as provided for in the Co-Development Agreement, the Co-Development Agreement shall also terminate; and

(ii) where such termination is only with respect to a Distinct Product or country, all licenses and options to license granted hereunder with respect to such terminated Distinct Product or country shall end and terminate, and all Technology Rights either licensed to Kuur as of such time, or, with respect to a terminated Distinct Product, to which Kuur has an option to license as of such time, covering or included in such terminated Distinct Product (and only such Distinct Products) shall revert or be retained, as the case may be, to Baylor with respect to such country(ies) (the Technology Rights described in this subsection (ii) together with the Technology Rights described in Section 11.5(a)(i), "Terminated Technology Rights".

(b) *Effect of Termination*. At the effective date of any such termination of this Agreement with respect to a Distinct Product (or if this Agreement is terminated in its entirety, then with respect to all Distinct Products), Kuur shall immediately cease using any such terminated Distinct Product(s) and Terminated Technology Rights and Kuur shall immediately destroy the terminated Distinct Product(s) (except where otherwise required by any Regulatory Authority), and send to Baylor a written affirmation of such destruction signed by an officer of Kuur; provided, however, that Kuur, its Affiliates or its sublicensees may sell any units of such terminated products actually in the possession of Kuur (or its Affiliates, sublicensees or contract manufacturers) on the date of termination, provided that Kuur continues to submit royalty reports to Baylor and pays to Baylor the Royalties on all such sales in accordance with Section 5.13 with respect thereto and otherwise complying with the terms of this Agreement.

(c) For clarity, if Kuur terminates, or otherwise discontinues its license rights, or if Baylor terminates such rights or the option to obtain a license to any Distinct Product or Baylor Target Antigen, Kuur shall lose its rights with respect to any Valid Claim covering such Distinct Product or Baylor Target Antigen or, in each case, its manufacture, but only solely as such Valid Claim covers such terminated product, and not as to other Licensed Core Product or Future Oncology Product or Future Non-Oncology Product which are not being terminated.

11.6 Effect of Termination on Sublicensees. Notwithstanding Sections 11.1 through 11.5, upon expiration or termination of this Agreement for any reason in its entirety or with respect to a Distinct Product,

(a) Kuur shall promptly send notice of such termination to each of its sublicensees; and

(b) each sublicense then-granted by Kuur to a sublicensee shall remain in effect as a direct license from Baylor to the sublicensee (each a "New License Agreement"), for the scope of the license granted to such sublicensee, either, as elected by Baylor, at its sole discretion:

(i) on the same terms as the relevant sublicense agreement (as and to the extent they relate to the sublicense of rights licensed to Kuur hereunder); or

(ii) the terms of this Agreement; in each case, provided (x) that the sublicensee is not at the time of such termination (aa) in breach of its sublicense agreement and (bb) culpable for any breach by Kuur under Section 11.1 through 11.4, and (y) that the financial terms of each New License Agreement shall be identical to the corresponding financial terms of the relevant sublicense agreement or this Agreement. In the event of termination of this Agreement and if Baylor grants a direct license to any sublicensee pursuant to the preceding sentence, Baylor will not be bound by any grant of rights broader than or will not be required to perform any obligation other than those rights and obligations contained in this Agreement. Baylor and the sublicensee will modify each such New License Agreement to include all of the rights of Baylor that are contained in the sublicense agreement or this Agreement, as elected by Baylor, at its sole discretion. Notwithstanding the foregoing, each sublicensee's right to a New License Agreement shall only be available to the extent (i) Kuur has provided Baylor with a copy of the sublicense agreement granting the sublicense to such Sublicensee as required under Article VIII and with all terms relating to the rights and obligations under this Agreement left unredacted, (ii) such sublicensee notifies Baylor within ninety (90) days after the termination of this Agreement that it wishes to enter into a New License Agreement, (iii) the obligations and/or duties of Baylor under the New License Agreement will not be greater than the obligations and/or duties of Baylor under this Agreement and (v) there is no outstanding or ongoing material breach of such sublicense by such sublicensee which remains uncured.

11.7 No Refund. Baylor is under no obligation to refund any payments made by Kuur to Baylor prior to the effective date of such termination or expiration, including, without limitation, in the event this Agreement is terminated pursuant to this Article XI or expires as provided for in Article X.

11.8 Survival of Termination. No termination of this Agreement shall constitute a termination or a waiver of any rights of either Party against the other Party accruing at or prior to the time of such termination. The obligations of Sections 11.5, 11.6, 11.7, 11.8, 16.1, 16.2, 16.3, and 16.4, and Articles VII (as stated therein), XIV, XV, XVII and XVIII shall survive termination of this Agreement, and any other provisions of this Agreement that by their nature are necessary to survive the expiration or other termination of this Agreement shall survive the expiration or other termination of this Agreement. Subject to the immediately preceding sentence, any provision in this Agreement related to (a) any royalty that is owed and due under this Agreement as of the effective date of termination or thereafter pursuant to Section 11.5(b), or (b) any Milestone Payment that is owed and due under this Agreement as of the effective date of termination shall survive termination of this Agreement for as long as such royalty or Milestone Payment is unpaid.

ARTICLE XII
ASSIGNMENT

Neither Party may assign or otherwise transfer this Agreement or any of its rights or obligations hereunder (either in whole or in part) to any person without the prior written consent of the other Party, or delegate any of its rights or obligations hereunder. Notwithstanding the foregoing, however, Kuur may delegate any of its rights or obligations hereunder and may assign or otherwise transfer this Agreement and its rights and obligations hereunder, either in whole or in part, without Baylor's consent: (a) in connection with any Change of Control, or the transfer or sale of all or substantially all of the assets, or the business of, Kuur to which this Agreement relates, or (b) to any Affiliate (and, for clarity, to a New Kuur Group Topco); so long as Kuur gives Baylor prompt notice of such action and the assignee or successor entity or Affiliate, as the case may be, acknowledges its consent and agreement to the terms of this Agreement and the License and Option Agreement (and, if and as applicable all Work Plans and SICRAs in effect at such time) in writing before such assignment; and so long as such action is not entered into solely to satisfy creditors of Kuur. This Agreement shall be binding upon and shall inure to the benefit of the Parties and each of their respective successors, legal representatives and assignees. Any attempted assignment or other transfer of this Agreement not effected in accordance with this Article XII shall be null and void.

ARTICLE XIII
GOVERNMENTAL COMPLIANCE

13.1 Compliance with Applicable Laws. Kuur shall at all times during the Term of this Agreement and for so long as it shall use the Licensed Technology and/or Patent Rights, or sell Licensed Products, comply and cause its sublicensees to comply with all laws that may control or apply to the import, export, manufacture, use, sale, marketing, distribution and other commercial exploitation of the Licensed Technology, Patent Rights, Licensed Products or any other activity undertaken pursuant to this Agreement.

