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

FORM 10-K

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

For the fiscal year ended December 31, 2022

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

Commission File Number 001-36818

TRACON Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**34-2037594**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
4350 La Jolla Village Drive, Suite 800, San Diego, CA	**92122**
(Address of Principal Executive Offices)	**(Zip Code)**

(858) 550-0780
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TCON	The Nasdaq Stock Market LLC

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 an 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant was approximately $42.2 million, based on the closing price of the registrant's common stock on the Nasdaq Capital Market on June 30, 2022 of $2.00 per share.

The number of outstanding shares of the registrant's common stock as of March 3, 2023 was 23,822,542.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the Registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

TRACON Pharmaceuticals, Inc.

FORM 10-K — ANNUAL REPORT
For the Fiscal Year Ended December 31, 2022

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Forward-Looking Statements

This Annual Report on Form 10-K (Annual Report), including the sections entitled "Summary of Risk Factors," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains forward-looking statements within the meaning of the safe harbor provisions for the U.S. Private Securities Litigation Reform Act of 1955. We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes, to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the success, cost and timing of results of our and our collaborators' ongoing clinical trials;
- our and our collaborators' plans to develop and commercialize our product candidates;
- the potential benefits of our collaboration arrangements and our ability to enter into additional collaboration arrangements;
- the potential outcome of our dispute with I-Mab Biopharma (I-Mab);
- our regulatory strategy and potential benefits associated therewith;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidates;
- the effects of unfavorable U.S. and global economic conditions on our business, financial condition and results of operations;
- the rate and degree of market acceptance and clinical utility of any approved product candidate;
- the success of competing products that are or may become available;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the potential effects of macroeconomic and geopolitical developments, such as the ongoing military conflict between Ukraine and Russia and the COVID-19 pandemic, on our operations;
- our intellectual property position;
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources, and our need for additional financing; and
- our ability to realize the anticipated benefits associated with our capital efficiency focused initiatives.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report and are subject to risks and uncertainties. We discuss many of these risks in greater detail under the section entitled "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. 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. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

We qualify all of the forward-looking statements in this Annual Report by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Summary of Risk Factors

Our business is subject to numerous risks, as more fully described immediately below. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

- We have incurred losses from operations since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability.
- We will require substantial additional financing to achieve our goals, and failure to obtain additional financing when needed could force us to delay, limit, reduce or terminate our drug development efforts. There is substantial doubt as to our ability to continue as a going concern.
- Unfavorable U.S. and global economic conditions could adversely affect our business, financial condition or results of operations.
- We are heavily dependent on the success of our lead clinical stage product candidate envafolimab. We cannot give any assurance that envafolimab will successfully complete clinical development or receive regulatory approval, which is necessary before it can be commercialized.
- Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.
- Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.
- The regulatory approval processes of the U.S. Food and Drug Administration (FDA), and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- We depend in part on NCI and other third-party sponsors to advance clinical development of TRC102. If these third-party sponsors ceased their support for our product candidates, our ability to advance clinical development of product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued.
- We are dependent on our corporate partners for the advancement of our product candidates. Specifically, we are dependent on 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) with respect to certain aspects of our development of envafolimab for sarcoma in North America. Similarly, we are dependent on Eucure (Beijing) Biopharma Co., Ltd. (Eucure) and Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen) with respect to certain aspects of our development of YH001 in North America. The failure to maintain these collaboration agreements, the failure of our corporate partners to perform their obligations under the agreements, or the actions of our corporate partners or their other partners with respect to envafolimab and YH001 in other indications or outside North America could negatively impact our business. Additionally, our ability to realize value from any product candidates developed under our agreements with I-Mab Biopharma (I-Mab) will depend in part on I-Mab's activities and willingness to fund future development.
- Our ability to realize value from any product candidates developed under our agreements with I-Mab will depend in part on I-Mab's activities and willingness to fund future development and the timing and outcome of our dispute with I-Mab of which we cannot predict the outcome and could materially adversely affect our ability to operate our business and financial results.
- The Loan Agreement with Runway Growth Capital (RGC) contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.
- We may not be able to protect our intellectual property rights throughout the world.
- We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

PART I

Item 1. Business.

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer and utilizing our cost efficient, contract research organization (CRO) independent product development platform to partner with other life science companies to develop and commercialize innovative products in the United States.

In December 2019, we entered into a collaboration and clinical trial agreement (the Envafolimab Collaboration Agreement) with 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) for the development of envafolimab, also known as KN035, an investigational PD-L1 single-domain antibody (sdAb) administered by rapid subcutaneous injection for the treatment of sarcoma in North America. The ENVASARC Phase 2 pivotal trial (the ENVASARC trial) is enrolling a total of 160 patients at 600mg of envafolimab, with 80 patients enrolling at 600mg of envafolimab every three weeks in cohort C, and 80 patients enrolling at 600mg of envafolimab every three weeks in combination with Yervoy® at 1mg/kg every three weeks for four doses in cohort D, in the sarcoma subtypes of undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS). Nine of 80 responses by blinded independent central review (BICR) in either cohort are needed to satisfy the primary objective of the trial which is to statistically exceed the known 4% objective response rate (ORR) of Votrient® (pazopanib), the only U.S. Food and Drug Administration (FDA)-approved treatment for patients with refractory UPS or MFS. Achieving the primary endpoint of exceeding the known 4% ORR could be the basis for accelerated approval of envafolimab by the FDA as a single agent and/or in combination with Yervoy. The trial will provide at least 86% power to demonstrate the lower bound of the 95% confidence interval is greater than 5% in each cohort, which would be greater than the 4% ORR of Votrient reported in soft tissue sarcoma in its package insert. Votrient is the only approved treatment for refractory soft tissue sarcoma, which includes UPS and MFS.

In August and October 2022, we announced that the ENVASARC trial will proceed as planned after the independent data monitoring committee (IDMC) reviewed three and twelve weeks of safety data, respectively, from more than 20 patients enrolled in the trial as of June 30, 2022. The safety data reviewed included data from more than 10 patients enrolled into cohort C of treatment with single agent envafolimab at 600mg every three weeks and more than 10 patients enrolled into cohort D of treatment with envafolimab at 600mg every three weeks in combination with Yervoy (ipilimumab).

In December 2022, we announced the IDMC recommended continued accrual as planned in both cohorts at the first planned interim efficacy analysis. The IDMC reviewed interim safety and efficacy data from 18 patients enrolled into each cohort who completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans). The double-digit ORR assessed by BICR in each cohort exceeded the prespecified futility rule that required at least one response among the initial 18 patients enrolled at 600mg into each cohort. Envafolimab monotherapy (cohort C) and in combination with Yervoy (cohort D) was well tolerated, with only a single related serious adverse event reported in 36 patients. A second interim efficacy analysis is planned following the 12-week efficacy scan in the 92nd dosed patient, to allow for determination of the preliminary ORR, which we expect in the third quarter of 2023. There must be at least three responses among the initial 46 patients enrolled at 600mg into each cohort to continue enrollment in that cohort per the futility rule of the trial.

In September 2022, we announced that the FDA had granted us fast track designation for the development of envafolimab for patients with locally advanced, unresectable or metastatic UPS and MFS who have progressed on one or two prior lines of chemotherapy. We are also eligible to apply for breakthrough therapy designation based on data from the ENVASARC clinical trial. We expect to complete enrollment by the end of 2023, have final response assessment data including duration of response in all patients from the ENVASARC trial in mid-2024, and, assuming positive data, to submit a biologics license application (BLA) to the FDA seeking accelerated approval in 2024. At any time that we reach nine responses in each cohort and meet the endpoint, we expect to discuss the submission process with the FDA.

Our other clinical stage oncology product candidates include YH001, which is a monospecific investigational cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) antibody, that we licensed from Eucure (Beijing) Biopharma Co., Ltd. (Eucure) and Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen) in October 2021, TRC102, which is a small molecule that has been studied in Phase 1 and Phase 2 trials for the treatment of mesothelioma, lung cancer, glioblastoma and solid tumors, and TJ004309, which is a CD73 antibody in Phase 1 clinical development for the treatment of solid tumors, that we licensed from I-Mab Biopharma (I-Mab) in November 2018.

YH001 is an investigational humanized CTLA-4 IgG1 monoclonal antibody that completed dosing in two Phase 1 trials sponsored by Eucure for the treatment of various cancer indications. CTLA-4 is a protein expressed on T-cells and expressed at high levels specifically on regulatory T-cells that act as a checkpoint to inhibit effector T-cell immune responses to cancer cells. The CTLA-4 inhibitor Yervoy (ipilimumab) marketed by BMS has been approved as a single agent in melanoma and approved in combination with other therapies in multiple indications including non-small cell lung cancer, renal cell carcinoma (RCC) and microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer. Data from the Phase 1 dose escalation trial in Australia of YH001 in combination with the PD-1 antibody, toripalimab, were presented at the American Society of Clinical Oncology 2022 Annual Meeting. YH001 was well tolerated up to 4 mg/kg when combined with toripalimab in the 24 patients as of the December 31, 2021 data cut-off date. The Phase 1 dose escalation trial in China of YH001 as a single agent, recently completed enrollment and determined a recommended Phase 2 dose. We expect data to be presented in the second half of 2023. No CTLA-4 therapy is approved by the FDA for the treatment of soft tissue sarcoma.

In August 2022, we announced that the FDA had approved the Investigational New Drug (IND) application for the initiation of a Phase 1/2 clinical trial of YH001 in combination with envafolimab and doxorubicin, an approved treatment for soft tissue sarcoma, for the treatment of sarcoma patients and in December 2022, we initiated dosing in the Phase 1/2 clinical trial. The Phase 1/2 trial will assess the safety and efficacy of the triplet combination of YH001, envafolimab and doxorubicin in the common sarcoma subtypes of leiomyosarcoma and dedifferentiated liposarcoma, and we expect Phase 1 data in the second half of 2023. In addition, the trial will assess the safety and efficacy of the doublet combination of YH001 and envafolimab in patients with the rare sarcoma subtypes of alveolar soft part sarcoma and chondrosarcoma. Additionally, we plan to initiate trials of YH001 as a single agent or in combination with immunotherapies in other tumor types.

TRC102 is a small molecule in clinical development to reverse resistance to specific chemotherapeutics by inhibiting DNA base excision repair (BER). In initial clinical trials of more than 100 patients, TRC102 has shown good tolerability and we believe promising anti-tumor activity in combination with alkylating and antimetabolite chemotherapy for the treatment of cancer patients. TRC102 has been studied in Phase 1 or Phase 2 trials in mesothelioma patients in combination with the approved chemotherapeutic Alimta® (pemetrexed), in glioblastoma, ovarian cancer, lung and colorectal cancer patients in combination with the approved chemotherapeutic Temodar® (temozolomide) and in lung cancer patients in combination with the approved chemotherapeutics Alimta and cisplatin as well as external beam radiation (i.e., chemoradiation). All current TRC102 trials are sponsored and funded by the National Cancer Institute (NCI). We retain global rights to develop and commercialize TRC102 in all indications. In October 2020, we received orphan drug designation (ODD) from the FDA for TRC102 for the treatment of patients with malignant glioma, including glioblastoma. O6-methylguanine DNA methyltransferase (MGMT) deficiency is observed in about one-third of glioblastoma patients, and a prior study of Temodar and TRC102 reported at the Society for Neuro-Oncology in 2018 demonstrated that two MGMT deficient glioblastoma patients had prolonged survival when treated with Temodar and TRC102 after progressing previously on Temodar and radiation therapy. A December 2020 publication in Cancer Cell also demonstrated Temodar and TRC102 were active in MGMT deficient patients with colorectal cancer. Based on these data, we believe a trial in first line glioblastoma patients of Temodar, radiation therapy and TRC102 is warranted and are discussing further development with investigators at this time. In addition, based on data presented at the ASCO 2020 virtual meeting that the combination of chemoradiation and TRC102 produced objective responses in all 15 evaluable patients with advanced localized lung cancer treated in a Phase 1 trial, in January 2022, the NCI initiated a randomized Phase 2 trial of chemoradiation with or without TRC102, followed by consolidative durvalumab treatment. The primary objective is to improve the 56% one-year progression free survival (PFS) rate with current standard of care to 75% with current standard of care plus TRC102. The trial began enrollment in June 2022 and is expected to be complete in 2025.

TJ004309, also known as TJD5 or ulileldimab, is a novel humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to the immunosuppressive metabolite adenosine. We are developing TJ004309 in collaboration with I-Mab under a strategic collaboration and clinical trial agreement that we entered into in November 2018 (the TJ004309 Agreement). In July 2019, we began enrollment in a Phase 1 clinical trial to assess safety and preliminary efficacy of TJ004309 as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® in patients with advanced solid tumors, and in June 2021 we presented data from the ongoing Phase 1 trial at the ASCO 2021 virtual meeting. In a poster presentation titled “The safety, pharmacokinetics (PK), pharmacodynamics (PD) and clinical efficacy of uliledlimab (TJ004309), a differentiated CD73 antibody, in combination with atezolizumab in patients with advanced cancer,” uliledlimab was found to be well-tolerated up to 20mg/kg every three weeks and 15mg/kg once weekly as a monotherapy and in combination therapy with atezolizumab 1200mg every three weeks and no dose limiting toxicity (DLT) was observed and the maximum tolerated dose (MTD) was not reached. There was one complete response in a PD-(L)1 naïve patient, two partial responses (PRs) with one PR in a PD-(L)1 naïve patient and one PR in a PD-(L)1 refractory patient, and three cases of stable disease (SD) following treatment with uliledlimab and atezolizumab.

We entered into a separate strategic collaboration and clinical trial agreement (the Bispecific Agreement) which allows for the development of up to five of I-Mab’s proprietary bispecific antibody (the BsAb) product candidates to be nominated by I-Mab within a five-year period for development and commercialization in North America, with the option to opt-in and acquire product rights outside of Greater China and Korea prior to completing the first pivotal clinical trial for any bispecific product candidate.

In March 2020, I-Mab issued a press release announcing a strategic partnership with Kalbe Genexine Biologics (KG Bio), whereby KG Bio received what the press release described as a right of first negotiation outside North America for TJ004309 for up to $340 million in potential payments to I-Mab. In March 2020, we also learned that I-Mab had entered into two license and collaboration agreements with ABL Bio in July 2018 (ABL Bio License 1 and ABL Bio License 2). Under ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I-Mab and ABL agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce (the ICC) before an arbitration tribunal seated in New York City (the Tribunal) after we invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations concerning two strategic collaboration and clinical trial agreements with us entered into in November 2018. Those strategic collaboration and clinical trial agreements relate to the development of TJ004309 and five of I-Mab's proprietary bispecific antibody product candidates to be nominated by I-Mab within a five-year period for development and commercialization in North America. We filed counterclaims in the arbitration seeking to recover over $200 million in damages from I-Mab based on I-Mab's breaches of the two strategic collaboration and clinical trial agreements. In 2021, I-Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is "Complete," as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I-Mab's termination. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking a variety of relief including an order of specific performance requiring us to comply with I-Mab's purported termination of the TJ004309 Agreement. In May 2021, the Delaware Court of Chancery stayed the lawsuit in favor of arbitration. The Tribunal held a hearing on the merits in February 2022, and final post-hearing briefs were submitted by us and I-Mab in May 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties submitted their respective cost submissions for attorney fees reimbursement in January 2023. The Tribunal did not indicate when it expects to render its final decision; however, it did note that it was far along in its deliberations and preparation of a final award. We expect the Tribunal to render its final decision in the first quarter of 2023.

Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal's discretion. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. The dispute with I-Mab has caused, and could continue to cause, us to incur significant costs.

The following table summarizes key information regarding ongoing and planned development of our clinical stage product candidates:

	Phase	Data Expected
Envafolimab		
Soft Tissue Sarcoma (UPS and MFS)	Pivotal Phase 2	Interim Data – Q3 2023 Final Data – mid-2024
Envafolimab + YH001		
Multiple Soft Tissue Sarcoma Subtypes	Phase 1/2 (planned)	Second half of 2023 and 2024
TRC102		
Lung Cancer	Randomized Phase 2	2025

We utilize a CRO-independent product development platform that emphasizes capital efficiency. Our experienced clinical operations, data management, quality assurance, product development and regulatory affairs groups manage significant aspects of our clinical trials with internal resources. We use these internal resources to reduce the costs associated with utilizing CROs to conduct clinical trials. In our experience, this model has resulted in capital efficiencies and improved communication with clinical trial sites, which can expedite patient enrollment and improve the quality of patient data as compared to a CRO-managed model. We have leveraged this platform in all of our sponsored clinical trials. We have also leveraged our product development platform to diversify our product pipeline without payment of upfront license fees through license agreements with Eucure and Biocytogen, 3D Medicines and Alphamab, I-Mab, and Janssen. We continue to evaluate life science companies that would benefit from a rapid and capital-efficient U.S. drug development solution that includes U.S. and European Union (EU) clinical development expertise. We believe we will continue to be recognized as a preferred U.S. clinical development partner through a cost- and risk-sharing partnership structure, which may include U.S. commercialization.