13.2 Requirement for U.S. Manufacture. Kuur agrees that, to the extent required under 37 CFR 401 and as applicable to a particular Licensed Product depending on the funding for the Core Subject Technology incorporated therein prior to the Effective Date, such Licensed Product leased or sold in the United States shall be manufactured substantially in the United States, and Baylor agrees to, upon request of Kuur, assist Kuur in requesting a waiver of any such obligation from the U.S. government where such manufacture is not reasonably feasible.

13.3 Export Control Regulations. The Licensed Product, Licensed Technology and Patent Rights are subject to, and Kuur agrees to comply in all respects with, U.S. law including but not limited to U.S. export controls under the Export Administration Regulations (15 C.F.R. Part 734 et seq.) and U.S. economic sanctions and embargoes codified in 31 C.F.R. Chapter V. Kuur agrees that Kuur bears sole responsibility for understanding and complying with current U.S. trade controls laws and regulations as applicable to its activities subject to this Agreement. Without limitation on the general agreement to comply set forth in the first sentence of this Section 13.3, Kuur agrees not to sell any goods, services, or technologies subject to this Agreement, or to release or disclose or re-export the same: (i) to any destination prohibited by U.S. law, including any destination subject to U.S. economic embargo; (ii) to any end-user prohibited by U.S. law, including any person or entity listed on the U.S. government's Specially Designated Nationals list, Denied Parties List, Debarred Persons List, Unverified List, or Entities List; (iii) to any foreign national in the U.S. or abroad without prior license if required; or (iv) to any user, for any use, or to any destination without prior license if required. Furthermore, Kuur agrees that any transfer of Patent Rights from Baylor to Kuur under this Agreement is subject to U.S. export license authorization as may be required under U.S. law.

ARTICLE XIV
DISPUTE RESOLUTION

14.1 Amicable Resolution. The Parties shall attempt to settle any controversy between them and arising under this Agreement amicably. To this end, a senior executive from each Party shall consult and negotiate in good faith to reach a solution. The Parties agree that the period of amicable resolution shall toll any otherwise applicable statute of limitations. If the senior executives from each Party fail to meet, or if the matter remains unresolved, for a period of thirty (30) days from the date such controversy first was raised with the other party by notice delivered under Section 15.1, either Party shall have the right to seek to settle the controversy by binding arbitration pursuant to Section 14.2.

14.2 Arbitration.

(a) Subject to Sections 14.3 and 14.4, any dispute, controversy, or claim arising out of or relating to this Agreement, or the breach, termination or invalidity thereof, including claims for tortious interference or other tortious or statutory claims arising before, during or after termination, providing only that such claim touches upon matters covered by this Agreement, shall be finally settled by arbitration administered by the American Arbitration Association pursuant to the Commercial Arbitration Rules in force at the time of the commencement of the arbitration, except as modified by the specific provisions of this Agreement. It is the specific intent of the Parties that this arbitration provision is intended to be the broadest form allowed by law. This agreement to arbitrate is intended to be binding upon the signatories hereto, their principals, successors, assigns, subsidiaries and Affiliates.

(b) The Parties agree that a final judgment on the arbitration award shall be binding, final and non-appealable other than for grounds to vacate the final award, and may be entered by any court having jurisdiction thereof.

(c) A panel of three arbitrators shall be appointed to conduct the arbitration, with each Party having the right to select one arbitrator, both of whom will agree on a third arbitrator to act as the chair of the panel. All three of such arbitrators shall be neutrals, i.e., having no affiliation with either Party.

(d) Each arbitrator must be an active or retired lawyer, having practiced actively in the field of commercial law and/or the law relevant to the subject matter of the arbitration, in each case, for at least fifteen (15) years.

(e) The law applicable to the validity of the arbitration clause, the conduct of the arbitration, including any resort to a court for provisional remedies, the enforcement of any award and any other question of arbitration law or procedure shall be the Federal Arbitration Act. The New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards of June 10, 1958 shall govern any and all disputes that may be the subject of arbitration pursuant to this Agreement.

(f) The arbitrator(s) shall hear and determine any preliminary issue of law asserted by a Party to be dispositive of any claim, in whole or part, in the manner of a court hearing a motion to dismiss for failure to state a claim or for summary judgment, pursuant to such terms and procedures as the arbitrator(s) deems appropriate.

(g) The Parties and the arbitrator(s) shall treat all aspects of the arbitration proceedings, including without limitation discovery, testimony and other evidence, briefs and the award, as strictly confidential. Further, except as may be required by law, neither Party nor the arbitrator(s) may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties.

(h) The seat of arbitration shall be New York, New York, USA.

(i) The arbitration shall be conducted in the English language. All submissions shall be made in English or with an English translation. Witnesses may provide testimony in a language other than English, provided that a simultaneous English translation is provided. Each Party shall bear its own translation costs.

14.3 Injunctive Relief. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction, at any time, in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the resolution of any dispute hereunder.

14.4 Construction and Jurisdiction. This Agreement shall be deemed to be subject to, and have been made under, and shall be construed and interpreted in accordance with the laws of the State of New York. No conflict-of-laws rule or law that might refer such construction and interpretation to the laws of another state, republic, or country shall be considered.

ARTICLE XV
NOTICES

15.1 Addresses for Notices. All notices, demands or other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given: (i) when delivered personally to the recipient to the address set forth below, if sent to the recipient by reputable express courier service (charges prepaid), or mailed to the recipient by certified or registered mail, return receipt requested and postage prepaid, or (ii) when sent to the recipient by electronic mail to the electronic mail address set forth below and the recipient has confirmed receipt of such electronic mail (and such confirmation of receipt can be confirmed by email). Such notices, demands and other communications shall be sent to the Parties at the addresses indicated below:

If to Baylor:
Baylor College of Medicine
One Baylor Plaza
Cullen Building, Suite 106A
Houston, Texas 77030
United States of America
Attn: Robert F. Corrigan

If to Kuur:
Cell Medica Inc., d/b/a Kuur Therapeutics
6200 Savoy Dr. #1200
Houston, Texas 77036
United States of America
Attn: Daniel Lang

Tel. No.: XXX-XXX-XXXX
E-Mail: [*]

With copy (which shall not constitute notice) to:

Norton Rose Fulbright US LLP
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
United States
Attn: William D. Davis II
E-Mail: [*]

With copy (which shall not constitute notice) to:

Hogan Lovells US LLP
609 Main Street, Suite 4200
Houston, TX 77002
Attn: Melinda Lackey
E-Mail: [*]

15.2 Use of Reference Number. Each such report, notice or other communication shall include BLG number(s) XX-XXX listed in Article I of this Agreement or the applicable BLG number as updated under Schedule C.

ARTICLE XVI
INDEMNITY, INSURANCE, AND WARRANTIES

16.1 Indemnity.

(a) EACH PARTY SHALL NOTIFY THE OTHER OF ANY THIRD PARTY'S CLAIM, LAWSUIT OR OTHER PROCEEDING RELATED TO THE LICENSED TECHNOLOGY, LICENSED PRODUCTS, AND TECHNOLOGY RIGHTS.

(b) KUUR AGREES THAT IT WILL DEFEND, INDEMNIFY AND HOLD HARMLESS BAYLOR AND ITS AFFILIATES AND THEIR RESPECTIVE FACULTY MEMBERS, SCIENTISTS, RESEARCHERS, EMPLOYEES, STUDENTS, OFFICERS, TRUSTEES AND AGENTS (OTHER THAN ANY SUBLICENSEE OR OTHER PARTY TO WHOM BAYLOR HAS CONVEYED ITS RESERVED RIGHTS UNDER SECTION 2.4 WHICH SUCH PARTIES SHALL NOT BE DEEMED AGENTS OF BAYLOR) AND EACH OF THEM (THE "BAYLOR INDEMNIFIED PARTIES"), FROM AND AGAINST, AND SHALL PAY BAYLOR THE MONETARY VALUE OF, ALL LIABILITIES AND LOSSES RELATED TO OR RESULTING FROM, DIRECTLY OR INDIRECTLY, ANY AND ALL THIRD PARTY CLAIMS, CAUSES OF ACTION, LAWSUITS OR OTHER PROCEEDINGS (THE "BAYLOR CLAIMS") FILED OR OTHERWISE INSTITUTED AGAINST ANY OF THE BAYLOR INDEMNIFIED PARTIES RELATED DIRECTLY OR INDIRECTLY TO OR ARISING OUT OF THE DESIGN, PROCESS, MANUFACTURE OR USE BY OR ON BEHALF OF KUUR, ITS AFFILIATES AND ITS SUBLICENSEES OF LICENSED TECHNOLOGY, PATENT RIGHTS, AND LICENSED PRODUCTS OR ANY OTHER EMBODIMENT OF THE LICENSED TECHNOLOGY, LICENSED PRODUCTS, AND PATENT RIGHTS EVEN THOUGH SUCH BAYLOR CLAIMS AND THE COSTS (INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE) RELATED THERETO RESULT IN WHOLE OR IN PART FROM THE NEGLIGENCE OF ANY OF THE BAYLOR INDEMNIFIED PARTIES OR ARE BASED UPON DOCTRINES OF

STRICT LIABILITY OR PRODUCT LIABILITY; PROVIDED, HOWEVER, THAT SUCH INDEMNITY SHALL NOT APPLY TO ANY BAYLOR CLAIMS TO THE EXTENT SUCH CLAIMS (1) ARISE FROM THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF, OR BREACH OF THIS AGREEMENT OR THE CO-DEVELOPMENT AGREEMENT BY, ANY BAYLOR INDEMNIFIED PARTY, OR (2) ARE SUBJECT TO BAYLOR'S INDEMNIFICATION OBLIGATIONS SET FORTH IN SECTION 16.1(c) OF THIS AGREEMENT OR SECTION 9.5(c) OF THE CO-DEVELOPMENT AGREEMENT. KUUR WILL ALSO ASSUME RESPONSIBILITY FOR ALL COSTS AND EXPENSES RELATED TO SUCH BAYLOR CLAIMS FOR WHICH IT IS OBLIGATED TO INDEMNIFY THE BAYLOR INDEMNIFIED PARTIES PURSUANT TO THIS SECTION 16.1, INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE.

(c) BAYLOR AGREES THAT IT WILL DEFEND, INDEMNIFY AND HOLD HARMLESS KUUR AND ITS AFFILIATES AND THEIR RESPECTIVE DIRECTORS, OFFICERS, EMPLOYEES AND AGENTS AND EACH OF THEM (THE "KUUR INDEMNIFIED PARTIES"), FROM AND AGAINST, AND SHALL PAY KUUR THE MONETARY VALUE OF, ALL LIABILITIES AND LOSSES RELATED TO OR RESULTING FROM, DIRECTLY OR INDIRECTLY, ANY AND ALL CLAIMS, CAUSES OF ACTION, LAWSUITS OR OTHER PROCEEDINGS (THE "KUUR CLAIMS") FILED OR OTHERWISE INSTITUTED AGAINST ANY OF THE KUUR INDEMNIFIED PARTIES BY OR ON BEHALF OF [*] ARISING OUT OF BAYLOR'S BREACH OF ITS REPRESENTATIONS AND WARRANTIES UNDER SECTION 16.8(a) OF THIS AGREEMENT; PROVIDED, HOWEVER, THAT SUCH INDEMNITY SHALL NOT APPLY TO ANY KUUR CLAIMS TO THE EXTENT ARISING FROM GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF, OR THE BREACH OF THIS AGREEMENT OR THE CO-DEVELOPMENT AGREEMENT BY ANY KUUR INDEMNIFIED PARTY. BAYLOR WILL ALSO ASSUME RESPONSIBILITY FOR ALL COSTS AND EXPENSES RELATED TO SUCH KUUR CLAIMS FOR WHICH IT IS OBLIGATED TO INDEMNIFY THE KUUR INDEMNIFIED PARTIES PURSUANT TO THIS SECTION 16.1, INCLUDING, BUT NOT LIMITED TO, THE PAYMENT OF ALL REASONABLE ATTORNEYS' FEES AND COSTS OF LITIGATION OR OTHER DEFENSE.

(d) THE PARTY SEEKING INDEMNIFICATION UNDER THIS SECTION 16.1 SHALL NOTIFY THE INDEMNIFYING PARTY WITHOUT UNDUE DELAY IN WRITING OF ANY CLAIM FOR WHICH IT SEEKS INDEMNITY HEREUNDER AND COOPERATE REASONABLY WITH THE INDEMNIFYING PARTY AT THE INDEMNIFYING PARTY'S SOLE COST AND EXPENSE. THE INDEMNIFYING PARTY SHALL PROMPTLY, AFTER BEING SO NOTIFIED, ASSUME THE DEFENSE OF ANY SUCH CLAIM WITH COUNSEL OF ITS CHOICE THAT IS REASONABLY SATISFACTORY TO THE INDEMNIFIED PARTY. THE INDEMNIFYING PARTY SHALL NOT SETTLE ANY SUCH CLAIM WITHOUT THE INDEMNIFIED PARTY'S PRIOR WRITTEN CONSENT UNLESS THE ONLY OBLIGATION AND LIABILITY OF, AND THE ONLY ADVERSE IMPACT ON, THE INDEMNIFIED PARTIES IS A PAYMENT OBLIGATION INDEMNIFIED IN FULL BY THE INDEMNIFYING PARTY. SUBJECT TO THE INDEMNIFYING PARTY'S RIGHT TO CONTROL THE DEFENSE AND SETTLEMENT THEREOF, THE INDEMNIFIED PARTY MAY PARTICIPATE IN AND OBSERVE THE PROCEEDINGS AT ITS OWN COST AND EXPENSE WITH COUNSEL OF ITS OWN CHOOSING.