Our goal is to be a leader in the development of targeted therapies for patients with cancer and other diseases of high unmet medical need.

Our Lead Clinical Stage Product Candidate – Envafolimab

Overview of PD-L1

PD-L1 is an immune-inhibitory checkpoint molecule expressed on epithelial and vascular endothelial cells, as well as by a number of immune cells, that is utilized by tumor cells as an immune escape mechanism. Numerous preclinical and clinical studies of PD-1/PD-L1 products have demonstrated that antibodies that block the interaction of PD-1 with its ligands, PD-L1 and PD-L2, or those that block only the interaction of PD-L1 with PD-1, can augment anti-tumor T-cell responses and lead to complete and durable tumor eradication in a certain proportion of patients. Potent therapeutic anti-tumor responses due to blocking of the PD-1/PD-L1 interaction has been demonstrated by these approved products in patients with various solid tumors including, but not limited to, NSCLC, small cell lung cancer, gastric cancer, melanoma, RCC, head and neck cancer, cutaneous squamous cell carcinoma (cSCC) and urothelial carcinoma.

About Envafolimab and Preclinical Studies

Envafolimab is a sdAb that binds selectively to PD-L1 and is administered by rapid subcutaneous injection without an adjuvant. In November 2021 we announced that our partners 3D Medicines and Alphamab had received marketing authorization for envafolimab from the Chinese National Medical Products Association (NMPA) in the indication of MSI-H/dMMR cancer, and is being further developed by 3D Medicines for the treatment of various cancer indications, including an ongoing first line biliary tract cancer (BTC) pivotal trial in China, and by us in the United States for the treatment of sarcoma in the pivotal ENVASARC trial.

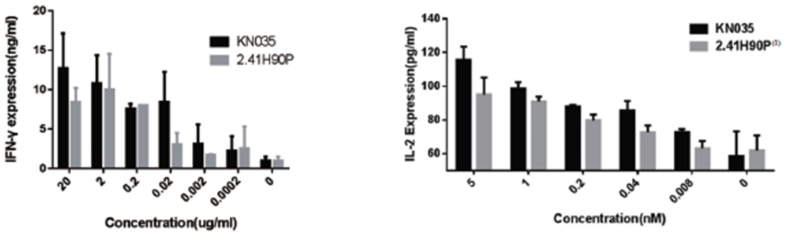
Single-domain antibodies are a novel class of therapeutic protein that contain the unique structural and functional properties of naturally-occurring antibodies from camels and llamas that contain heavy chains and lack light chains. On February 6, 2019, the FDA approved the first sdAb, Cablivi® (caplacizumab), for adults with acquired thrombotic thrombocytopenic purpura.

Envafolimab is a camelid IgG1 sdAb with single digit nanomolar affinity to PD-L1. Benefitting from the sdAb format, envafolimab has approximately half the molecular weight compared to a typical monoclonal antibody with better stability and high solubility, which enables the development of a high concentration formulation suitable for rapid subcutaneous injection. In addition, the effector functions are muted in envafolimab to help limit side effects and limit its exposure to the immune system to avoid unwanted adverse immune responses. As a result, compared with approved PD-(L)1 inhibitors, envafolimab potentially has the following advantages:

- *Better patient compliance with increased convenience*. Subcutaneous injection enables more rapid administration and the potential for self-injection, which enables better patient compliance with the treatment regimen;
- *Relatively stable plasma-drug concentration*. The plasma-drug concentration of envafolimab is relatively stable without significant fluctuations due to the nature of subcutaneous administration. This unique PK profile compared with intravenous formulations may result in lower risks to patients; and
- *Potential for improved tumor penetration*. Envafolimab is approximately half the size of a typical monoclonal antibody, which may provide for improved tumor penetration in cancer patients as was observed in pre-clinical experiments. This unique tumor penetration compared with typical monoclonal antibodies may improve efficacy.

In pre-clinical studies in human cell models and a humanized mouse model, envafolimab was compared with 2.41H90P, an antibody with a sequence that is identical to durvalumab, an approved PD-L1 inhibitor marketed by AstraZeneca, and envafolimab showed the following potential advantages:

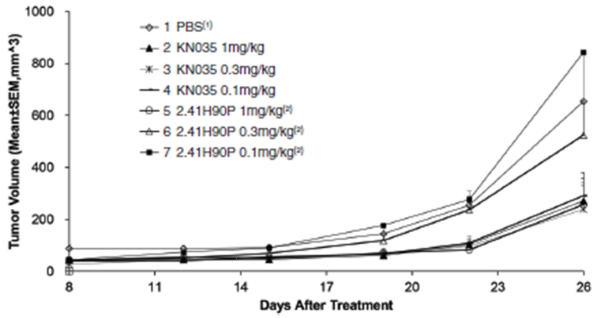
- *Stronger T-cell activation effect*. The level of T-cell activation can be measured by the secretion levels of IFN- and IL-2. Higher secretion levels are generally associated with stronger T-cell activation. In pre-clinical studies, envafolimab (referred to as KN035) demonstrated higher potency and a higher maximal stimulatory effect on IFN- and IL-2 secretion compared to 2.41H90P, as illustrated in the following figure.



(1) 2.41H90P was an in-house produced durvalumab with the same amino acid sequence as MedImmune's Imfinzi (durvalumab), and cloned using the 2.14H9 method.

Source: Investigator's Brochure (v.4.0) on KN035

- *Higher anti-tumor efficacy*. Envafolimab and 2.41H90P were each injected intraperitoneally in mice at 0.1mg/kg, 0.3mg/kg and 1.0mg/kg dose levels. As illustrated in the following graph, envafolimab showed more potent tumor growth inhibition effects with maximum inhibition demonstrated at a ten-fold lower dose.



(1) The control group was given PBS alone.

(2) 2.41H90P was an in-house produced durvalumab with the same amino acid sequence as MedImmune's Imfinzi (durvalumab), and cloned using the 2.14H9 method.

Source: Investigator's Brochure (v.4.0) on KN035

- *More rapid tumor penetration*. After injection of envafolimab and 2.4H90P in tumor bearing nude mice, the tumor radioactivity signal was consistently higher in the envafolimab group up to 52 hours post injection. The tumor radioactivity signal in the envafolimab group between 1 hour to 2.5 hours was statistically significantly higher, which suggests potentially better distribution of envafolimab into the tumor.

Clinical Trials of Envafolimab

As of December 31, 2022, envafolimab had been dosed in more than 1,000 patients in a total of more than 7 ongoing or completed clinical trials in the United States, China or Japan, including our ENVASARC trial, a pivotal Phase 2 trial in MSI-H/dMMR cancer patients in China, a Phase 2 trial of envafolimab plus chemotherapy in gastric cancer, a Phase 3 randomized trial of envafolimab plus chemotherapy versus chemotherapy alone in BTC in China, a Phase 1 dose escalation and dose exploration trial in the United States, a Phase 1 dose escalation and dose exploration trial in China, and a Phase 1 dose escalation and dose exploration trial in Japan.

Phase 1 Dose Escalation Clinical Trial in China

An open-label, single-arm Phase 1 dose escalation and exploration clinical trial of envafolimab has completed enrollment in China. The safety and efficacy data from this trial were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2019. Based on the data presented at the 2019 ASCO Annual Meeting (the ASCO Presentation), 17 subjects were enrolled in the dose escalation phase in this trial as of May 1, 2019. A total of 287 subjects were enrolled in this Phase 1 trial at dose levels shown to be tolerable during dose escalation.

Trial purpose. The primary objectives of the Phase 1 dose escalation were to assess the safety and tolerability profile and MTD of single agent envafolimab administered subcutaneously in subjects with advanced solid tumors. The secondary objectives were to evaluate the PK profile, immunogenicity and anti-tumor activity.

Trial design of the dose escalation phase. This trial adopted a modified "3+3" design with a DLT evaluation period of 28 days. Subjects received envafolimab in six cohorts at 0.1mg/kg, 0.3mg/kg, 1.0mg/kg, 2.5mg/kg, 5.0mg/kg and 10.0mg/kg once every week (QW) subcutaneously. Starting from the 1.0mg/kg cohort, a traditional "3+3" design was followed. Safety and tolerability were assessed by monitoring treatment emergent adverse events (TEAEs). Tumor assessments were performed based on RECIST version 1.1.

Safety of dose escalation phase. The majority of the subjects received two or more prior systemic oncology treatments. According to the ASCO Presentation, 16 of the subjects discontinued treatment due to disease progression (n=15) or consent withdrawal (n=1). All of the enrolled subjects experienced TEAEs. 13 (76.5%) subjects experienced treatment-related TEAEs. Three (17.6%) subjects experienced serious TEAEs, although none were determined to be treatment-related. A TEAE led to treatment discontinuation in one subject and was also determined to be not treatment-related. No DLT was reported and the MTD was not reached. Details of the TEAEs observed from the 17 subjects enrolled in the Phase 1 dose escalation trial are summarized in the following table.

TEAE categories[1]	n (%) (N=17)
AE	17 (100%)
Any TEAE	17 (100%)
TEAE, Grade ≥ 3	7 (41.2%)
Treatment-related TEAE[2]	13 (76.5%)
Treatment-related TEAE, Grade ≥ 3[3]	1 (5.9%)
SAEs	3 (17.6%)
Treatment-related SAEs	0
IrAEs	1 (5.9%)
IrAEs, Grade ≥ 3[3]	1 (5.9%)
TEAE leading to permanent treatment discontinuation	1 (5.9%)
Treatment-related TEAE leading to permanent treatment discontinuation	0
TEAE leading to death	0
Treatment-related TEAE leading to death	0

(1) Reported under National Cancer Institute Common Terminology Criteria for Adverse Events v. 4.03.
(2) The most frequent treatment-related TEAEs (all grades ≥ 10%) included increased alanine aminotransferase (n=6, 35.3%), increased aspartate aminotransferase (n=6, 35.3%), dermatitis/rash (n=3, 17.6%), blood bilirubin increased (n=3, 17.6%), injection site reaction (n=2, 11.8%).
(3) An immune-related dermatitis that occurred in the 0.3 mg/kg cohort. The subject recovered completely after the study drug was withheld.

Source: Phase I Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Patients with Advanced Solid Tumors in China, Abstract No. 2608, Poster No. 252, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

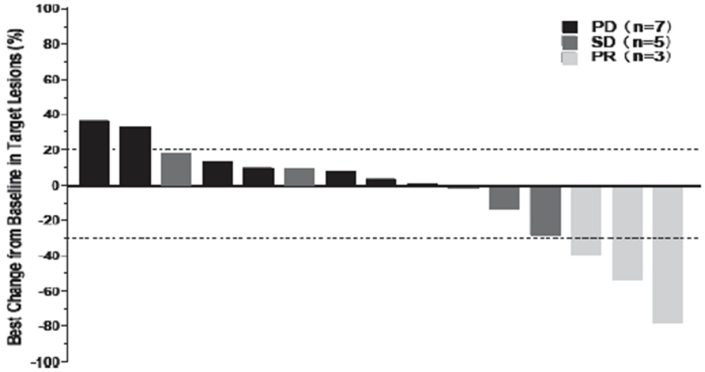
Efficacy. According to the ASCO Presentation, 15 out of 17 subjects were evaluable for the efficacy analysis. Three subjects had confirmed PR, including one RCC subject in the 2.5mg/kg cohort, one intrahepatic cholangiocarcinoma subject from the 5.0mg/kg cohort and one BTC subject from the 10.0mg/kg cohort. In addition, five subjects achieved stable disease. All 15 subjects completed at least one post-baseline tumor assessment, according to the ASCO Presentation. Two enrolled subjects who had not reached the first post-baseline tumor assessment were excluded. The table below summarizes the best overall response in the efficacy analysis of this trial, according to the ASCO Presentation.

Response	0.1 mg/kg (N=1)	0.3 mg/kg (N=2)	1.0 mg/kg (N=3)	2.5 mg/kg (N=3)	5.0 mg/kg (N=3)	10.0 mg/kg (N=3)	Total (N=15)
				n (%)			
CR	0	0	0	0	0	0	0
PR	0	0	0	1	1	1	3 (20.0%)
SD	0	0	2	2	1	0	5 (33.3%)
PD	1	2	1	0	1	2	7 (46.7%)
CR+PR	0	0	0	1	1	1	3 (20.0%)
DCR (CR+PR+SD)	0	0	2	3	2	1	8 (53.3%)

Abbreviations: CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease, DCR=disease control rate.

Source: Phase I Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Patients with Advanced Solid Tumors in China, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

The following waterfall plot shows the best overall response of the 15 evaluable subjects receiving envafolimab as measured by percentage of change of target lesions from baseline, according to the ASCO Presentation.



Abbreviations: PD=progressive disease, SD=stable disease, PR=partial response.

Source: Phase I Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Patients with Advanced Solid Tumors in China, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

Conclusion. According to the ASCO Presentation, envafolimab exhibited a tolerable safety profile and preliminary efficacy in patients with advanced malignancies in the Phase 1 dose escalation trial in China.

Phase 1 Dose Escalation Clinical Trial in the United States

An open-label Phase 1 dose escalation and dose exploration clinical trial of envafolimab was conducted in the United States. Safety and efficacy data from the dose escalation phase of the trial were presented at the 2018 Annual Congress of the European Society for Medical Oncology (ESMO) in October 2018. Based on the data presented at ESMO (the ESMO Presentation), 18 subjects were enrolled in the dose escalation phase of this trial as of July 5, 2018.

Trial purpose of the dose escalation phase. The primary objectives of the Phase 1 dose escalation clinical trial were to evaluate and characterize the tolerability and safety profile of single agent envafolimab in subjects with locally advanced or metastatic solid tumors. The secondary objectives were to characterize the PK profile, determine MTD and to evaluate anti-tumor activity.

Trial design of the dose escalation phase. This trial adopted a modified "3+3" design with a DLT evaluation period of 28 days. Subjects received envafolimab across eight cohorts at 0.01mg/kg, 0.03mg/kg, 0.1mg/kg, 0.3mg/kg, 1.0mg/kg, 2.5mg/kg, 5.0mg/kg and 10.0mg/kg QW subcutaneously. Starting from the 0.3mg/kg cohort, a traditional "3+3" design was followed. Safety and tolerability were assessed by monitoring TEAEs. Tumor assessments were performed based on RECIST version 1.1.

Safety of dose escalation phase. The median duration of exposure to envafolimab was 9 weeks with a range of 6 to 32 weeks. As of July 5, 2018, two of the subjects (11.1%) remained in the trial, 11 subjects had discontinued treatment due to disease progression, three subjects had discontinued treatment due to TEAEs, and two subjects had discontinued treatment due to the opinion of the investigator that no more clinical benefit could be obtained or for other reasons. All of the 18 enrolled subjects experienced TEAEs. Treatment-related TEAEs at grade 3 or above included increased aspartate aminotransferase (10.5%), increased alanine aminotransferase (10.5%) and lymphopenia (10.5%). No DLT was observed and the planned maximum dose of 10.0mg/kg was reached.

Efficacy of dose escalation phase. According to the ESMO Presentation, 17 out of 18 subjects were evaluable for the efficacy analysis. Two subjects had confirmed PR, including one NSCLC subject from the 0.3mg/kg QW cohort (response duration of 9 months) and one MSI-H prostate cancer subject from the 2.5mg/kg QW cohort. In addition, five subjects achieved SD. All 17 evaluable subjects completed at least one post-baseline tumor assessment according to the ESMO Presentation. One enrolled subject who had not reached the first post-baseline tumor assessment was excluded. The table below summarizes the best overall response in the efficacy analysis of this trial according to the ESMO Presentation.