16.2 Insurance.

(a) Kuur shall for so long as Kuur manufactures or uses any Licensed Technology, Patent Rights, or Licensed Product under this Agreement, Kuur shall maintain in full force and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than one million U.S. dollars ($1,000,000) per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than one million U.S. dollars ($1,000,000) per occurrence with an annual aggregate of two million U.S. dollars ($2,000,000) and (d) upon initiation of any human clinical study of a Licensed Product, products liability insurance, with limits of not less than three million U.S. dollars ($3,000,000) per occurrence with an annual aggregate of five million U.S. dollars ($5,000,000) unless liability associated with such clinical study is otherwise assumed by the United States government or other governmental entity.

(b) Notwithstanding Section 16.2(a), following regulatory approval for a Licensed Product, Kuur shall for so long as Kuur commercially manufactures or sells any such Licensed Product(s), also maintain in full force

and effect policies of (a) worker's compensation insurance within statutory limits, (b) employers' liability insurance with limits of not less than one million U.S. dollars ($1,000,000) per occurrence, (c) general liability insurance (with Broad Form General Liability endorsement) with limits of not less than twenty million U.S. dollars ($20,000,000) per occurrence with an annual aggregate of forty million U.S. dollars ($40,000,000) and (d) products liability insurance, with limits of not less than twenty million U.S. dollars ($20,000,000) per occurrence with an annual aggregate of forty million U.S. dollars ($40,000,000); provided that if annual sales of Licensed Products are less than one hundred million U.S. dollars ($100,000,000), the insurance limits set forth above may be reduced to 0.2x projected sales per instance during the coverage year with 2x that amount in aggregate (for purposes of example only, if sales of Licensed Products are projected to be fifty million U.S. dollars ($50,000,000), each of the general liability and products liability coverage requirements would be ten million U.S. dollars ($10,000,000) per instance and twenty million U.S. dollars ($20,000,000) in aggregate).

(c) Such coverage(s) shall be purchased from a carrier or carriers having an A. M. Best rating of at least A- (A minus) and shall name Baylor as an additional insured. Kuur shall provide to Baylor copies of certificates of insurance within thirty (30) days after the Effective Date. Upon request by Baylor, Kuur shall provide to Baylor copies of said policies of insurance. It is the intention of the Parties hereto that Kuur shall, throughout the Term of this Agreement, continuously and without interruption, maintain in force the required insurance coverages set forth in this Section 16.2. Failure of Kuur to comply with this requirement shall constitute an Essential Breach of Kuur allowing Baylor, at its option, to terminate this Agreement in accordance with Section 11.1(b).

(d) Baylor reserves the right to request additional policies of insurance where appropriate and reasonable in light of Kuur's business operations and availability of coverage.

16.3 DISCLAIMER OF WARRANTY. EXCEPT AS EXPRESSLY SET FORTH IN SECTIONS 16.5, 16.8 and 16.9, BAYLOR MAKES NO WARRANTIES OR REPRESENTATIONS, AND HEREBY DISCLAIMS ALL WARRANTIES AND REPRESENTATIONS, RELATED TO THIS AGREEMENT AND ANY PERFORMANCE OR ACTIVITY HEREUNDER, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF FITNESS OR MERCHANTABILITY OR WORKMANSHIP, REGARDING OR WITH RESPECT TO THE LICENSED TECHNOLOGY, PATENT RIGHTS OR LICENSED PRODUCTS AND BAYLOR MAKES NO WARRANTIES OR REPRESENTATIONS, EXPRESS OR IMPLIED, OF THE PATENTABILITY OF THE LICENSED TECHNOLOGY, LICENSED PRODUCTS, PATENT RIGHTS OR LICENSED PRODUCTS OR OF THE ENFORCEABILITY OF ANY PATENTS ISSUING THEREUPON, IF ANY, OR THAT THE LICENSED TECHNOLOGY, PATENT RIGHTS OR LICENSED PRODUCTS ARE OR SHALL BE FREE FROM INFRINGEMENT OF ANY PATENT OR OTHER RIGHTS OF THIRD PARTIES. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS UNDER ANY PATENTS OF BAYLOR OTHER THAN THE PATENT RIGHTS, REGARDLESS OF WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS.

16.4 EXCLUSION AND LIMITATION OF LIABILITY. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER, OR ANYBODY CLAIMING THROUGH SUCH OTHER PARTY FOR ANY CONSEQUENTIAL, INCIDENTAL, PUNITIVE, SPECIAL, OR LIQUIDATED DAMAGES OR LOSS, INCLUDING, WITHOUT LIMITATION, LOST BUSINESS OR LOST PROFITS, OF ANY KIND UNDER OR IN CONNECTION WITH THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, ANY SUCH DAMAGES THAT ARISE FROM ANY USE OF ANY LICENSED TECHNOLOGY OR FROM ANY LICENSED PRODUCT. IF BAYLOR IS LIABLE FOR ANY DIRECT DAMAGES OR LOSSES UNDER THIS AGREEMENT, OR FOR ANY DAMAGES OR LOSSES THAT CANNOT BE VALIDLY EXCLUDED UNDER THE FOREGOING PROVISION OF THIS SECTION 16.4, THE TOTAL AND AGGREGATE DAMAGES AND LOSSES FOR WHICH BAYLOR IS LIABLE UNDER THIS AGREEMENT SHALL BE LIMITED IN THE AGGREGATE TO (A) THE SUM OF THE ROYALTIES AND OTHER LICENSE OR OPTION FEES PAID BY KUUR TO BAYLOR UNDER THIS AGREEMENT WITHIN TWELVE (12) MONTHS PRIOR TO ASSERTING SUCH CLAIM FOR SUCH DAMAGES AND LOSSES, OR (B) WITH RESPECT TO BAYLOR'S INDEMNIFICATION UNDER SECTION 16.1(c) THE SUM OF THE ROYALTIES AND OTHER LICENSE OR OPTION FEES PAID BY KUUR TO BAYLOR UNDER THIS AGREEMENT WITHIN TWENTY-FOUR (24) MONTHS PRIOR TO ASSERTING SUCH CLAIM FOR SUCH DAMAGES AND LOSSES.

16.5 Representations and Warranties. Each Party represents and warrants to the other Party that as of the Second Restatement Effective Date:

(a) it has the full right, power and authority to enter into this Agreement, and to perform its obligations hereunder;

(b) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

(c) that all representations and warranties made and provided in the Original and First Restated Agreements remain in place beginning with their respective Effective Dates and through this Second Restated Effective Date.

16.6 Covenants of Kuur. Kuur shall not, during the Term, hire, engage, contract, employ or otherwise seek to acquire or acquire any services of Dr. Metelitsa or any member of Dr. Metelitsa's laboratory other than as provided under this Agreement, the Co-Development Agreement, and any Work Plan or Specific Industrial Clinical Research Agreement without prior, written approval from Baylor, which shall not be unreasonably withheld.

16.7 Representations and Warranties of Kuur.

(a) Neither Party's conduct of its activities pursuant to the Development Plan as it exists as of the Second Restatement Effective Date and in accordance with the terms of the Co-Development Agreement, to the knowledge of Kuur, will breach any written agreement between Kuur and any Third Party, nor give rise to a right by any such Third Party to enforce any Technology Right licensed to Kuur by such Third Party.

(b) Kuur is duly incorporated, in existence and registered under the laws of the state of Texas and is wholly owned by Kuur Therapeutics Inc.

(c) Kuur Therapeutics Inc. is duly incorporated, in existence and registered under the laws of the state of Delaware and is wholly owned by Athenex Inc..

(d) Athenex Inc. is duly incorporated, in existence and registered under the laws of the state of Delaware.

(e)

(f) No step has been taken to initiate any process by or under which:

(i) (the ability of the creditors of any of the Group Companies to take any action to enforce their debts is suspended, restricted or prevented;

(ii) some or all of the creditors of the Group Companies accept, by agreement or under a court order, an amount less than the sums owing to them in satisfaction of those sums with a view to preventing the dissolution of any Group Company;

(iii) a person is appointed to manage the affairs, business and assets of any Group Company on behalf of their respective creditors; or

(iv) the holder of a charge over any Group Company's assets is appointed to control the business and assets of any Group Company.

(g) In relation to each Group Company:

(i) no administrator has been appointed;

(ii) no documents have been filed with the court for the appointment of an administrator; and

(iii) no notice of an intention to appoint an administrator has been given by the relevant company, its directors or by a qualifying floating charge holder (as defined in paragraph 14 of Schedule B1 to the United Kingdom Insolvency Act 1986).

16.8 Representations and Warranties of Baylor. Baylor represents and warrants to Kuur that as of the Effective Date:

(a) Baylor's Office of General Counsel has no actual knowledge of (i) any written claim made against it asserting the invalidity, or unenforceability or non-infringement of any of the Core Platform Patent Rights or Baylor Target Patent Rights or (ii) any written claim made against it challenging Baylor's ownership of the Core Platform Patent Rights or Baylor Target Patent Rights or making any adverse claim of ownership (whether sole or joint) thereof or license thereto;

(b) Baylor's Office of General Counsel and the Baylor Licensing Group have no actual knowledge of any written agreement granting to any Third Party a license, an option to acquire a license, or a covenant not to sue under any of the Core Platform Patent Rights, Baylor Target Patent Rights or any Core Subject Technology to research, develop, make, use, offer for sale, sell, or otherwise commercialize a Licensed Product in any field, which license, option or covenant not to sue has not expired or been terminated prior to the Effective Date, and which license, option or covenant not to sue would conflict with any license right granted to Kuur under this Agreement, other than (i) to academic or non-profit entities, (ii) pursuant to federal or state laws related to government-sponsored research, (iii) the [*] , and (iii) the SICRAs executed pursuant to the Co-Development Agreement;

(c) Baylor's Office of General Counsel and the Baylor Licensing Group have no actual knowledge of any written agreement granting to any Third Party a license, an option to acquire a license, or a covenant not to sue under any of the Core Platform Patent Rights or any Core Subject Technology (but excluding the Baylor Target Patent Rights and the NKT CAR Subject Technology) which license, option or covenant not to sue has not expired or been terminated prior to the Effective Date, and which license, option or other right would conflict with the options granted hereunder to Future Products, Future Oncology Technology and Future Non-Oncology Technology, other than (i) to academic or non-profit entities, (ii) pursuant to federal or state laws related to government-sponsored research, and (iii) pursuant to the [*]

(d) Baylor's Office of General Counsel has no actual knowledge of any written claim, legal action, or judgment or settlement of infringement of any patent rights of any Third Party made against Baylor or any of its Affiliates asserting such infringement by the manufacture of any current Licensed Core Product.

(e) Neither Party's conduct of its activities pursuant to the Development Plan as it exists as of the Effective Date and in accordance with the terms of the Co-Development Agreement, to the knowledge of Baylor's Office of General Counsel, will breach any written agreement between Baylor and any Third Party, nor give rise to a right by any such Third Party to enforce any Technology Right licensed to such Third Party by Baylor.

16.9 Baylor Private Placement Representations and Warranties. Baylor represents and warrants to Kuur that as of the Effective Date and as of any date on which Kuur issues shares to Baylor pursuant to this Agreement; and Baylor further covenants to confirm by officer's certificate on any future date on which Kuur issues shares to Baylor pursuant to this Agreement, if so requested by Kuur, the following:

(a) Baylor acknowledges that such shares are being issued for Baylor's own account and not with the view to, or for resale in connection with, any distribution or public offering thereof within the meaning of the U.S. Securities Act of 1933, as amended (the "Securities Act"). Baylor understands that none of such shares have been registered under the Securities Act by reason of their issuance in transactions exempt from the registration and

prospectus delivery requirements of the Securities Act pursuant to Section 4(a)(2) thereof, the availability of which depends upon, inter alia, the bona fide nature of Baylor's intent and the accuracy of Baylor's representations in this Agreement. Baylor further understands that such shares will bear the following legend and Baylor agrees that it will hold such shares subject thereto:

"THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND HAVE NOT BEEN ACQUIRED WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO TRANSFER OF THESE SECURITIES MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE ISSUER AND/OR THE SUBMISSION TO THE ISSUER OF SUCH OTHER EVIDENCE AS MAY, IN THE ISSUER'S SOLE DISCRETION, BE SATISFACTORY TO THE ISSUER TO THE EFFECT THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933, AS AMENDED."

Baylor acknowledges that Kuur need not register a transfer of legended shares unless the conditions specified in the legend are satisfied.