	0.01 mg/kg weekly (N=1)	0.03 mg/kg weekly (N=1)	0.1 mg/kg weekly (N=1)	0.3 mg/kg weekly (N=3)	1.0 mg/kg weekly (N=3)	2.5 mg/kg weekly (N=3)	5.0 mg/kg weekly (N=3)	10.0 mg/kg weekly (N=3)	Total (N=18)
	n (%)	*n (%)*	*n (%)*	*n (%)*	*n (%)*	*n (%)*	*n (%)*	*n (%)*	*n (%)*
CR	0	0	0	0	0	0	0	0	0
PR	0	0	0	1 (33.3)	0	1 (33.3)	0	0	2 (11.1)
SD	0	1 (100)	0	1 (33.3)	1 (33.3)	0	1 (33.3)	1 (33.3)	5 (27.8)
PD	1 (100)	0	1 (100)	0	2 (66.7)	2 (66.7)	2 (66.7)	1 (33.3)	9 (50.0)
NE	0	0	0	0	0	0	0	1 (33.3)	1 (5.6)
CR+PR	0	0	0	1 (33.3)	0	1 (33.3)	0	0	2 (11.1)
DCR: (CR+PR+SD)	0	1 (100)	0	2 (66.7)	1 (33.3)	1 (33.3)	1 (33.3)	1 (33.3)	7 (38.9)

Abbreviations: CR=complete response, PR=partial response, SD=stable disease, PD=progressive disease, NE=not evaluable, DCR=disease control rate.

Source: *Phase I Study of KN035, A Novel Fusion Anti-PD-L1 Antibody Administered Subcutaneously in Patients with Advanced Solid Tumors in the USA, 2018 Annual Congress of the European Society for Medical Oncology (ESMO)*

PK profile of dose escalation phase. This trial showed that the exposure to envafolimab was dose-dependent and increased proportionally across all eight dose levels. Mean half-life of envafolimab was approximately 200 hours.

Conclusion. According to the ESMO Presentation, envafolimab exhibited a favorable safety profile in subjects with advanced solid tumors and preliminary efficacy results demonstrated encouraging anti-tumor activity. Based on the PK profile, patients in the trial were treated with envafolimab at 300mg every 4 weeks by subcutaneous injection.

Phase 1 Clinical Trial in Japan

An open-label Phase 1 dose escalation and dose exploration clinical trial of envafolimab was conducted in Japan. The safety, efficacy and PK data of this trial as of May 5, 2019 were presented at the ASCO Annual Meeting in June 2019. Based on the data presented in the ASCO Annual Meeting (the Japan Trial ASCO Presentation), 26 subjects were enrolled in this trial as of May 5, 2019.

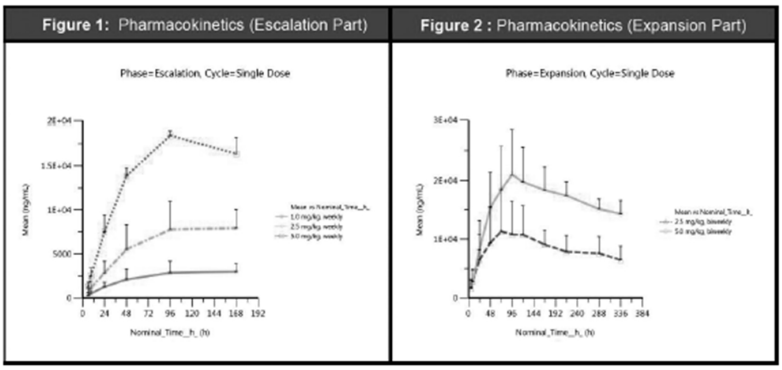
Trial purpose. The primary objectives of the Phase 1 clinical trial were to assess the safety and tolerability profile of single agent envafolimab in Japanese subjects with previously treated advanced solid tumors. The secondary objectives were to characterize the PK profile, determine MTD and evaluate the anti-tumor activity.

Trial design. This Phase 1 trial consisted of a multi-dose escalation phase followed by a dose exploration phase. Subjects received envafolimab across five cohorts at 1.0mg/kg, 2.5mg/kg and 5.0mg/kg QW subcutaneously, and 2.5mg/kg and 5.0mg/kg Q2W subcutaneously. The QW schedule adopted a traditional "3+3" design. For the Q2W schedule, six patients were planned for each cohort. Safety and tolerability were assessed by monitoring TEAEs under common terminology criteria for adverse events (CTCAE) version 4.0. Tumor assessments were performed based on RECIST version 1.1. Full PK sampling was performed after the first dose of cycle 1 (28 days) and sparse PK samples were collected at pre-dose and around Cmax during the subsequent cycles.

Safety. According to the Japan Trial ASCO Presentation, as of May 5, 2019, no MTD had been reached. As of the same date, three subjects had remained in the trial. 21 subjects had discontinued treatment due to disease progression and two subjects had discontinued treatment due to TEAEs. All of the enrolled subjects experienced TEAEs, 17 subjects (65.4%) experienced treatment-related TEAEs, and only one grade 3 treatment-related TEAE (cerebral infraction) was reported. There were no grade 4/5 treatment-related TEAEs. There were a total of four serious adverse events, two of which were treatment-related. No DLT was reported.

Efficacy. According to the Japan Trial ASCO Presentation, nine out of 26 patients were evaluable for the efficacy analysis as of May 5, 2019. Two subjects had confirmed PR and two subjects had unconfirmed PR. The other five evaluable subjects had achieved SD. 17 enrolled subjects who did not reach the first post-baseline tumor assessment were excluded.

PK profile. In the dose escalation phase, the exposure to envafolimab was dose-dependent and increased proportionally. Tmax varied from 96 to 168 hours after a single dose as shown in Figure 1 below. In the dose exploration phase, the exposure to envafolimab was dose-dependent and increased proportionally. Preliminary PK suggested a prolonged half-life that may support a less frequent dosing schedule than once every 2 weeks.



Source: *Phase I Study and Pharmacokinetic Study of KN035, the First Subcutaneous Administered, Novel Fusion Anti-PD-L1 Antibody in Japanese Patients with Advanced Solid Tumors, 2019 American Society of Clinical Oncology (ASCO) Annual Meeting*

Conclusion. Envafolimab exhibited a favorable safety profile in patients with advanced malignancies and preliminary efficacy results demonstrated promising anti-tumor activity in the Phase 1 clinical trial in Japan. Based on the PK profile, patients in the trial were treated with envafolimab at 300mg every 4 weeks by subcutaneous injection.

Pivotal Clinical Trial in China in MSI-H/dMMR tumors

A pivotal clinical trial of envafolimab dosed as a single agent for the treatment of MSI-H/dMMR tumors was initiated in August 2018. The trial was a non-randomized trial enrolling approximately 110 patients in China, including CRC patients who are required to have been previously treated with standard therapies, which must include fluoropyrimidine, oxaliplatin or irinotecan, and other solid tumor patients, who are required to have been previously treated with at least one line of systemic standard of care therapy. Patients received 150mg of envafolimab subcutaneously dosed weekly and ORR was the primary endpoint defined by RECIST version 1.1. In a presentation at the CSCO 2020 Virtual Scientific Program entitled, "Subcutaneous Injection of PD-L1 Antibody Envafolimab (KN035) in Advanced Tumors with Mismatch-Repair Deficiency," single agent envafolimab was shown to have a 32% confirmed ORR by central radiographic review in 41 patients with MSI-H/dMMR CRC who failed a fluoropyrimidine, oxaliplatin and irinotecan, and had at least two on-study tumor assessments. The 32% ORR is nearly identical to the 28% ORR reported for Opdivo and 33% ORR reported for Keytruda in separate trials of MSI-H/dMMR CRC patients who failed a fluoropyrimidine, oxaliplatin and irinotecan. DOR was greater than or equal to 12 months in 75% of patients and OS was greater than or equal to 12 months in 65% of patients. The ORR in the overall population (n=103) of MSI-H/dMMR cancer patients, including tumor types other than CRC, was 43%, DOR was greater than or equal to 12 months in 92% of patients and OS was greater than or equal to 12 months in 75% of patients. In November 2021, envafolimab received marketing authorization from the Chinese NMPA and was approved for adult patients with MSI-H/dMMR advanced solid tumors, including those patients with advanced colorectal cancer who have experienced disease progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as well as patients with other advanced solid tumors who have experienced disease progression following prior systemic treatment and have no satisfactory alternative treatment options.

Clinical Development in Sarcoma in the United States

The ENVASARC trial is enrolling a total of 160 patients at 600mg of envafolimab, with 80 patients enrolling at 600mg of envafolimab every three weeks in cohort C, and 80 patients enrolling at 600mg of envafolimab every three weeks in combination with Yervoy® at 1mg/kg every three weeks for four doses in cohort D, in the sarcoma subtypes of UPS and MFS. Nine of 80 responses by BICR in either cohort are needed to satisfy the primary objective of the trial which is to statistically exceed the known 4% ORR of Votrient® (pazopanib), the only FDA-approved treatment for patients with refractory UPS or MFS. Achieving the primary endpoint of ORR could be the basis for accelerated approval of envafolimab by the FDA as a single agent and/or in combination with Yervoy. The trial will provide at least 86% power to demonstrate the lower bound of the 95% confidence interval is greater than 5% in each cohort, which would be greater than the 4% ORR of Votrient reported in soft tissue sarcoma in its package insert. Votrient is the only approved treatment for refractory soft tissue sarcoma, which includes UPS and MFS.

In August and October 2022, we announced that the ENVASARC trial will proceed as planned after the IDMC reviewed three and twelve weeks of safety data, respectively, from more than 20 patients enrolled in the trial as of June 30, 2022. The safety data reviewed included data from more than 10 patients enrolled into cohort C of treatment with single agent envafolimab at 600mg every three weeks and more than 10 patients enrolled into cohort D of treatment with envafolimab at 600mg every three weeks in combination with Yervoy (ipilimumab).

In December 2022, we announced the IDMC recommended continued accrual as planned in both cohorts at the first planned interim efficacy analysis. The IDMC reviewed interim safety and efficacy data from 18 patients enrolled into each cohort who completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans). The double-digit ORR assessed by BICR in each cohort more than satisfied the prespecified futility rule that required at least one response among the initial 18 patients enrolled at 600mg into each cohort. Envafolimab monotherapy (cohort C) and in combination with Yervoy (cohort D) was well tolerated, with only a single related serious adverse event reported in 36 patients. A second interim efficacy analysis is planned following the 12-week efficacy scan in the 92nd dosed patient, to allow for determination of the preliminary ORR, which we expect in the third quarter of 2023. There must be at least three responses among the initial 46 patients enrolled at 600mg into each cohort to continue enrollment in that cohort per the futility rule of the trial.

In September 2022, we announced that the FDA had granted us fast track designation for the development of envafolimab for patients with locally advanced, unresectable or metastatic UPS and MFS who have progressed on one or two prior lines of chemotherapy. We are also eligible to apply for breakthrough therapy designation based on data from the ENVASARC clinical trial. We expect to complete enrollment by the end of 2023, have final response assessment data including duration of response in all patients from the ENVASARC trial in mid-2024, and, assuming positive data, to submit a BLA to the FDA seeking accelerated approval in 2024. At any time that we reach nine responses in each cohort and meet the endpoint, we expect to discuss the submission process with the FDA.

UPS has an incidence of 0.8 to 1.0 cases per 100,000 patients in the western world per orpha.net and accounts for 10-15% of new cases of soft tissue sarcoma in the United States, with prevalence rates estimated at approximately 1.5 to 2.0 times incidence, and MFS accounts for half as many cases as UPS in the United States. We estimate that marketing envafolimab in refractory UPS and MFS could generate peak annual sales of up to $200 million in the United States without considering a price premium to the reference PD-1 inhibitors Opdivo (nivolumab) or Keytruda (pembrolizumab) that are administered intravenously. We estimate that marketing envafolimab in rarer sarcoma subtypes where the activity of checkpoint inhibition has been demonstrated could generate annual sales of up to $100 million in the United States.

Other Ongoing Clinical Trials

A Phase 3 randomized clinical trial in BTC was initiated by 3D Medicines in April 2018. This trial is an open-label trial to assess the safety and efficacy of envafolimab plus standard of care gemcitabine-based chemotherapy compared to gemcitabine-based chemotherapy alone with OS as the primary endpoint. In the envafolimab arm, envafolimab will be dosed at 2.5mg/kg subcutaneously QW, along with gemcitabine and oxaliplatin at recommended doses. The trial is expected to enroll over 390 patients in China and data are expected in 2023.

A Phase 2 clinical trial of envafolimab in combination with folinic acid, fluorouracil and oxaliplatin chemotherapy (FOLFOX) in the first line treatment of advanced gastric cancer was fully enrolled (n=15) as of January 15, 2019. In an abstract at the ASCO 2020 Virtual Scientific Program entitled "Envafolimab plus chemotherapy in advanced gastric or gastroesophageal junction (G/GEJ) cancer" data were reported in 15 patients who were evaluable for response. The Eastern Cooperative Oncology Group (ECOG) performance status was 1 in 80% of subjects and the majority had gastric cancer (86.7%). At the time of data cutoff, the minimum follow-up was 6 months. The occurrence of TEAEs was 100% (all grades) and 73.3% (grades 3-4). The most frequent grade 3-4 TEAEs included neutrophil count decreased 46.7%, anemia 20.0%, and platelet disorder 20% (3/15). Confirmed ORR was 60% (unconfirmed ORR: 73.3%). Median DOR was not reached. Median PFS was 6.8 months.

Our Second Clinical Stage Product Candidate – YH001

YH001 is an investigational humanized CTLA-4 IgG1 monoclonal antibody. YH001 is being developed by Eucure for the treatment of various cancer indications. In October 2021, we entered into a collaborative development and commercialization agreement with Eucure and Biocytogen pursuant to which we obtained an exclusive license to develop and commercialize YH001 in North America for the treatment of multiple specified indications.

CTLA-4 is a protein expressed on all T-cells but which is expressed at the highest level on Tregs and contributes to the suppressor function of Tregs and acts as a checkpoint that prevents T-cell immune responses to cancer cells. A CTLA-4 inhibitor has been approved as a single agent in melanoma and approved in combination with other therapies in multiple indications including NSCLC, RCC and MSI-H colorectal cancer.

Clinical Development of YH001

As of December 31, 2021, YH001 had been dosed to more than 41 patients in China and Australia in two completed Phase 1 clinical trials. YH001 is also being studied in additional ongoing Phase 1 clinical trials in combination with investigational and approved immunotherapies China sponsored by Eucure.

Phase I Dose Escalation Clinical Trial in Australia

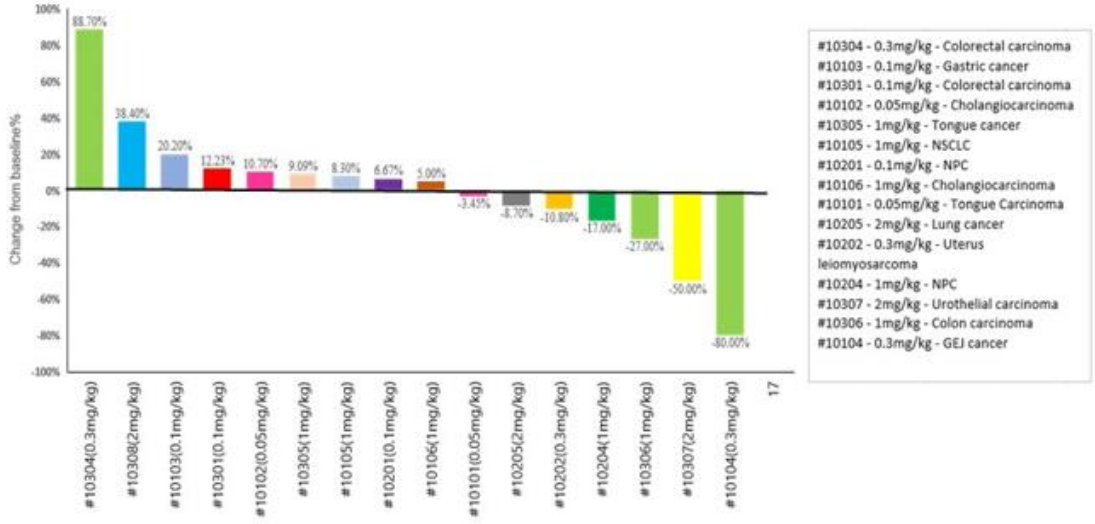
An open-label, single-arm Phase 1 dose escalation clinical trial of YH001 in combination with the PD-1 antibody, toripalimab, was completed in Australia. The safety and efficacy data from this trial were presented at the 2022 ASCO Annual Meeting in June 2022. Based on the data presented in the ASCO presentation, 24 subjects were enrolled in this trial as of December 31, 2021.