(b) Baylor has such knowledge and experience in financial and business matters that it is capable of independently evaluating the risks and merits of the acquiring such shares; Baylor has independently evaluated the risks and merits of acquiring such shares and has independently determined that such shares are a suitable investment for it; Baylor has sufficient financial resources to bear the loss of its entire investment in such shares; and Baylor has had the opportunity to review this Agreement and the Exhibits and Schedules hereto and thereto and the transactions contemplated by this Agreement with its own legal counsel.

(c) Baylor believes, after due inquiry and investigation, that it has received all of the information that it considers necessary or appropriate for deciding whether to acquire such shares. Baylor further represents that it has had an opportunity to ask questions and receive answers from Kuur regarding the terms and conditions of the issuance of such shares by Kuur and the business, properties, prospects and financial condition of Kuur and to obtain additional information (to the extent Kuur possessed such information or could acquire it without unreasonable effort or expense) necessary to verify the accuracy of any information furnished to Baylor.

(d) Baylor acknowledges that such shares may not be sold in the United States unless subsequently registered under the Securities Act or unless an exemption from such registration is available. Baylor is aware of the provisions of Rule 144 promulgated under the Securities Act which permit limited resale of securities purchased in a private placement subject to the satisfaction of certain conditions.

(e) Baylor is an "accredited investor" as defined in Rule 501(a)(3) of Regulation D promulgated under the Securities Act.

(f) Baylor's address set forth in this Agreement is the office of Baylor's principal place of business, upon which Kuur may rely for the purpose of complying with applicable state securities or "Blue Sky" laws. Baylor shall cooperate, to the extent commercially reasonable, with Kuur in any applicable state securities or "Blue Sky" filings.

ARTICLE XVII
CONFIDENTIALITY AND NON-DISCLOSURE

17.1 Scope. Neither Party, as the Receiving Party, shall, directly or indirectly, divulge or reveal to any person or entity the Confidential Information of the other Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this Agreement or the Co-Development Agreement. Subject to Section 17.2, Kuur shall maintain the Licensed Technology and unpublished Patent Rights in strictest confidence and use the same only in accordance with this Agreement, the Co-Development Agreement or any other written agreements with Baylor. Employees, agents or subcontractors of the Receiving Party shall be given access to the Disclosing Party's Confidential Information only on a reasonable "need to know" basis and after agreeing to be legally bound to protect the Confidential Information in a manner consistent with this Article XII. The public

disclosure (with or without the permission of the Disclosing Party) of any one component of that which was identified as or constituted the Confidential Information of the Disclosing Party shall not prevent the other components from retaining their status as Confidential Information and the property of such Party. In addition, Baylor shall maintain all of its Confidential Information that is subject to Kuur's licenses and options hereunder in the same manner as it is obligated to treat Kuur's Confidential Information under this Article XII, subject to Section 17.5.

17.2 Exclusion. Such obligation of confidentiality shall not apply to information (including any Patent Rights or Licensed Technology) which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this Agreement or the Co-Development Agreement by the Receiving Party; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; (v) was disclosed pursuant to Section 17.3; or (vi) was approved for public release by prior written permission of the Disclosing Party.

17.3 Authorized Disclosure. A Receiving Party may disclose Confidential Information of the Disclosing Party or the terms of this Agreement:

(a) To such Receiving Party's Affiliates and, as applicable, sublicensees; provided that such Affiliates and/or sublicensees are bound by legally enforceable obligations to maintain the confidentiality of the Disclosing Party's Confidential Information in a manner consistent with the confidentiality provisions of this Agreement;

(b) To employees, directors, agents, contractors, consultants and advisers of the Receiving Party and its Affiliates and sublicensees, its legal counsel, and legal counsel representing any of the foregoing, including, without limitation, the individuals and entities listed in Exhibit B, in each case to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that each such individual and entity is bound by legally enforceable obligations to maintain the confidentiality of the Disclosing Party's Confidential Information in a manner consistent with the confidentiality provisions of this Agreement; and further provided that each Party shall remain responsible for any failure by its Affiliates and sublicensees, and its Affiliates' and sublicensees' respective employees, directors, agents, consultants, advisors, and contractors, to treat such Confidential Information as required under this Article XVII (as if such Affiliates, licensees, sublicensees employees, directors, agents, consultants, advisors and contractors were Parties directly bound to the requirements of this Article XVII);

(c) To the extent such disclosure is reasonably necessary in the following situations:

(i) filing or prosecuting of Patent Rights as contemplated by this Agreement or conducting or defending litigation;

(ii) submitting regulatory filings and other filings with governmental authorities (including Regulatory Authorities);

(iii) complying with Applicable Laws, including regulations promulgated by securities exchanges, it being expressly understood that Kuur shall have the right to disclose the existence and terms of this Agreement, the Co-Development Agreement and status of activities conducted hereunder and thereunder in connection with its IPO, as required by applicable Law and/or any securities exchange rules on which it lists its shares in such IPO, or in connection with subsequent public filings as required under Applicable Laws or such securities exchange rules;

(d) to a Party's Affiliates, directors, employees, agents, independent contractors, licensors, attorneys, independent accountants or financial advisors on a need-to-know basis for the sole purpose of performance of this Agreement or the Co-Development Agreement or providing advice with respect to this Agreement or the Co-Development Agreement, provided that in each such case on the condition that such disclosee is bound by confidentiality and non-use obligations substantially consistent with those contained in this Agreement;

(e) to actual or bona fide potential investors, acquirors, sublicensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, license or collaboration (and any attorney, accountant or other advisor, of the Receiving Party or any of its Affiliates, advising on such matter); provided that in each such case on the condition that such persons are bound by confidentiality and non-use obligations substantially consistent with those contained in this Agreement, save that such obligations may be for a term of no less than five (5) years following the disclosure of such Confidential Information to such persons; and further provided that in each such case where such Confidential Information is also entitled to attorney-client privilege, the attorney work product privilege, or any other similar privilege, protection, or immunity ("Privileged and Confidential Information"), the Receiving Party shall ensure that each such actual or bona fide potential investor, acquiror, sublicensee and other financial or commercial partner (or attorney, accountant or other advisor) has a common legal interest with the Disclosing Party and the Receiving Party at the time of disclosure and that such Privileged and Confidential Information is disclosed solely pursuant to a written common interest agreement sufficient to protect the privileged status of such Privileged and Confidential Information; and

(f) where such disclosure is required by judicial or administrative process, provided that in such event such Party shall promptly notify the other Party in writing of such required disclosure and provide the other Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Article XVII, and the Party disclosing Confidential Information pursuant to law or court order shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information.

17.4 Confidentiality of Agreement. Unless otherwise provided for in this Agreement, the Parties agree that this Agreement and the Co-Development Agreement and their terms are to be considered Confidential Information of each Party and shall be treated as such.