Study purpose. The primary objectives of the Phase 1 dose escalation clinical trial were to assess the safety and tolerability profile and MTD of YH001 in combination with the PD-1 inhibitor toripalimab in subjects with advanced solid tumors. The secondary objectives were to evaluate the PK profile and anti-tumor activity.

Study design. This trial adopted a modified "3+3" design. Subjects receive YH001 in six cohorts at 0.05mg/kg, 0.1mg/kg, 0.3mg/kg, 1.0mg/kg, 2.0mg/kg, 4.0mg/kg, and 6.0mg/kg by IV administration during a three week run-in period, after which subjects receive YH001 in combination with 240mg of the PD-1 antibody toripalimab every three weeks for four doses.

Safety. At the December 31, 2021 data cutoff, the maximum tolerated and recommended Phase 2 dose of YH001 when given with toripalimab was 4 mg/kg i.v. every three weeks for up to one year of dosing.

Efficacy. Among 23 patients that had tumor imaging assessments available at the December 31, 2021 data cut-off, four achieved PR by RECIST, including in one patient with urothelial cancer who had failed prior treatment with a PD-1 antibody, and nine had stable disease.



Conclusion. The authors concluded that YH001 was well tolerated up to 4 mg/kg when combined with toripalimab and demonstrated activity in patients with advanced solid tumors.

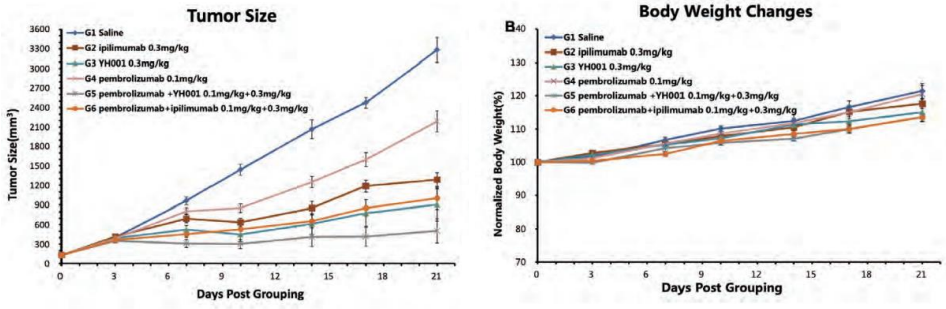
Phase I Dose Escalation Clinical Trial in China

An open-label, single-arm Phase 1 dose escalation clinical trial of YH001 was completed in China.

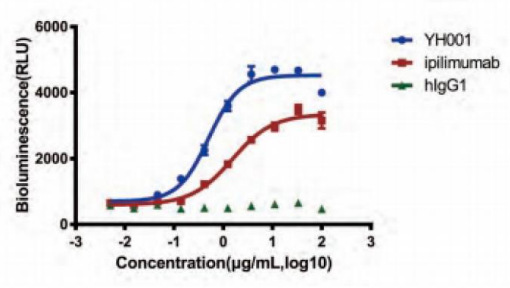
Preclinical Studies

In pre-clinical studies in mice, YH001 was compared with ipilimumab, an approved CTLA-4 inhibitor marketed by BMS, and YH001 showed the following potential advantages:

- *Superior in vivo activity compared to ipilimumab as a single agent and when combined with pembrolizumab, a PD-1 antibody marketed by Merck*. The following graphs illustrate the tumor size growth and body weight changes in mice.



- *More potent and active than ipilimumab*. YH001 was more potent and active than ipilimumab in blocking hCTLA-4 inhibition of CD80/86 activity. The following graph illustrates an *in vitro* reporter assay demonstrating the ability of YH001 or ipilimumab to induce T-cell proliferation by inhibiting the interaction of hCTLA-4 with CD80/86.



Clinical Development in North America

In August 2022, we announced that the FDA had approved the IND application for the initiation of a Phase 1/2 clinical trial of YH001 in combination with envafolimab and doxorubicin, an approved treatment for soft tissue sarcoma, for the treatment of sarcoma patients and in December 2022, we initiated dosing in the Phase 1/2 clinical trial. The Phase 1/2 trial will assess the safety and efficacy of the triplet combination of YH001, envafolimab and doxorubicin in the common sarcoma subtypes of leiomyosarcoma and dedifferentiated liposarcoma, and we expect Phase 1 data in the second half of 2023. In addition, the trial will assess the safety and efficacy of the doublet combination of YH001 and envafolimab in patients with the rare sarcoma subtypes of alveolar soft part sarcoma and chondrosarcoma. Additionally, we plan to initiate trials of YH001 as a single agent or in combination with immunotherapies in other tumor types.

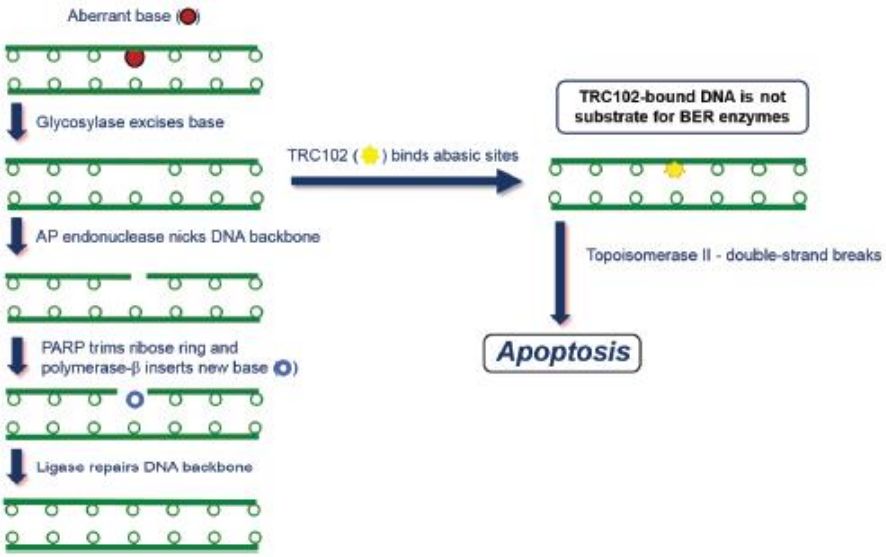
Our Third Clinical Stage Product Candidate – TRC102

Overview of Base Excision Repair and the Mechanism of Action of TRC102

Base-excision repair (BER) is a complex and fundamental cellular process used by cancer cells to repair the DNA damage caused by chemotherapeutics, especially the classes of chemotherapeutics known as alkylating agents, including Temodar, dacarbazine and bis-dichloroethyl-nitrosourea (BCNU), and anti-metabolite agents, including Fludara and Alimta. The process of BER removes DNA bases damaged by chemotherapy, resulting in the formation of gaps in the DNA strand called apurinic and apyrimidinic (AP) sites. The appropriate base is then inserted in this gap to restore the proper tumor DNA sequence. By this process, cancer cells can circumvent the anti-tumor effects of chemotherapy.

Inhibition of BER has been proposed as a way to improve the efficacy of chemotherapeutics; however, to our knowledge, no inhibitors of BER have been tested in clinical trials. We are developing TRC102 (methoxyamine hydrochloride) to reverse resistance to specific chemotherapeutics by inhibiting BER. TRC102 interrupts BER by rapidly and covalently binding within AP sites, converting the AP site to a substrate for the enzyme topoisomerase II, which cleaves TRC102-bound DNA, resulting in an accumulation of DNA strand breaks that trigger cellular apoptosis, or programmed cell death, as illustrated in the figure below:

TRC102 binding results in apoptosis



The induction of apoptosis by TRC102 is relatively selective for cancer cells, which typically overexpress topoisomerase II. In nonmalignant cells with low topoisomerase II expression, TRC102-bound DNA is excised and replaced by a separate DNA repair system.

In November 2020, we announced the publication of clinical data in the journal *Cancer Cell* that provides molecular insight into TRC102's mechanism of action and patient populations most likely to respond to treatment. The article, entitled, "Molecular Features of Cancers Exhibiting Exceptional Responses to Treatment," highlighted the clinical features and tumor biology of an exceptional responder patient treated with TRC102 at the NCI. The patient was diagnosed with metastatic and highly refractory CRC and received Temodar and TRC102. Following treatment, the patient was considered an exceptional responder through the achievement of a near complete response lasting 45 months at the most recent follow-up. Detailed molecular analyses of the patient's tumor showed silencing of DNA repair pathways that may have resulted in sensitivity to the inhibition of DNA BER pathway by TRC102. Specifically, MGMT expression was silenced by promoter methylation, and RAD50, a mediator of DNA double strand break repair, was silenced by genetic mutation and loss of heterozygosity. The publication authors hypothesized that the combination of Temodar and TRC102 was effective because all necessary DNA repair pathways were compromised genetically or through the activity of TRC102. MGMT expression was also assessed in biopsies from 11 colorectal patients who subsequently enrolled in an expansion cohort, one of whom demonstrated a PR. The tumor associated with the PR did not express MGMT, whereas each of the 10 tumors that did not respond to therapy expressed this enzyme robustly. MGMT deficiency is observed in about one third of glioblastoma patients, and a prior study of Temodar and TRC102 reported at the Society for Neuro-Oncology in 2018 demonstrated that two MGMT deficient glioblastoma patients had prolonged survival when treated with Temodar and TRC102 after progressing previously on Temodar and radiation therapy. Based on these data, we believe a trial in first line glioblastoma patients of Temodar, radiation therapy and TRC102 is warranted and are discussing further development with investigators at this time.

TRC102 Development in Oncology

TRC102 is being developed to reverse resistance to Temodar, an alkylating chemotherapeutic, as well as to Alimta and Fludara, two antimetabolite chemotherapeutics. We consider it advantageous to combine TRC102 with Alimta because Alimta is approved in one large market indication (lung cancer) and one orphan drug indication (mesothelioma). Temodar is an approved chemotherapeutic used as a standard of care agent to treat glioblastoma, and Fludara is an approved chemotherapeutic used as a standard of care agent to treat lymphoma and leukemia. In initial clinical trials of more than 100 patients, TRC102 has shown good tolerability and promising anti-tumor activity in combination with alkylating and antimetabolite chemotherapy.

We filed an IND application for TRC102 in March 2008, Case Western filed an IND application for TRC102 in March 2006, and NCI filed an IND for TRC102 in March 2013, all for the treatment of patients with advanced solid tumors. The IND application filed by NCI cross references our IND application.

The following table summarizes certain key information regarding ongoing clinical trials of TRC102 in cancer patients:

Phase	Indication	Sponsor	Companion Treatment	Design (Number of Patients)
1	Solid Tumors and Lymphomas	NCI	Temodar	Dose escalation (65)
2	Non-Squamous Non-Small Cell Lung Cancer	NCI	Chemoradiation + Durvalumab	Randomized Phase 2 (78 patients)

In May 2020, positive data from multiple TRC102 clinical trials were presented at the 2020 ASCO Virtual Scientific Program. Dr. Koczywas of City of Hope Medical Center presented Phase 1 data for TRC102 in combination with cisplatin and Alimta in patients with advanced solid tumors, and Phase 2 data for TRC102 in combination with Alimta in patients with mesothelioma refractory to Alimta and platinum therapy. Notably two of 14 mesothelioma patients who progressed previously on Alimta had objective responses following treatment with Alimta and TRC102. Multiple responses were also noted in the Phase 1 trial of Alimta, cisplatin and TRC102, with particular activity noted in parotid salivary gland tumors. Dr. Biswas of Case Comprehensive Cancer Center presented Phase 1 data of TRC102 in combination with chemoradiation for locally advanced non-squamous non-small cell lung cancer. All 15 patients demonstrated an objective response, including three patients with a complete response to treatment. The 100% ORR compares favorably to historical data of the same combination of chemoradiation without TRC102 in locally advanced lung cancer. For example, the PROCLAIM clinical trial reported an ORR of 36% and the PACIFIC clinical trial reported an ORR of 51% in locally advanced non-squamous non-small cell lung cancer patients treated with Alimta, cisplatin and thoracic radiation. In addition, based on data presented at the ASCO 2020 virtual meeting that the combination of chemoradiation and TRC102 produced objective responses in all 15 evaluable patients with advanced localized lung cancer treated in a Phase 1 trial, in January 2022, the NCI initiated a randomized trial of chemoradiation with or without TRC102, followed by consolidative durvalumab treatment. The primary objective is to improve the 56% PFS rate with current standard of care to 75% with current standard of care plus TRC102. The trial began enrollment in June 2022 and is expected to be complete in 2025.

Phase 1 ascending dose clinical trials evaluating the safety, tolerability, PK, PD and anti-tumor activity of TRC102 were completed with Alimta in patients with advanced solid tumors, with Fludara in patients with hematologic malignancy and with Temodar in patients with solid tumors. In each trial, TRC102 was tolerable with the companion chemotherapeutic, and demonstrated signs of activity. One patient treated with TRC102 and Alimta had a PR as assessed by RECIST 1.1 and remained in our clinical trial without cancer progression for 14 months. In addition, 14 patients had SD including patients with squamous cell lung cancer (three patients), epithelial ovarian cancer (three patients), CRC (two patients), non-squamous non-small cell lung cancer (one patient), pancreatic cancer (one patient), prostate cancer (one patient), endometrial cancer (one patient), head and neck cancer (one patient) and breast cancer (one patient). These data were published in *Investigational New Drugs* in 2012. Case Western reported data from a trial of intravenous TRC102 given in combination with Fludara in a Phase 1 clinical trial that were published in *Oncotarget* in 2017. Anti-tumor activity, including PR, was noted in patients with lymphoma and chronic lymphocytic leukemia, including patients treated previously with Fludara. TRC102 combined with Fludara was safe and well tolerated. Hematologic toxicity was comparable to single agent Fludara and activity appeared to correlate with increased levels of DNA damage. Case Western reported data from a trial of TRC102 given intravenously in combination with Temodar in a Phase 1 clinical trial at the ASCO annual meeting in June 2015. Anti-tumor activity was noted in patients with ovarian cancer and neuroendocrine tumors.

The NCI reported data from the Phase 1 trial of TRC102 in combination with Temodar in relapsed solid tumors and lymphoma patients at ASCO in 2017. There were no pharmacologic interactions between the two drugs and TRC102 target concentrations were achieved. Based on PRs in patients with ovarian cancer, non-small cell lung cancer, and KRAS-positive CRC, the NCI decided to enroll expansion cohorts in each of these tumor types at the recommended Phase 2 oral dose of TRC102. The authors concluded that the combination of Temodar and TRC102 is active, and DNA damage response markers (Rad51, ϒ-H2AX and/or pNbs1) were induced in four of five paired colonic biopsies, indicating DNA damage following treatment. Updated data in the cohort of patients with CRC reported by the NCI at AACR in 2019 indicated a low response rate in patients with CRC treated with Temodar and TRC102.

The combination of TRC102 and Temodar was assessed in a Phase 2 trial of patients with recurrent glioblastoma that was reported at the Society for Neuro-Oncology annual meeting in November 2018. The combination of Temodar and TRC102 was tolerable, but did not meet the primary efficacy endpoint of demonstrating objective responses by Response Assessment in Neuro-Oncology criteria in the 19 enrolled patients, most of whom were treated at Cleveland Clinic. Two patients (10.5%) demonstrated evidence of clinical benefit and met the secondary endpoint of PFS beyond six months. Both patients who demonstrated PFS for more than 11 months were alive over 30 months following treatment initiation with TRC102 and Temodar for recurrent glioblastoma. PFS of greater than 11 months was associated with N-methylpurine DNA glycosylase expression, a biomarker that initiates the BER pathway of resistance that is inhibited by TRC102. Efforts to identify whether DNA glycosylase expression or other biomarkers can be used as a predictive biomarker of TRC102 activity are expected to continue in ongoing TRC102.

Our Fourth Clinical Stage Product Candidate – TJ004309

TJ004309, is a novel, humanized antibody against CD73, an ecto-enzyme expressed on stromal cells and tumors that converts extracellular AMP to the immunosuppressive metabolite adenosine. In December 2018, we submitted an IND application to the FDA for the initiation of a Phase 1 clinical trial in patients with advanced solid tumors, which was cleared by the FDA in January 2019. In July 2019, we began enrollment in a Phase 1 clinical trial to assess safety and preliminary efficacy of TJ004309 as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® in patients with advanced solid tumors, and in June 2021 we presented data from the ongoing Phase 1 trial at the ASCO 2021 virtual meeting. In a poster presentation titled "The safety, pharmacokinetics (PK), pharmacodynamics (PD) and clinical efficacy of uliledlimab (TJ004309), a differentiated CD73 antibody, in combination with atezolizumab in patients with advanced cancer," uliledlimab was found to be well-tolerated up to 20mg/kg every three weeks and 15mg/kg once weekly as a monotherapy and in combination therapy with atezolizumab 1200mg every three weeks and no dose limiting toxicity (DLT) was observed and the maximum tolerated dose (MTD) was not reached. There was one complete response in a PD-(L)1 naïve patient, two partial responses (PRs) with one PR in a PD-(L)1 naïve patient and one PR in a PD-(L)1 refractory patient, and three cases of stable disease (SD) following treatment with uliledlimab and atezolizumab.

Collaboration and License Agreements

Collaboration Agreement with 3D Medicines and Alphamab

In December 2019, we, 3D Medicines, and Alphamab entered into the Envafolimab Collaboration Agreement for the development of envafolimab, an investigational PD-L1 sdAb, or nanobody, administered by rapid subcutaneous injection, for the treatment of sarcoma in North America.

Pursuant to the Envafolimab Collaboration Agreement, we were granted an exclusive license to develop and commercialize envafolimab for the treatment of sarcoma in North America. We are responsible for conducting and will bear the costs of any Phase 1, Phase 2, and Phase 3 or post-approval clinical trial in North America for envafolimab in the indications of refractory and first line treatment of sarcoma. 3D Medicines and Alphamab are responsible for conducting and will bear the costs of IND-enabling studies (other than those specific to the sarcoma indication) and the preparation of the chemistry, manufacturing and controls (CMC) activities sections of an IND application for envafolimab. 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third-party manufacturer to manufacture and supply, envafolimab to us at pre-negotiated prices that vary based on clinical or commercial use. 3D Medicines and Alphamab retained the right to develop envafolimab in all territories outside of North America as well as within North America for all indications other than sarcoma.

We will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue, unless (a) envafolimab is first approved in North America for an indication other than sarcoma and launched in North America, or (b) envafolimab is first approved in North America for sarcoma and subsequently approved in North America for an additional non-orphan indication and sold commercially by 3D Medicines and/or Alphamab, or licensee, in which case 3D Medicines and Alphamab will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue. If 3D Medicines and Alphamab become responsible for commercialization under the Envafolimab Collaboration Agreement, we have the option to co-market envafolimab for sarcoma in North America. In the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace us as the party responsible for commercialization, and we elect and 3D Medicines and Alphamab agree for us to not co-market envafolimab for sarcoma in North America, then 3D Medicines and Alphamab will be required to compensate us for our costs associated with preparing for and conducting commercial activities.

If we have the responsibility for commercialization under the Envafolimab Collaboration Agreement, we will owe 3D Medicines and Alphamab tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits. If 3D Medicines and Alphamab have responsibility for commercialization under the Envafolimab Collaboration Agreement, we will be entitled to (a) tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if we have elected to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if we have chosen to co-market envafolimab in sarcoma. Payment obligations under the Envafolimab Collaboration Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

3D Medicines and Alphamab retain the right to reacquire the rights to envafolimab for sarcoma in North America in connection with an arm's length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications, provided that the sale may not occur prior to completion of a pivotal trial of envafolimab in sarcoma without our written consent and the parties must negotiate in good faith and agree to fair compensation be paid to us for the value of and opportunity represented by the reacquired rights.

Each party agreed that during the term of the Envafolimab Collaboration Agreement, it would not develop or license from any third party a monospecific inhibitor to PD-L1 or PD-1 in sarcoma.

The term of the Envafolimab Collaboration Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in North America or the expiration of all payment obligations. The Envafolimab Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab. In the event we elect, or a joint steering committee (JSC) determines, to cease further development or commercialization of envafolimab, or if we fail to use commercially reasonable efforts to develop (including progress in clinical trials) and commercialize envafolimab and do not cure such failure within a specified time period, then our rights and obligations under the Envafolimab Collaboration Agreement will revert to 3D Medicines and Alphamab.

Collaboration Agreement with Eucure and Biocytogen

In October 2021, we, Eucure and Biocytogen entered into a collaborative development and commercialization agreement (the YH001 Collaboration Agreement) for the development of YH001, a monospecific investigational CTLA-4 antibody. Pursuant to the YH001 Collaboration Agreement, we were granted an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment, through administration of YH001 by intravenous or subcutaneous means, of multiple human indications, including sarcoma, microsatellite stable colorectal cancer, RCC, and K-ras positive non-small cell lung cancer (collectively, the Initial Indications) or one or more of bladder cancer, endometrial cancer, and melanoma as substitute indications, which may be substituted for Initial Indications at our discretion (each upon such substitution, a Substitute Indication). We are responsible for, and will bear the costs of, preparing and filing all regulatory submissions and conducting any Phase 1, Phase 2, Phase 3, or post-approval clinical trials in North America for YH001 in the Initial Indications and potentially the Substitute Indications, while Eucure is responsible for conducting, and will bear the costs of, the preparation of CMC activities for YH001. Eucure has agreed to manufacture and supply, or to arrange for a third-party manufacturer to manufacture and supply, YH001 to us for clinical trials pursuant to the terms of a clinical supply and quality agreement that will be separately negotiated and agreed in good faith between the parties.

Eucure may pursue clinical trials for YH001 in North America outside of the Initial Indications or Substitute Indications, and also within the Initial Indications or Substitute Indications as part of a combination therapy of YH001 and an additional Eucure product. During a specified period, we have the option, subject to Eucure's prior written approval, to expand the license to include the development and commercialization of YH001 for the treatment, through administration by intravenous or subcutaneous means, of all human and veterinary therapeutic indications in North America for a payment to Eucure in the low single digit millions (the Company Option).

Pursuant to the YH001 Collaboration Agreement, we granted Eucure an irrevocable, perpetual, royalty-free, exclusive license, with the right to grant sublicenses to develop, register, sell, offer to sell, have sold, market and distribute YH001 in all territories outside of North America as well as within North America for all indications other than the Initial Indications and the Substitute Indications.

We will be responsible for commercializing YH001 in North America, including booking of sales revenue in the Initial and Substitute Indications. We will owe Eucure escalating double digit royalties on net sales of YH001 in North America ranging from the mid-twenties to mid-double digits; provided that until the end of the first full calendar year following the first commercial sale of YH001, royalties will range from the lower double digits to the mid-double digits. If sales of YH001 exceed a pre-determined sales threshold in the first full year of sales following first commercial sale, we will owe a milestone to Eucure in the high single digit millions. Payment obligations under the YH001 Collaboration Agreement continue on a country-by-country basis until the latest of (i) expiration of the last to expire licensed patent covering YH001, (ii) expiration of marketing or regulatory exclusivity covering YH001 and (iii) 10 years from the first commercial sale of YH001 in such country in North America. Eucure has agreed to manufacture and supply, or to arrange for a third-party manufacturer to manufacture and supply, YH001 to us at cost plus a low double-digit markup for commercial sales pursuant to the terms of a commercial supply and quality agreement that will be separately negotiated and agreed in good faith between the parties within 180 days prior to the anticipated first commercial sale in North America.

Pursuant to the YH001 Collaboration Agreement, each party agreed that during the term of the YH001 Collaboration Agreement, it would not develop, manufacture, commercialize or license from any third party a monospecific inhibitor to CTLA-4.

The term of the YH001 Collaboration Agreement continues until the earlier of (i) the date that the parties cease further development and commercialization of YH001 in North America or (ii) on a country-by-county basis, the expiration of the royalty obligations in such country. The YH001 Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to YH001. In the event of a termination of the YH001 Collaboration Agreement, other than by us as a result of Eucure's material uncured breach or bankruptcy, (i) our license shall terminate and (ii) we would be obligated to grant Eucure an irrevocable, perpetual, royalty-free, non-exclusive license with the right to grant sublicenses under its rights in all development data and intellectual property to develop, register, sell, offer to sell, have sold, market and distribute YH001 in North America. In the event of a termination of the YH001 Collaboration Agreement by us as a result of Eucure's material uncured breach or bankruptcy, the license shall continue in the Initial Indications in North America, provided that (i) such license shall remain exclusive during the royalty term and non-exclusive thereafter; (ii) we shall have the right to have YH001 manufactured for its development and commercialization requirements in the Initial Indications in North America; and (iii) the license shall terminate in the event of an uncured material breach by us of any provision (including payment obligations) that survives termination of the YH001 Collaboration Agreement. In the event the YH001 Collaboration Agreement terminates for safety reasons related to YH001, by mutual agreement of the parties or by Eucure in the event of an uncured material breach or bankruptcy by us, then our rights and obligations under the YH001 Collaboration Agreement will revert to Eucure. In the event Eucure does not approve the Company Option, we may terminate the YH001 Collaboration Agreement for convenience with a 30-day notice to Eucure, provided that such termination is given within 12 months of the effective date of the YH001 Collaboration Agreement (the Company Option Termination). In the event of a Company Option Termination, Eucure would be obligated to reimburse us for all costs and expenses that we incurred in performing the development activities.

Collaboration Agreements with I-Mab Biopharma

In November 2018, we entered into two separate strategic collaboration and clinical trial agreements with I-Mab for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 as well as up to five proprietary bispecific antibodies currently under development by I-Mab.

In the TJ004309 Agreement, we are collaborating with I-Mab on developing TJ004309, and will bear the costs of filing an IND application and for Phase 1 clinical trials, share costs equally for Phase 2 clinical trials, and we will bear 40% and I-Mab 60% of the costs for pivotal clinical trials. I-Mab will also be responsible for the cost of certain non-clinical activities and the supply of TJ004309 and any reference drugs used in the development activities. We also agreed with I-Mab for a specified period of time to not develop or license to or from a third party any monoclonal antibody targeting CD73 or any other biologic for certain indications that a JSC, as set up under the TJ004309 Agreement, selects for TJ004309 development.

In the event that I-Mab licenses rights to TJ004309 to a third party, we would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to territories outside of Greater China. In the event that I-Mab commercializes TJ004309, we would be entitled to receive a royalty on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the EU and Japan in the mid-single digits. The portions of certain third party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which we would be entitled escalate based on the phase of development and relevant clinical trial obligations we complete under the TJ004309 Agreement, ranging from a high-single digit to a mid-teen percentage of non-royalty consideration as well as a double digit percentage of royalty consideration. In March 2020, I-Mab issued a press release announcing a strategic partnership with KG Bio, whereby KG Bio received what the press release described as a right of first negotiation outside North America for TJ004309 for up to $340 million in potential payments to I-Mab. On April 8, 2020, we issued a notice of dispute regarding possible breach of the TJ004309 Agreement, which resulted in a binding arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal. The latest developments in the dispute with I-Mab are discussed in more detail below following the discussion of the Bispecific Agreement.

The TJ004309 Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to TJ004309. I-Mab may also terminate the TJ004309 Agreement if we cause certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJ004309 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical trial, in which case we would be entitled to a minimum termination fee of $9.0 million, or following the completion of the first Phase 2 clinical trial, in which case we would be entitled to a pre-specified termination fee of $15.0 million and either a percentage of non-royalty consideration I-Mab may receive as part of a license to a third party or an additional payment if TJ004309 is approved for marketing outside Greater China before a third party license is executed, in addition to a double digit percentage of royalty consideration. In 2021, I-Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is "Complete," as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I-Mab's termination. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking an order of specific performance requiring us to comply with I-Mab's effort to terminate the agreement. We disagreed with I-Mab's position and in May 2021, the Delaware Court of Chancery stayed the lawsuit filed by I-Mab and subsequently this matter was remanded and included in the proceeding before the Tribunal.

Pursuant to the Bispecific Agreement, we and I-Mab may mutually select through a JSC up to five of I-Mab's BsAb product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, we will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical trials, and we will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical trials, in each case within North America. Subject to I-Mab's right to co-promote an approved product candidate, we will be responsible for commercializing any approved product candidates in North America, and we will share profits and losses equally with I-Mab in North America. We would also be entitled to receive tiered low single digit royalties on net sales of product candidates in the EU and Japan.

At any time prior to completing the first pivotal clinical trial for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical trial costs for a product candidate or the JSC decides to cease development over our objections after initiating Phase 3 clinical trials, we will have an option to obtain an exclusive license to such product candidate in all territories except Greater China and Korea and any other territories in which I-Mab previously licensed rights to a third party subject to our right of first refusal for any licenses I-Mab may grant to third-parties.

If we exercise our licensing option, we would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, we would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time we obtained the exclusive license as follows: (i) if before IND-enabling studies and the preparation of the CMC activities of the collaborative product, we would owe I-Mab a one-time upfront payment of $10.0 million, development and regulatory based milestone payments totaling up to $90.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the mid-single digits on annual net sales; (ii) if after IND submission but before completion of a Phase 1a clinical trial of the collaborative product, we would owe I-Mab a one-time upfront payment of $25.0 million, development and regulatory based milestone payments totaling up to $125.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the high single digits on annual net sales; (iii) if after completion of a Phase 1a clinical trial but before completion of a Phase 2 proof of concept clinical trial for the collaborative product, we would owe I-Mab a one-time upfront payment of $50.0 million, development and regulatory based milestone payments totaling up to $250.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the low double digits on annual net sales; and (iv) if after completion of a Phase 2 proof of concept clinical trial and before completion of a pivotal trial for the collaborative product, we would owe I-Mab a one-time upfront payment of $80.0 million, development and regulatory based milestone payments totaling up to $420.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the high-teens on annual net sales.

Each party agreed that for a specified period of time, it would not develop or license to or from any third party any bispecific monoclonal antibody targeting the same two biological targets as those of any selected product candidates under the Bispecific Agreement.

If development of any selected product candidates is terminated by a decision of the JSC, all rights to the product candidate will revert to I-Mab, subject to our rights to obtain an exclusive license in certain circumstances. If development is terminated after submission of an IND and prior to initiating Phase 3 clinical studies or after initiating Phase 3 clinical studies and with our concurrence, we would be entitled to tiered low single digit royalties on net sales of the product candidate in North America, the EU and Japan.

The Bispecific Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or with respect to any selected product candidate, for safety reasons related to that product candidate.

In March 2020, we learned that I-Mab had entered into two license and collaboration agreements with ABL Bio in July 2018. Under ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I-Mab and ABL agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal after we invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations concerning the TJ004309 Agreement and Bispecific Agreement. We filed counterclaims in the arbitration seeking to recover over $200 million in damages from I-Mab based on I-Mab's breaches of the two strategic collaboration and clinical trial agreements. The Tribunal held a hearing on the merits in February 2022, and final post-hearing briefs were submitted by us and I-Mab in May 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties submitted their respective cost submissions for attorney fees reimbursement in January 2023. The Tribunal did not indicate when it expects to render its final decision; however, it did note that it was far along in its deliberations and preparation of a final award. Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal's discretion. As of the date of this Annual Report, the TJ004309 Agreement and Bispecific Agreement disputes remain under consideration by the Tribunal, and we expect the Tribunal to render its final decision in the first quarter of 2023. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. The dispute with I-Mab has caused, and could continue to cause, us to incur significant costs.

License Agreement with Case Western

In August 2006, we entered into a license agreement with Case Western, under which we obtained an exclusive, worldwide license to certain patents, know-how and other intellectual property controlled by Case Western related to methoxyamine, which we refer to as the TRC102 Technology. Under the agreement, as amended, we have the right to use, manufacture and commercialize products utilizing the TRC102 Technology for all mammalian therapeutic uses, and to sublicense these rights.

Under the agreement, we are generally obligated to use our best efforts to commercialize the TRC102 Technology as soon as possible. We are also required to meet specified diligence milestones, and if we fail to do so and do not cure such failure, Case Western may convert our license into a non-exclusive license or terminate the agreement.