17.5 Publication. Each Party will provide the other Party with a copy of any proposed publication or other disclosure, including by any Third Party that is a party to a SIRA or SICRA, of:

(a) Core Subject Technology and/or Future Technology and/or

(b) relating to activities conducted pursuant to the Co-Development Agreement, for review and comment at least sixty (60) days prior to submission for publication or other disclosure (the "Publication Review Period"). Each Party will cooperate with the other Party regarding the publication or other disclosure as finalized, including, without limitation and at the Disclosing Party's election, deleting any of Disclosing Party's Confidential Information specifically identified in writing by the Disclosing Party for deletion by the Receiving Party during the Publication Review Period, and/or delaying publication or other disclosure for up to thirty (30) additional days to facilitate filing a patent application if so requested by the Receiving Party.

ARTICLE XVIII
ADDITIONAL PROVISIONS

18.1 Use of Names.

(a) Kuur agrees that it shall not use in any way the name of "Baylor College of Medicine" or any logotypes or symbols associated with Baylor or any marks confusingly similar thereto or the names of any of the scientists or other researchers at Baylor without the prior written consent of Baylor.

(b) Notwithstanding Section 18.1(a) above, Kuur shall have the right:

(i) as required by Applicable Laws, to refer to Baylor as its licensor and to this Agreement and its related agreements in a factual manner, it being expressly understood that Kuur shall have the right to so refer to Baylor as its licensor and to this Agreement in connection with its IPO, as required by Applicable Law and/or any securities exchange on which it lists its shares in such IPO, or in connection with subsequent public filings as required under applicable Law or such securities exchanges; and

(ii) to make appropriate attribution to Baylor as a source of data in keeping with good scientific practice.

Nothing in this Section 18.1(b) shall relieve Kuur of its obligations under Article XVII with respect to the material with which such use of Baylor's name is associated.

(c) Baylor shall have the right, as required by Applicable Laws, to refer to Kuur as its licensee and to this Agreement and its related agreements in a factual manner. Baylor shall also have the right to so refer to Kuur as its licensee and to this Agreement in connection with its submissions regulatory, tax, and/or grant authorities. Nothing in this Section 18.1(c) shall relieve Baylor of its obligations under Article XVII with respect to the material with which such use of Kuur's name is associated.

18.2 Marketing of Licensed Products. To the extent commercially feasible and consistent with prevailing business practices, Kuur shall mark, and shall cause its sublicensees to mark, all Licensed Products that are manufactured or sold under this Agreement with the number of each issued patent under the Patent Rights that applies to such Licensed Product.

18.3 Baylor's Disclaimers. Neither Baylor, nor any of its faculty members, scientists, researchers, employees, students, officers, trustees or agents assume any responsibility for the manufacture, product specifications, sale or use of the Licensed Technology, Patent Rights or Licensed Products which are manufactured by or sold by Kuur.

18.4 Remedies; Injunctive Relief. Each Party recognizes that any actual or potential violation, breach, or non-performance of, or default under, any provision in Article XVI may cause irreparable injury to the other Party for which such other Party may have no adequate remedy at law. Therefore, each Party agrees that such other Party shall be entitled to seek injunctive relief or specific performance, without need or obligation to post any bond, to enforce any obligation, agreement, covenant, term and condition under Article XVI, in addition to any other rights and remedies available to such other Party, all as the other Party elects in its sole discretion.

18.5 Independent Contractors. The Parties hereby acknowledge and agree that each is an independent contractor and that neither Party shall be considered to be the agent, representative, master or servant of the other Party for any purpose whatsoever, and that neither Party has any authority to enter into a contract, to assume any obligation or to give warranties or representations on behalf of the other Party. Nothing in this relationship shall be construed to create a relationship of joint venture, partnership, fiduciary or other similar relationship between the Parties.

18.6 Non-Waiver. The Parties covenant and agree that if a Party fails or neglects for any reason to take advantage of any of the terms provided for the termination of this Agreement or if a Party, having the right to declare this Agreement terminated, shall fail to do so, any such failure or neglect by such Party shall not be a waiver or be deemed or be construed to be a waiver of any cause for the termination of this Agreement subsequently arising, or as a waiver of any of the terms, covenants or conditions of this Agreement or of the performance thereof. None of the terms, covenants and conditions of this Agreement may be waived by a Party except by its written consent.

18.7 Severability. The Parties hereby agree that neither Party intends to violate any public policy, statutory or common law, rule, regulation, treaty or decision of any government agency or executive body thereof of any country or community or association of countries, and that if any word, sentence, paragraph or clause or combination thereof of this Agreement is found, by a court or executive body with judicial powers having jurisdiction over this Agreement or any of the Parties hereto, in a final, unappealable order to be in violation of any such provision in any country or community or association of countries, such words, sentences, paragraphs or clauses or combination shall be inoperative in such country or community or association of countries, and the remainder of this Agreement shall remain binding upon the Parties hereto. In lieu of such inoperative words, sentences, paragraphs or clauses, or combination of clauses, there will be added automatically as part of this Agreement, a valid, enforceable and operative provision as close to the original language as may be possible which preserves the economic benefits to the Parties.

18.8 Force Majeure. No liability hereunder shall result to a Party by reason of delay in performance caused by force majeure, that is circumstances beyond the reasonable control of the Party, including, without limitation, acts of God, fire, flood, war, terrorism, civil unrest, labor unrest, or shortage of or inability to obtain material or equipment.

18.9 Entire Agreement. The terms and conditions herein as well as those of the Co-Development Agreement, constitute the entire agreement between the Parties and shall supersede all previous agreements, whether electronic, oral or written, between the Parties hereto with respect to the subject matter hereof and thereof. No agreement of understanding bearing on this Agreement shall be binding upon either Party hereto unless it shall be in writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement. Electronic communication between the Parties shall not constitute an agreement of understanding, unless it is subsequently reduced to writing and signed by the duly authorized officer or representative of each of the Parties and shall expressly refer to this Agreement.

18.10 Counterparts. The Parties may execute this Agreement in multiple counterparts, each of which constitutes an original as against the Party that signed it, and all of which together constitute one agreement. This Agreement is effective upon delivery of one executed counterpart from each Party to the other Party. The signatures of the Parties need not appear on the same counterpart. The delivery of signed counterparts by facsimile or email transmission that includes a copy of the sending Party's signature is as effective as signing and delivering the counterpart in person.