In consideration of the rights granted to us under the agreement, we paid a one-time upfront fee to Case Western. In addition, we may be required to pay up to an aggregate of approximately $9.8 million in milestone payments, of which $0.7 million relates to the initiation of certain development activities and approximately $9.1 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals. If products utilizing the TRC102 Technology are successfully commercialized, we will be required to pay Case Western a single-digit royalty on net sales, subject to adjustments in certain circumstances. Beginning on the earlier of a specified number of years from the effective date of the agreement and the anniversary of the effective date following the occurrence of a specified event, we will be required to make a minimum annual royalty payment of $75,000, which will be credited against our royalty obligations. In the event we sublicense any of our rights under the agreement relating to the TRC102 Technology, we will be obligated to pay Case Western a portion of certain fees we may receive under the sublicense. Our royalty obligations will continue through the later of (i) the expiration of any orphan drug marketing exclusivity for a product utilizing the TRC102 Technology, (ii) August 2026, or (iii) on a country-by-country basis upon the expiration of the last valid claim under the TRC102 Technology or any patent we receive that is a derivative of the TRC102 Technology.

We may unilaterally terminate this agreement in its entirety, for any reason or for no reason, upon at least 30 days' notice to Case Western. If we do so, we will be required to pay Case Western a termination fee. If we fail to pay any amount required under the agreement and do not cure the default within 90 days of receiving notice, Case Western will have the right to convert our exclusive license to a non-exclusive license or to terminate the agreement entirely. Either party may terminate the agreement in the event of the other party's material breach of the agreement that remains uncured 60 days after receiving notice of the breach.

Cooperative Research and Development Agreements with NCI

We are a party to a Cooperative Research and Development Agreement (CRADA) with the U.S. Department of Health and Human Services, as represented by NCI, for the development of TRC102 for the treatment of cancer. We entered into the CRADA governing the development of TRC102 (TRC102 CRADA) in August 2012 with NCI's Center for Cancer Research.

Under the CRADA, as amended, NCI conducts clinical trials and non-clinical studies of TRC102. Pursuant the TRC102 CRADA, we are required to pay NCI $20,000 per year per Phase 1 clinical trial and $25,000 per year per Phase 2 clinical trial, as well as expenses incurred by NCI in connection with carrying out its responsibilities under the TRC102 CRADA, up to an aggregate maximum per year of $200,000. We may also provide funding to support assays and other studies, and if NCI supplies TRC102 for additional mutually approved clinical trials beyond the planned trials, we will reimburse NCI for costs associated with manufacturing TRC102. In addition, we made a one-time payment of $20,000 for the initial IND filing and may be required to make additional one-time payments of $10,000 each for additional IND filings. Funding for clinical trials beyond those contemplated by the TRC102 CRADA will be determined in an amendment to the applicable CRADA.

Under the CRADA, each party individually owns all inventions, data and materials produced solely by its employees in the course of performing research activities pursuant to the CRADA. The parties jointly own any inventions and materials that are jointly produced by employees of both parties. Subject to certain conditions, we have the option under the CRADA to negotiate commercialization licenses from the government to intellectual property conceived or first reduced to practice in performance of the CRADA research plan that was developed solely by NCI employees or jointly by us and NCI employees.

The TRC102 CRADA had an original five-year term and was subsequently amended to extend the term to August 7, 2023. The CRADA may be terminated at any time by mutual written consent, and we or NCI may unilaterally terminate the CRADA for any reason or no reason by providing written notice at least 60 days before the desired termination date.

Manufacturing

We do not own or operate, nor do we expect to own or operate, facilities for product manufacturing, storage, distribution or testing. We contract with third parties or our collaboration partners for the manufacture of our product candidates and we intend to continue to do so in the future.

Envafolimab is manufactured by AlphaMab in China and fill finish is performed by a contract manufacturer in the United States. Pursuant to the Envafolimab Collaboration Agreement, 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to us at pre-negotiated prices that vary based on clinical or commercial use.

YH001 is manufactured by an experienced contract manufacturer in China. Pursuant to the YH001 Collaboration Agreement, Eucure and Biocytogen have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, YH001 to us at pre-negotiated prices that vary based on clinical or commercial use pursuant to the terms of a clinical supply and quality agreement to be separately negotiated.

TRC102 drug substance is manufactured through a standard chemical synthesis and may be obtained from multiple manufacturers.

TJ004309 is supplied to us from a contract manufacturer contracted by I-Mab as I-Mab is responsible for the supply of TJ004309 and all related drug supply activities under the terms of the TJ004309 Agreement.

Competition

The development and commercialization of new drugs is highly competitive, and we and our collaborators face competition with respect to each of our product candidates in their target indications. Many of the entities developing and marketing potentially competing products have significantly greater financial, technical and human resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

If our product candidates are approved, they will compete with currently marketed drugs and therapies used for treatment of the following indications, and potentially with drug candidates currently in development for the same indications.

The key competitive factors affecting the success of any approved product will include its efficacy, safety profile, price, method of administration and level of promotional activity.

Oncology Therapies

There is no PD-1 or PD-L1 therapy approved by the FDA for the treatment of sarcoma. Keytruda (marketed by Merck) has a compendia listing for the treatment of UPS, and is used off-label for the treatment of patients with UPS. If envafolimab is approved, it may nevertheless compete with currently marketed PD-1 and PD-L1 inhibitors, including Opdivo (marketed by BMS), Keytruda (marketed by Merck), Imfinzi (marketed by AstraZeneca), and Tecentriq (marketed by Roche) which are approved by the FDA in multiple indications other than soft tissue sarcoma. The global PD-1 and PD-L1 inhibitors market had an approximate value of over $30 billion in 2022.

There is no CTLA-4 therapy approved by the FDA for the treatment of soft tissue sarcoma. If YH001 is approved, it may nevertheless compete with the currently marketed CTLA-4 inhibitor ipilimumab (Yervoy, marketed by BMS), which is approved by the FDA in multiple indications other than soft tissue sarcoma. Other antibodies to CTLA-4 are being studied in clinical trials of cancer patients.

We are developing TRC102 to be used in combination with alkylating chemotherapeutics (including Temodar) and antimetabolite chemotherapeutics (including Alimta and Fludara) for the treatment of cancer. If TRC102 is approved, it could compete with other inhibitors of DNA repair. Tesaro, Inc. (now GSK), Clovis Oncology and Astra Zeneca each market inhibitors of DNA repair that work by a mechanism of action that is distinct from that of TRC102. In addition to the therapies mentioned above, there are many generic chemotherapeutics and other regimens commonly used to treat various types of cancer, including soft tissue sarcoma and glioblastoma.

We are developing TJ004309 for the treatment of solid tumors. If TJ004309 is approved, it could compete with other anti-CD73 immunotherapies including CD73 antibodies as well as adenosine receptor inhibitors already in clinical development sponsored by BMS, AstraZeneca, Arcus Biosciences and Corvus Pharmaceuticals.

Commercialization

We hold North America commercialization rights in the field of sarcoma for envafolimab (subject to certain rights held by 3D Medicines and Alphamab), North America commercialization rights of multiple human indications, including the Initial Indications or one or more of the Substitute Indications, which may be substituted for Initial Indications at our discretion, for YH001, and worldwide commercialization rights for TRC102. If any of our product candidates are approved in oncology indications, our plan is to build an oncology-focused specialty sales force in the United States to support their commercialization and seek a partner(s) to support commercialization outside the United States to the extent we have commercial rights in other territories. We believe that a specialty sales force will be sufficient to target key prescribing physicians in oncology. We currently do not have any sales or marketing capabilities or experience as a company. We plan to establish the required capabilities within an appropriate time frame ahead of any product approval and commercialization to support a product launch.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our protein therapeutics, novel biological discoveries, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we expect to benefit from a variety of statutory frameworks in the United States, Europe, Japan and other countries that relate to the regulation of biosimilar molecules and orphan drug status. These statutory frameworks provide periods of non-patent-based exclusivity for qualifying molecules. See “Government Regulation.”

Our patenting strategy is focused on our protein and small molecule therapeutics. We seek composition of matter and method of treatment patents for each such protein or small molecule in key therapeutic areas. We also seek patent protection with respect to companion diagnostic methods and compositions and treatments for targeted patient populations. We have sought patent protection alone or jointly with our collaborators, as dictated by our collaboration agreements.

Individual patents extend for varying periods of time depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued from applications filed in the United States are effective for twenty years from the earliest non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period; however, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also twenty years from the earliest international filing date. Our issued patents and pending applications with respect to our protein therapeutic candidates (excluding licensed rights) will expire on dates ranging from 2027 to 2030, exclusive of possible patent term extensions. However, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of extensions of patent term, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

National and international patent laws concerning protein therapeutics remain highly unsettled. No consistent policy regarding the patent-eligibility or the breadth of claims allowed in such patents has emerged to date in the United States, Europe or other countries. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries can diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that may be granted in our patents or in third-party patents. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our drugs and technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own or may receive in the future, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. The patent positions for our most advanced programs are summarized below:

Envafolimab Patent Coverage

Specific to the development of envafolimab for the treatment of sarcoma in North America, we hold an exclusive license from 3D Medicines and Alphamab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering envafolimab. We also hold a non-exclusive license for the conduct of clinical trials in the EU in support of the development of envafolimab for the treatment of sarcoma in North America. 3D Medicines and Alphamab retain ownership of any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering any pharmaceutical composition or preparation comprising envafolimab.

YH001 Patent Coverage

Eucure has an issued patent on the composition of matter and a pending application on the methods of use of YH001 in the United States. The terms of the patent would expire in 2037, exclusive of any patent term extension. We hold an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment, through administration of YH001 by intravenous or subcutaneous means, of multiple human indications, including the Initial Indications or one or more of the Substitute Indications, which may be substituted for Initial Indications at our discretion.

TRC102 Patent Coverage

We hold issued patents directed to combination of TRC102 and pemetrexed in the United States, Australia, Canada, Europe, Japan, Mexico, Norway, Russia, Singapore, South Africa, South Korea, Ukraine, and the United Kingdom. We also have pending applications in other jurisdictions, including Brazil, China, Hong Kong, and India. The expected expiration date for these patents is 2027, exclusive of possible patent term extensions.

We hold an issued patent on further combinations of TRC102 in Europe. The expected expiration date for these patents is 2031, exclusive of possible patent term extensions.

TJ004309 Patent Coverage

Specific to the development of TJ004309 in North America, we hold a non-exclusive license from I-Mab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering any pharmaceutical composition or preparation comprising or containing TJ004309. I-Mab retains ownership of any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering any pharmaceutical composition or preparation comprising or containing TJ004309.

Trade Secrets, Trademarks and Know-How

In addition to patents, we rely upon unpatented trade secrets, trademarks and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants 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. In addition, we seek trademark protection in the United States and internationally where available and when we deem appropriate. Furthermore, we are a party to a number of license agreements under which we are granted intellectual property rights to know-how that are important to our business.

U.S. Government Regulation

The preclinical studies and clinical testing, manufacture, labeling, storage, record keeping, advertising, promotion, export, marketing and sales, among other things, of our product candidates and future products, are subject to extensive regulation by governmental authorities in the United States and other countries. In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA), and other laws, including, in the case of biologics, the Public Health Service Act (PHSA), in addition to the FDA's implementing regulations. We expect envafolimab to be regulated by the FDA as a biologic, which requires the submission of a BLA and approval by the FDA prior to being marketed in the United States. We expect our small molecule product candidate TRC102 to be regulated as a drug and subject to New Drug Application, or NDA, requirements, which are substantially similar to the BLA requirements discussed below. Manufacturers of our product candidates may also be subject to state regulation. Failure to comply with FDA requirements, both before and after product approval, may subject us or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA refusal to approve applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines and/or criminal prosecution.

The steps required before a biologic may be approved for marketing of an indication in the United States generally include:

- completion of preclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices, or GLPs, and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may commence;
- completion of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices, or GCPs, to establish that the biological product is "safe, pure and potent," which is analogous to the safety and efficacy approval standard for a chemical drug product for its intended use;
- submission to the FDA of a marketing application;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with applicable current Good Manufacturing Practice requirements, or cGMPs; and
- FDA review of the marketing application and issuance of a biologics license which is the approval necessary to market a biologic therapeutic product.

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation as well as animal studies to assess the potential safety and efficacy of the biologic candidate. Preclinical studies must be conducted in compliance with FDA regulations regarding GLPs. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Nonclinical testing may continue after the IND is submitted. In addition to including the results of the preclinical testing, the IND 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 or phases of the clinical trial lends themselves to an efficacy determination. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA within the 30-day time period places the IND on clinical hold because of its concerns about the drug candidate or the conduct of the trial described in the clinical protocol included in the IND. The FDA can also place the IND on clinical hold at any time during drug development for safety concerns related to the investigational drug or to the class of products to which it belongs. The IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

All clinical trials must be conducted under the supervision of one or more qualified principal investigators in accordance with GCPs. They must be conducted under protocols detailing the objectives of the applicable phase of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to the FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution, approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, and monitor the trial until completed.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap and different trials may be initiated with the same drug candidate within the same phase of development in similar or differing patient populations. Phase 1 clinical trials may be conducted in a limited number of patients, but are usually conducted in healthy volunteer subjects for indications other than oncology. The drug candidate is initially tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, PD and PK.

Phase 2 usually involves trials in a larger, but still limited, patient population to evaluate preliminarily the efficacy of the drug candidate for specific, targeted indications to determine dosage tolerance and optimal dosage and to identify possible short-term adverse effects and safety risks.

Phase 3 trials are undertaken to further evaluate clinical efficacy of a specific endpoint and to test further for safety within an expanded patient population at geographically dispersed clinical trial sites. Phase 1, Phase 2, or Phase 3 testing might not be completed successfully within any specific time period, if at all, with respect to any of our product candidates. Results from one trial are not necessarily predictive of results from later trials. Furthermore, the FDA or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the 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 drug candidate has been associated with unexpected serious harm to patients.

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a marketing application requesting approval to market the drug candidate for a proposed indication. Under the PDUFA, the fees payable to the FDA for reviewing a marketing application, as well as annual program fees for approved products, can be substantial. The fees typically increase each year. Each marketing application submitted to the FDA for approval is reviewed for administrative completeness and reviewability within 60 days following receipt by the FDA of the application. If the application is found complete, the FDA will file the marketing application, triggering a full review of the application. The FDA may refuse to file any marketing application that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goal is to review 90% of priority marketing applications within six months after the application is accepted for filing and 90% of standard marketing applications within 10 months of the acceptance date, whereupon a review decision is to be made. The FDA, however, may not approve a drug candidate within these established goals and its review goals are subject to change from time to time. Further, the outcome of the review, even if generally favorable, may not be an actual approval but a "complete response letter" that describes additional work that must be done before the application can be approved. Before approving a marketing application, the FDA may inspect the facility or facilities at which the product is manufactured and will not approve the product unless the facility complies with cGMPs. The FDA may deny approval of a marketing application if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can extend the review process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval may impose limitations on the uses for which the product may be marketed, may require that warning statements be included in the product labeling, may require that additional studies be conducted following approval as a condition of the approval, and may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a Risk Evaluation and Mitigation Strategy, or REMS, or otherwise limit the scope of any approval. The FDA must approve a marketing application supplement or a new marketing application before a product may be marketed for other uses or before certain manufacturing or other changes may be made. Further post-marketing testing and surveillance to monitor the safety or efficacy of a product is required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

The Biologics Price Competition and Innovation Act of 2009 (the BPCIA) created a pathway for licensure, or approval, of biological products that are biosimilar to, and possibly interchangeable with, earlier biological products licensed under the PHSA. Also under the BPCIA, innovator manufacturers of original reference biological products are granted 12 years of exclusivity before biosimilars can be approved for marketing in the United States.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the marketing application for the product are subject to comprehensive regulatory oversight. For example, quality control and manufacturing procedures must conform, on an ongoing basis, to cGMP requirements, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to spend time, money and effort to maintain cGMP compliance.

Additionally, the FDA strictly regulates marketing, labeling, advertising and promotion of products. The FDA and other agencies 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. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

Other Healthcare Laws

Although we currently do not have any products on the market in the United States, we may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal, fraud and abuse, including anti-kickback and false claims, privacy and security and physician sunshine laws and regulations, many of which may become more applicable if our product candidates are approved and we begin commercialization. For additional details regarding the federal, state and foreign healthcare laws that may affect our ability to operate, see "Risk Factors—Risks Related to Our Business and Industry— "We are subject to extensive federal, state, and foreign regulation, and our failure to comply with these laws could harm our business." If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, significant civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, imprisonment, and additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results.