18.11 Effect of Second Restatement. The Parties agree that this Second Restated Agreement supersedes and replaces the Restated Agreement from and after the Second Restatement Effective Date. Notwithstanding the foregoing, the terms of the Restated Agreement shall continue to apply with respect to matters that occurred prior to the Second Restatement Effective Date, and the Original Agreement shall continue to apply with respect to matters that occurred prior to the Restatement Effective Date, unless expressly noted herein.

18.12 365(n) - Bankruptcy. The Parties hereby agree that the rights to the Technology, Patent Rights and other Technology Rights licensed by Baylor to Kuur under this Agreement (the "Licensed Intellectual Property") constitute licenses of rights to "intellectual property" as defined in Section 101(35A) of the United States Bankruptcy Code and that this Agreement shall be governed by Section 365(n) of the United States Bankruptcy Code, as applicable, or any successor provision addressing this subject, in the event Baylor voluntarily or involuntarily becomes subject to the protection of the United States Bankruptcy Code and Baylor or the trustee in bankruptcy rejects this Agreement under the United States Bankruptcy Code (a "Triggering Event"). Upon the occurrence of a Triggering Event, Kuur shall have the right to: (a) treat this Agreement as terminated as set forth in 11 U.S.C. §365(n)(1)(A); or (b) retain Kuur's rights under this Agreement, specifically including the right to exercise its rights granted herein to the Licensed Intellectual Property. Failure by Kuur to assert its right to retain its benefits to the Licensed Intellectual Property pursuant to Section 365(n)(1)(B) of the United States Bankruptcy Code with respect to an executory contract rejected by Baylor or the trustee in bankruptcy shall not be construed by the courts a s a termination of such contract by Kuur under Section 365(n)(1)(A) of the United States Bankruptcy Code. Any attempted assignment of the Agreement by Baylor or the trustee in bankruptcy to a Third Party shall be subject to such Third Party providing "adequate assurance of future performance4" (as referenced in Section 365(f) of the United States Bankruptcy Code or any successor provision addressing this subject) to Kuur.

Signature page follows

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement in multiple originals by their duly authorized officers and representatives on the respective dates shown below, but effective as of the Effective Date.

CELL MEDICA, INC.	BAYLOR COLLEGE OF MEDICINE
Name: /s/ Daniel Lang Daniel Lang, M.D.	Name: /s/ Michael B. Dilling Michael B. Dilling Ph.D., CLP
Title: President Date: October 13, 2021	Title: Director, Baylor Licensing Group Date: October 12, 2021

[Signature Page to the Exclusive License and Option Agreement]

Exhibit 21.1

SUBSIDIARIES OF ATHENEX, INC.

Subsidiary Companies	Jurisdiction of Incorporation
Athenex API Limited	Hong Kong
Athenex Belgium	Belgium
Athenex Biomedical International Holdings Limited	Hong Kong
ATHENEX CIDAL HOLDINGS I, S.A.	Panama
ATHENEX CIDAL HOLDINGS II, S.A.	Panama
ATHENEX CIDAL PANAMA, S.A.	Panama
Athenex Cidal Columbia S.A.S.	Columbia
Athenex Cidal Argentina S.A.U.	Argentina
Athenex Cidal Chile SpA	Chile
Athenex Cidal Costa Rica S.A.	Costa Rica
Athenex Cidal Peru, S.A.C.	Peru
Athenex Cidal Ecuador ATHENEXCUA S.A.	Ecuador
Athenex Cidal Guatemala S.A.	Guatemala
Athenex Euro Limited	United Kingdom
Athenex HK Innovative Limited	Hong Kong
Athenex Manufacturing China Limited	British Virgin Islands
Athenex Pharma Solutions, LLC	Delaware
Athenex Pharmaceuticals Co., Ltd.	Taiwan
Athenex Pharmaceutical Division, LLC	Delaware
Athenex Pharmaceuticals (China) Limited	Hong Kong
Athenex Pharmaceuticals (Chongqing) Limited	People’s Republic of China
Athenex Pharmaceuticals (Hong Kong) Limited	Hong Kong
Athenex Pharmaceuticals International Holdings Limited	Hong Kong
Athenex Pharmaceuticals LLC	Delaware
Athenex R&D LLC	Delaware
Athenex Therapeutics Limited	Hong Kong
AtheSino Holdings Limited	British Virgin Islands
Atis Science and Technology Company Limited	Hong Kong
Axis Therapeutics Limited	Hong Kong
Bioksy Investments Ltd.	British Virgin Islands
Chongqing MJ Medical Devices Co., Ltd.	People’s Republic of China
Chongqing MJ Medical Sciences Co., Ltd.	People’s Republic of China
Chongqing Taihao Pharmaceutical Co., Ltd.	People’s Republic of China
Chongqing Sintaho Pharmaceutical Co., Ltd.	People’s Republic of China
Comprehensive Drug Enterprises Limited	Hong Kong
Excel Bloom Limited	British Virgin Islands
Maxinase Life Sciences Limited	Hong Kong
Meridian East Limited	British Virgin Islands
MJ Medical Gel Systems Limited	Hong Kong
Nuwagen Limited*	Hong Kong
Peterson Athenex Pharmaceuticals, LLC*	Delaware
Polymed Therapeutics, Inc.	Texas
Renascence Therapeutics Limited*	Hong Kong

* Minority-owned

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-227492, 333-232772, 333-236104, 333-241665 and 333-258185 on Form S-3 and No. 333-218984, 333-241666 and 333-258192 on Form S-8 of our reports dated March 16, 2022, relating to the financial statements of Athenex, Inc. and subsidiaries (the "Company") and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Deloitte & Touche LLP

Williamsville, New York
March 16, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Johnson Y.N. Lau, certify that:

1. I have reviewed this Annual Report on Form 10-K of Athenex, Inc. (the registrant);

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2022

/s/ Johnson Y.N. Lau
Name: Johnson Y.N. Lau

Title: Chief Executive Officer and Board Chairman

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Joe Annoni, certify that:

1. I have reviewed this Annual Report on Form 10-K of Athenex, Inc. (the registrant);

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2022

/s/ Joe Annoni
Name: Joe Annoni

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In accordance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Johnson Y.N. Lau, Chief Executive Officer and Board Chairman (Principal Executive Officer) of Athenex, Inc. (the "registrant"), and Joe Annoni, Chief Financial Officer of the registrant (Principal Financial and Accounting Officer), each hereby certifies that, to the best of their knowledge:

1. The registrant's Annual Report on Form 10-K for the period ended December 31, 2021, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition of the registrant at the end of the period covered by the Report and results of operations of the registrant for the period covered by the Report.

Date: March 16, 2022

/s/ Johnson Y.N. Lau
Name: Johnson Y.N. Lau

Title: Chief Executive Officer and Board Chairman

(Principal Executive Officer)

/s/ Joe Annoni
Name: Joe Annoni

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)