Orphan Drug Act

The United States Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation (ODD). ODD must be requested before submitting a BLA. ODD does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, the holder of the approval is entitled to a seven-year exclusive marketing period in the United States for that product except in very limited circumstances. For example, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug.

Legislation similar to the Orphan Drug Act has been enacted outside the United States, including in the EU and Japan. The orphan legislation in the EU is available for therapies addressing chronic debilitating or life-threatening conditions that affect five or fewer out of 10,000 persons or are financially not viable to develop. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity. The market exclusivity may be extended to 12 years if sponsors complete a pediatric investigation plan agreed upon with the relevant committee of the European Medicines Agency. Orphan legislation in Japan similarly provides for ten years of marketing exclusivity for drugs that are approved for the treatment of rare diseases and conditions.

Exclusivity

New biological products will benefit, if approved, from the data exclusivity provisions legislated in the United States, the EU and Japan. All three regions effectively provide a period of data exclusivity to innovator biologic products. U.S. legislation provides a 12-year period of data exclusivity from the date of first licensure of a reference biologic product. EU legislation provides a period of 10 to 11 years and Japan legislation provides a period of 8 years during which companies cannot be granted approval as generic drugs to approved biologic therapies. Protection from generic competition is also available for new chemical entities, including potentially the small molecule TRC102, in the United States for 5 years, in the EU for 10 to 11 years and in Japan for 8 years.

Exclusivity in the European Union

The EU has led the way among the International Council for Harmonisation regions in establishing a regulatory framework for biosimilar products. The marketing authorization of generic medicinal products and similar biological medicinal products are governed in the EU by Article 10(1) of Directive 2001/83/EC (2001). Unlike generic medicinal products, which only need to demonstrate bioequivalence to an authorized reference product, similar biological medicinal products are required to submit preclinical and clinical data, the type and quantity of which is dictated by class and product specific guidelines. In order to submit a marketing authorization for a similar biological medicinal product, the reference product must have been authorized for marketing in the EU for at least 8 years. Biosimilars can only be authorized for use once the period of data exclusivity on the biological reference medicine has expired. In general, this means that the biological reference medicine must have been authorized for at least 10 years before a similar biological medicine can be made available by another company. The 10-year period can be extended to a maximum of 11 if, during the first 8 years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization are held to bring a significant clinical benefit in comparison to existing therapies.

Many EU countries have banned interchangeability of biosimilars with their reference products to ensure adequate characterization of the safety profile of the biosimilar and to enable comparison to that of reference product.

Exclusivity in Japan

In 2009, Japan's Ministry of Health, Labour and Welfare, or MHLW, and Pharmaceuticals and Medical Device Agency, or PMDA, issued the first Japanese guidance on biosimilars. The guideline (currently available only in Japanese), which shares common key features to EU guidelines, outlines the nonclinical, clinical and CMC requirements for biosimilar applications and describes the review process, naming conventions and application fees.

Japan does not grant exclusivity to pharmaceutical products; however, the country does have a Post Marketing Surveillance, or PMS, system that affects the timing of generic entry and, in effect, provides a period of market exclusivity to innovator products. This system allows safety data to be acquired for each product. A PMS period is set for most of new drug approvals, and until this period is over, generic companies cannot submit their applications for drug approvals as generic drugs. Recently, this period was extended to 8 years for all new drug approvals. Japan's regulations do not allow currently for interchangeability of biosimilars with their reference products.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs and biologics, and/or provide for the approval of a drug or biologic on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs 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 drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Breakthrough therapy designation is for products that are intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. 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 drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. 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 may require that a sponsor of a drug candidate receiving accelerated approval perform post-marketing clinical trials to confirm the clinically meaningful outcome as predicted by the surrogate marker trial.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA, or a Written Request, relating to the use of the active moiety of the drug in children. The FDA may decline to issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

We have not received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for most drugs and biologicals, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, BLAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must include the evaluation of the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request 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 drug or biologic 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 FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In both domestic and foreign markets, sales and reimbursement of any approved products will depend, in part, on the extent to which third-party payors, such as government health programs, commercial insurance and managed healthcare organizations provide coverage, and establish adequate reimbursement levels, for such products. Third-party payors are increasingly challenging the prices charged for medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Additionally, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products after approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis.

The containment of healthcare costs also has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results.

Outside the United States, ensuring adequate coverage and payment for our products will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. Recent budgetary pressures in many EU countries are also causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates. If budget pressures continue, governments may implement additional cost-containment measures. Cost-control initiatives could decrease the price we might establish for products that we may develop or sell, which would result in lower product revenues or royalties payable to us. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

Healthcare Reform

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the healthcare system of the United States. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for medical goods and services may take in response to any healthcare reform proposals or legislation. Adoption of new legislation at the federal or state level could further limit reimbursement for pharmaceuticals, including our product candidates if approved. We cannot predict the effect medical or healthcare reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect. For additional details regarding health reform activity, see "Risk Factors—Risks Related to Commercialization of Product Candidates — "Healthcare legislative reform measures may have a material adverse effect on our business and results of operations."

Foreign Regulation

In addition to regulations in the United States, we and our collaborators will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates. Whether or not we or our collaborators obtain FDA approval for a product candidate, we or our collaborators must obtain approval from the comparable regulatory authorities of foreign countries or economic areas, such as the EU, before we or our collaborators may commence clinical trials or market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be approved by the competent national health authority and by independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country. In all cases, the clinical trials must be conducted in accordance with good clinical practices, or GCPs and other applicable regulatory requirements.

Under EU regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure is compulsory for medicinal products produced by biotechnology or those medicinal products containing new active substances for specific indications such as the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, viral diseases and designated orphan medicines, and optional for other medicines which are highly innovative. Under the centralized procedure, a marketing application is submitted to the European Medicines Agency where it will be evaluated by the Committee for Medicinal Products for Human Use. A favorable opinion typically results in the grant by the European Commission of a single marketing authorization that is valid for all EU member states within 67 days of receipt of the opinion. The initial marketing authorization is valid for five years, but once renewed is usually valid for an unlimited period. The decentralized procedure provides for approval by one or more "concerned" member states based on an assessment of an application performed by one member state, known as the "reference" member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

In China, the NMPA monitors and supervises the administration of pharmaceutical products, as well as medical devices and equipment. In order to conduct clinical trials in China a clinical trial application must be submitted and approved by the NMPA. When clinical trials have been completed, an applicant must apply to the NMPA for approval of a new drug application. The NMPA, the Center for Drug Evaluation (CDE), and the Drug Inspection Institution will then conduct reviews and on-site inspections. The NMPA determines whether to approve the application according to the comprehensive evaluation opinions produced by the reviews and on-site inspections. We or our collaborators must obtain approval of new drug applications before our product candidates can be manufactured and sold in the Chinese market. In addition, all facilities and techniques used in the manufacture of products for clinical use or for sale in China must be operated in conformity with good manufacturing practice guidelines as established by the NMPA. Failure to comply with applicable requirements could result in the termination of manufacturing and significant fines.

Additional Regulation

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involves the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Employees

As of December 31, 2022, we had a total of 18 full-time employees, 12 of whom are involved in research, development or manufacturing, and three of whom have Ph.D., Pharm.D. or M.D. degrees. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

Corporate and Other Information

We were incorporated in the state of Delaware on October 28, 2004. Our principal executive offices are located at 4350 La Jolla Village Dr., Suite 800, San Diego, California 92122, and our telephone number is (858) 550-0780. Our corporate website address is www.traconpharma.com and we regularly post copies of our press releases as well as additional information about us on our website. Information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

Access to our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports filed with or furnished to the Securities and Exchange Commission (SEC) may be obtained through the investor section of our website at https://ir.traconpharma.com/. We do not charge for access to and viewing of these reports. Information in the investor section and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings. Our filings with the SEC may be accessed through the SEC's website at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included unless otherwise specified, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

This Annual Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Item 1A. Risk Factors.

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report as well as our other public filings with the Securities and Exchange Commission.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred losses from operations since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability.

We are a clinical stage biopharmaceutical company with limited operating history. All the product candidates we are developing will require substantial additional development time and resources before we or our partners would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred losses from operations in each year since our inception, including net losses of $29.1 million and $28.7 million for the twelve months ended December 31, 2022 and 2021, respectively. At December 31, 2022, we had an accumulated deficit of $236.9 million.

We expect to continue to incur substantial expenses as we expand our development activities and advance our clinical programs. To become and remain profitable, we or our partners must succeed in developing product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we or our partners may obtain regulatory approval. We or they may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any product candidates. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates or continue our operations.

We will require substantial additional financing to achieve our goals, and failure to obtain additional financing when needed could force us to delay, limit, reduce or terminate our drug development efforts. There is substantial doubt as to our ability to continue as a going concern.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our current level of research and development expenses to increase in 2023 primarily due to the continued enrollment of the ENVASARC trial and Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes.

At December 31, 2022, we had cash and cash equivalents totaling $17.5 million, of which $0.1 million is pledged as collateral for our obligations under our corporate headquarters facility lease. Based upon our current operating plan, we believe that our cash and cash equivalents as of December 31, 2022 will be sufficient to fund our operating expenses and capital requirements into mid-2023. We will need additional funding to complete the development and commercialization of product candidates, including envafolimab and YH001. In addition, in December 2019 we entered into a collaboration and clinical trial agreement with 3D Medicines and Alphamab and in October 2021, we entered into a collaborative development and commercialization agreement with Eucure and Biocytogen. Under these agreements, we are responsible for various portions of the costs to conduct clinical trials, among other development obligations. We will need additional funds to advance the development of these programs and meet our cost-sharing obligations, and these requirements may be substantial depending on how many programs are selected for development and the stage of development each program reaches. As more fully discussed in Note 1 to our consolidated financial statements included in this Annual Report, the uncertainties around our ability to obtain additional funding raise substantial doubt regarding our ability to continue as a going concern for a period of 12 months following the date these accompanying consolidated financial statements were issued.

Regardless of our expectations, changing circumstances beyond our control, including the effects of macroeconomic and geopolitical developments, such as the COVID-19 pandemic, rising inflation rates and the ongoing conflict between Ukraine and Russia may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties or we could encounter difficulties obtaining clinical trial material or other supplies that could increase our development costs more than we expect. In addition, we may continue to incur substantial legal expenses in connection with our on-going dispute with I-Mab, including in connection with enforcing and collecting any award from the arbitration process. In any event, we will require additional capital prior to completing clinical development, filing for regulatory approval, or commercializing any product candidates.

In December 2022, we entered into a non-recourse financing agreement (the Investment Agreement) with certain investors (collectively the Investors) pursuant to which the Investors will pay us a maximum aggregate amount (Maximum Capital) equal to $30.0 million or a lesser amount based on the amount awarded (the Award), if any, to us in connection with our ongoing arbitration proceeding with I-Mab (the Arbitration). Of the Maximum Capital, (i) $3.5 million (the Initial Capital) was paid to us shortly after execution, (ii) 25% will be paid to us within 15 business days of issuance of an Award, subject to the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement, and (iii) the remainder will be paid to us in tranches over a multi-year period, subject again to the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement. While the Investment Agreement provides us with access to additional capital under certain circumstances, we cannot predict the outcome of the arbitration and are unable to estimate whether the Award will meet or exceed the prespecified threshold required in the Investment Agreement. If the Award does not meet or exceed the prespecified threshold, we may not have access to additional capital under the Investment Agreement.

In December 2020, as amended in March 2022, we entered into a Sales Agreement with JonesTrading pursuant to which we could sell from time to time, at our option, up to an aggregate of $50.0 million of shares of our common stock through JonesTrading, as sales agent or principal, $45.7 million of which remains available for sale as of December 31, 2022. While the Sales Agreement provides us with an additional option to raise capital through issuances and sales of our common stock, there can be no guarantee that we will be able to sell shares under the Sales Agreement in the future, or that any sales will generate sufficient proceeds to meet our capital requirements. In particular, JonesTrading is under no obligation to sell any shares of our common stock that we may request to be sold under the Sales Agreement from time to time. If sales are made under the Sales Agreement, our existing stockholders may experience dilution and such sales, or the perception that such sales are or will be occurring, may cause the trading price of our common stock to decline.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. As a result of macroeconomic and geopolitical developments, such as the COVID-19 pandemic and actions taken to slow its spread, ongoing military conflict between Ukraine and Russia, actual or anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate further, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of product candidates or otherwise significantly curtail, or cease, operations. If we are unable to pursue or are forced to delay our planned drug development efforts due to lack of financing, it would have a material adverse effect on our business, financial condition, operating results and prospects.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through equity offerings and debt financings. 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 stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to product candidates, or grant licenses on terms that are not favorable to us.

The RGC Loan Agreement contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.

In September 2022, as amended December 2022, we entered into a loan and security agreement (the RGC Loan Agreement) with Runway Growth Finance Corp. (RGC or the Lender) that provides a term loan commitment in an aggregate principal amount of up to $35.0 million in three tranches: (i) a Term A loan in an aggregate principal amount of $10.0 million, with the full amount funded on the closing of the RGC Loan Agreement and repaid in January 2023 in connection with the execution of our arbitration financing arrangement; (ii) a Term B loan in an aggregate principal amount of up to $15.0 million to be funded in one or more disbursements at our request on or prior to June 30, 2024, subject to certain conditions being met; and (iii) a Term C loan in an aggregate principal amount of up to $10.0 million that may be disbursed in a single disbursement in the lender's sole discretion upon our request at any time from closing of the RGC Loan Agreement through and including December 31, 2024. Pursuant to the December 2022 amendment (the RGC Loan Amendment): (i) we repaid all amounts of principal and accrued but unpaid interest in respect of the Term A Loan (as defined in the RGC Loan Agreement) on January 3, 2023 without the obligation for us to pay the final payment fee or the prepayment fee described in the RGC Loan Agreement; (ii) on or before March 31, 2023, at our request, if we have raised at least $25.0 million in net cash proceeds from certain equity or debt transactions (including amounts raised in connection with our arbitration financing arrangement) prior to making such request, Lender will loan to us an aggregate principal amount of $10.0 million, with the full amount funded in a single disbursement; (iii) we will not issue an additional warrant to Lender in connection with the loan, if any, described in clause (ii) above; and (iv) Lender's security interest in specific collateral will be subordinated to the arbitration financing investors' security interest in the specific collateral. If the loan described in clause (ii) above is not made by March 31, 2023, the RGC Loan Agreement will terminate on that date, and we will not be obligated to pay the prepayment fee described in the RGC Loan Agreement but the final payment fee described in the RCG Loan Agreement will become immediately due and payable.

The RGC Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- convey, sell, lease or otherwise dispose of certain parts of our business or property;
- merge or consolidate with another entity;
- incur or assume certain debt;
- incur certain types of liens on our assets;
- make changes to certain collateral accounts or fall below a prespecified amount of liquidity;
- pay dividends or make other distributions to our stockholders;
- make certain loans or investments;
- enter into material transactions with affiliates; and
- voluntarily repay or prepay certain indebtedness.

The restrictive covenants of the RGC Loan Agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the RGC Loan Agreement. An event of default will also occur upon the occurrence of, among other things, a material adverse effect on our business, operations, properties, assets or condition (financial or otherwise), which could potentially include receipt of negative results in clinical trials, a material impairment in the perfection or priority of the lien in any collateral or value of such collateral, or a material adverse effect on the prospect of our repayment of any portion of the amounts we owe under the RGC Loan Agreement or in the ability of RGC to enforce its rights and remedies. In the case of a continuing event of default under the RGC Loan Agreement, RGC, on behalf of all lenders, could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted a security interest under the RGC Loan Agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the RGC Loan Agreement are secured by substantially all of our assets, excluding intellectual property, which is subject to a negative pledge arrangement. Should an event of default or continuing event of default occur or if RGC elects to exercise its rights or remedies in accordance with the RGC Loan Agreement, including accelerating any payments or proceeding against any collateral, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Clinical Development and Regulatory Approval of Product Candidates

If the response rate of envafolimab as a single agent or in combination with ipilimumab in UPS/MFS is not significantly higher than existing therapies, our strategy of pursuing accelerated approval of envafolimab on ORR as the primary endpoint could delay or prevent the approval of envafolimab in UPS/MFS.

We are initially developing envafolimab in refractory UPS/MFS, where the PD-(L)1 inhibitors given as single agents or in combination with ipilimumab demonstrated response rates which were significantly higher than the response rate demonstrated by the approved treatment Votrient or chemotherapy in UPS/MFS. If the response rate of envafolimab as a single agent or in combination with ipilimumab in UPS/MFS is not significantly higher than Votrient or other chemotherapy, our strategy of pursuing accelerated approval of envafolimab on ORR as the primary endpoint will be unlikely to succeed, which could delay or prevent the approval of envafolimab in UPS/MFS.

Our plan to develop envafolimab in combination with ipilimumab and YH001 in combination with envafolimab exposes us to additional risks.

We intend to develop envafolimab in combination with ipilimumab and to develop YH001 in combination with envafolimab, and may in the future develop other product candidates in combination with other approved therapies or therapies in development. Patients may not be able to tolerate envafolimab or any of our other product candidates in combination with ipilimumab, YH001 or other therapies or dosing of envafolimab in combination with ipilimumab, YH001 or other therapies may have unexpected consequences. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.

Clinical development 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. Even if product candidates demonstrate favorable results in ongoing or planned Phase 1 and 2 clinical trials, many product candidates fail to show desired safety and efficacy traits in late-stage clinical trials despite having progressed through earlier trials. In addition to the potential lack of safety or efficacy of product candidates, clinical trial failures may result from a multitude of factors including flaws in trial design, manufacture of clinical trial material, dose selection and patient enrollment criteria, or differences in determination of progression events by investigators compared to central radiographic reviewers. With respect to envafolimab and YH001, while results of trials conducted by others outside of the United States have been promising, they may not be predictive of results in U.S. trials due to differences in trial design, target indications, patient populations, availability of alternative treatments and other factors. Based upon the recommendation of the IDMC following an interim analysis of data from the ENVASARC trial, we have proceeded in the trial using a dose of envafolimab that is twice the dose administered to the first patients in the trial. While dosing at higher levels has shown promising results in other trials outside of the United States, we cannot be certain that we will observe similar results in the ENVASARC trial, including whether the higher dose will result in tolerability issues that were not encountered with the lower dose. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or our partners may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. If patients drop out of our trials, miss scheduled doses or follow-up visits or otherwise fail to follow trial protocols, or if our trials are otherwise disrupted due to COVID-19 actions taken to slow its spread or adverse macroeconomic and geopolitical developments, such as the ongoing military conflict between Ukraine and Russia, the integrity of data from our trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

If any product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our stock price would be materially and adversely affected.

Interim, topline and preliminary data from preclinical studies and clinical trials may change as more data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

We and our collaboration partners publicly disclose from time to time, interim, topline or preliminary data from preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as more data become available. We and our collaboration partners may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. We and our collaboration partners also make assumptions, estimations, calculations and conclusions as part of the analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. In addition, the manner in which clinical data and results are reported may differ depending on the jurisdiction in which a trial is conducted or between us and our collaboration partners. As a result, the interim, topline or preliminary results that we or our collaboration partners report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the previously published preliminary data. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects.

From time to time, we or our collaboration partners may also disclose interim data from clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us, our collaboration partners, or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, our company in general and our common stock. In addition, the information we or our collaboration partners choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we or our collaboration partners determine to be material or otherwise appropriate information to include in such disclosure, and any information we or our collaboration partners determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that is reported for our product candidates differ from future or more comprehensive data, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of product candidates. Our ongoing and planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- adverse findings in toxicology studies, including chronic toxicology studies;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in enrollment caused by the availability of alternative treatments;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays in our ability to acquire sufficient supply of clinical trial materials.

For example, the FDA may require additional or different data in order to move forward with a BLA submission for envafolimab for patients with local advanced, unresectable or metastatic UPS and MFS, which could ultimately delay regulatory approval and could have a material adverse effect on our business.

In addition, the COVID-19 pandemic has impacted clinical trials broadly, including our own with some sites pausing enrollment or not completing all assessments specified in the protocol, and some patients choosing not to enroll or continue participating in ongoing trials. We and our collaborators may continue to experience delays in site initiation and patient enrollment, failures to comply with trial protocols, delays in the manufacture of product candidates for clinical testing, supply chain disruptions and other difficulties in starting or competing our clinical trials due to the COVID-19 pandemic and other macroeconomic and geopolitical developments.

If initiation or completion of our ongoing or planned clinical trials are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize product candidates could be materially harmed, which could have a material adverse effect on our business.

Our product candidates or those of our partners may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events (AEs) caused by product candidates or other potentially harmful characteristics of product candidates could cause us, our partners, including Eucure, Biocytogen, 3D Medicines, Alphamab or the NCI, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval.

Envafolimab has produced AEs consistent with other inhibitors of the PD-L1 and PD-1 pathways, including rare fatal immune related toxicities. Only a single related serious adverse event was reported in 36 patients in the ENVASARC interim efficacy data review in December 2022. Based on the August 9, 2021 data cutoff from the YH001 Phase 1 dose escalation clinical trial being conducted in Australia, no dose limiting toxicities had occurred and a single related serious adverse event of grade 3 colitis was reported, which led to treatment discontinuation. Phase 1 or Phase 2 clinical trials of TRC102 conducted to date have generated AEs related to the trial drug, some of which have been serious. The most common AE identified in our clinical trials of TRC102 has been anemia. There can be no assurance that AEs associated with product candidates will not be observed. As is typical in drug development, we have a program of ongoing toxicology studies in animals for clinical stage product candidates and cannot provide assurance that the findings from such studies or any ongoing or future clinical trials will not adversely affect our clinical development activities.

Further, if any approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; or
- 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 product candidates.

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

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions. For example, for certain oncology indications where the FDA has traditionally granted approval to therapies that can demonstrate progression-free survival, the agency may later require us to demonstrate overall survival, which would greatly extend the time and increase the capital required to complete clinical development. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of product candidates may not be sufficient to support the submission of a BLA or a New Drug Application (NDA), or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates or those of our partners.

We have not previously submitted a marketing application, or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any product candidates will be successful in clinical trials or receive regulatory approval. Further, product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such product candidates, if approved.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could negatively impact our business.

The ability of the FDA to review and approve proposed clinical trials or new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most foreign and domestic inspections of manufacturing facilities. In July 2020, the FDA restarted on-site inspections on a risk-based basis. Regulatory authorities outside the United States have and may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We may attempt to secure approval from the FDA through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may in the future seek accelerated approval for one or more of our product candidates, including envafolimab in UPS/MFS. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug. In addition, the FDA currently requires pre-approval of promotional materials for accelerated approval products, once approved.

If we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA could require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may not receive fast track designation for our product candidates from the FDA, or fast track designation may not actually lead to a faster development or regulatory review or approval process.

Fast track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. A new drug or biologic is eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for the disease or condition. While the FDA did grant us fast track designation for the development of envafolimab for patients with locally advanced, unresectable or metastatic UPS and MFS who have progressed on one or two prior lines of chemotherapy, it has broad discretion whether or not to grant this designation for our other product candidates. Even if we believe another particular product candidate is eligible for this designation, we cannot assure you that the FDA will grant it. Further, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may be unsuccessful in our efforts to obtain orphan drug designations (ODDs) from the FDA for product candidates, and even if these designations are obtained, we may not ultimately realize the potential benefits of ODD.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 people in the United States, or a patient population of greater than 200,000 people in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and may be eligible for a market exclusivity period of seven years.

In June 2021, we received ODD for envafolimab for the treatment of soft tissue sarcoma subtypes and in October 2020, the FDA granted ODD for TRC102 for the treatment of patients with malignant glioma, including glioblastoma. Generally, if a drug with an ODD subsequently receives the first marketing approval for the indication for which it has such designation, the drug may be entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same orphan designated indication for that time period. The applicable period is seven years in the United States, which may be extended by six months, in the case of product candidates that have complied with the respective regulatory agency's agreed upon pediatric investigation plan. Orphan drug exclusivity may be lost if the FDA 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 addition, even after a drug is granted orphan exclusivity and approved, the FDA can subsequently approve another drug for the same condition before the expiration of the seven-year exclusivity period if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, if an orphan designated product receives marketing approval for an indication broader than or different from what is designated, such product may not be entitled to orphan exclusivity. Even though the FDA has granted ODD, if we receive approval for a modified or different indication, our current orphan designations may not provide us with exclusivity.

ODD does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Also, regulatory approval for any product candidate may be withdrawn, and other product candidates may obtain approval before us and receive orphan drug exclusivity, which could block us from entering the market. For example, 3D Medicines has U.S. ODD for envafolimab for the treatment of BTC, an indication that is outside the scope of our current license agreement with 3D Medicines.

Orphan drug exclusivity also may not effectively protect us from competition because different drugs can be approved for the same condition and the same drug can be approved for different conditions before the expiration of any orphan drug exclusivity period.

If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering our eligible product candidates, we could be subject to generic competition earlier than we anticipate. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as any product candidates that receive marketing approval, we may face increased competition and lose market share regardless of orphan drug exclusivity.

Although we intend to seek breakthrough therapy designation for envafolimab for the treatment of soft tissue sarcoma subtypes, such designation may not be granted, and even if granted this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that envafolimab will receive marketing approval in the United States.

A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Although we intend to seek breakthrough therapy designation for envafolimab for the treatment of soft tissue sarcoma, we may not be granted such designation and even if designated this may not lead to a faster development, regulatory review or approval process, and it does not increase the likelihood that envafolimab will receive marketing approval in the United States. In addition, if granted breakthrough therapy designation, the FDA may later decide that envafolimab no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as studies or trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we would intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates or those of our partners will be harmed.

Even if we receive regulatory approval of product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with product candidates.

Any product candidates for which we receive regulatory approvals will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy (REMS) in order to approve product candidates, which could entail requirements for 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 or a comparable foreign regulatory authority approves product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing, as well as continued compliance with regulatory requirements for current good manufacturing practices (cGMPs) and current good clinical practices (cGCPs) for any clinical trials that we conduct post-approval. Although physicians, in the practice of medicine, may prescribe an approved drug for unapproved indications, pharmaceutical companies are prohibited from promoting uses that are not approved by the FDA as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses of approved pharmaceutical products, and a company that is found to have improperly promoted off-label may be subject to significant liability. Later discovery of previously unknown problems with product candidates, including AEs of unanticipated severity or frequency, or with our third party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, 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 existing approvals;
- product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States 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 marketing approval that we may have obtained and we may not achieve or sustain profitability.

Risks Related to Our Reliance on Third Parties

We and our partners rely on third party manufacturers to make product candidates, and any failure by a third party manufacturer may delay or impair our ability to complete clinical trials or commercialize our product candidates.

Manufacturing drugs and biologics is complicated and is tightly regulated by regulatory authorities, including the FDA and foreign equivalents. We currently rely on third party manufacturers to supply us with drug substance for preclinical and clinical trials. Moreover, the market for contract manufacturing services for drug products is highly cyclical, with periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide tight capacity, we may not be able to access the required capacity on a timely basis or on commercially viable terms, which could result in delays in initiating or completing clinical trials or our ability to apply for or receive regulatory approvals.

We rely on other third parties for drug substance and to perform additional steps in the manufacturing process, including filling into vials, shipping and storage. For our clinical stage pipeline programs, there can be no guarantee that lack of clinical supplies will not force us or our partners to delay or terminate any ongoing or planned clinical trials.

We expect to continue to rely on third party manufacturers for any drug required for commercial supply and do not intend to build our own manufacturing capability. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is costly, time consuming and subject to potential difficulties and delays. With respect to envafolimab, pursuant to the Envafolimab Collaboration Agreement, 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to us at pre-negotiated prices that vary based on clinical or commercial use. With respect to YH001, Eucure has agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, YH001 to us for clinical trials pursuant to the terms of a clinical supply and quality agreement to be separately negotiated, but we cannot guarantee that we will successfully negotiate and enter into the contemplated clinical supply and quality agreement or do so on commercially favorable terms.

We do not have any long-term supply agreements for the manufacture of product candidates and cannot guarantee that any third party manufacturer would be willing to continue supplying drug product for clinical trials or commercial sale at a reasonable cost or at all. In addition, manufacturing agreements are often subject to early termination by the third party manufacturer under certain circumstances.

The facilities used by our current or future third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit a BLA or an NDA to the FDA. While we work closely with our third party manufacturers on the manufacturing process for product candidates, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our third party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both drug substances and finished drug products. If our third party manufacturers or those of our collaborators cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or other regulatory authorities, we may experience delays in initiating planned clinical trials and we may not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers or other third party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or commercialize product candidates.

We depend in part on NCI and other third party sponsors to advance clinical development of TRC102. If these third party sponsors ceased their support for our product candidates, our ability to advance clinical development of product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued.

NCI is currently sponsoring and funding multiple clinical trials involving TRC102. In addition, Case Western has sponsored and funded two separate clinical trials involving TRC102. The advancement of TRC102 depends in part on the continued sponsorship and funding of clinical trials by these organizations, as our resources and capital would not be sufficient to conduct these trials on our own. None of these third party sponsors are obligated to continue sponsorship or funding of any clinical trials involving our product candidates and could stop their support at any time. If these third party sponsors ceased their support for our product candidates, our ability to advance clinical development of product candidates could be limited and we may not be able to pursue the number of different indications for our product candidates that are currently being pursued.

Even if these third party sponsors continue to sponsor and fund clinical trials of our product candidates, our reliance on their support subjects us to numerous risks. For example, we have limited control over the design, execution or timing of their clinical trials and limited visibility into their day-to-day activities, including with respect to how they are providing and administering our product candidates. If a clinical trial sponsored by a third party has a failure due to poor design of the trial, errors in the way the clinical trial is executed or for any other reason, or if the sponsor fails to comply with applicable regulatory requirements or if there are errors in the reported data, it could represent a major set-back for the development and approval of our product candidates, even if we were not directly involved in the trial and even if the clinical trial failure was not related to the underlying safety or efficacy of the product candidate. In addition, these third party sponsors could decide to de-prioritize clinical development of our product candidates in relation to other projects, which could adversely affect the timing of further clinical development. We are also subject to various confidentiality obligations with respect to the clinical trials sponsored by third party sponsors, which could prevent us from disclosing current information about the progress or results from these trials until the applicable sponsor publicly discloses such information or permits us to do so. This may make it more difficult to evaluate our business and prospects at any given point in time and could also impair our ability to raise capital on our desired timelines.

We are dependent on 3D Medicines and Alphamab with respect to certain aspects of our development of envafolimab for the treatment of sarcoma in North America and on Eucure and Biocytogen with respect to certain aspects of our development of YH001 for the treatment of certain sarcoma subtypes in North America. The failure to maintain these collaboration and clinical trial agreements, the failure of 3D Medicines, Alphamab, Eucure or Biocytogen to perform their obligations under the agreements, or the actions of 3D Medicines, Alphamab, Eucure or Biocytogen or their other partners with respect to envafolimab and YH001 in other indications or outside North America could negatively impact our business.

Pursuant to the terms of our collaboration and clinical trial agreement with 3D Medicines and Alphamab, we were granted an exclusive license to develop and commercialize envafolimab for sarcoma in North America. Pursuant to the terms of our collaborative development and commercialization agreement with Eucure and Biocytogen, we were granted an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment of multiple human indications, including the Initial Indications or one or more of the Substitute Indications, which may be substituted for Initial Indications at our discretion. While we are generally responsible for clinical development, 3D Medicines and Alphamab are responsible for certain critical activities associated with envafolimab and Eucure and Biocytogen are responsible for certain critical activities associated with YH001, including, as applicable, the manufacture and supply of envafolimab and YH001, CMC activities and prosecution and enforcement of intellectual property rights. We have limited control over the amount and timing of resources that 3D Medicines, Alphamab, Eucure and Biocytogen will dedicate to their respective efforts, and their failure to perform their obligations would impair our ability to develop envafolimab for sarcoma in North America and YH001 for certain sarcoma subtypes in North America. In addition, we have very limited influence or control over 3D Medicines', Alphamab's, Eucure's or Biocytogen's (or their respective other partners') activities with respect to the development and commercialization of envafolimab and YH001 in non-licensed indications or indications outside of North America, even though these activities could have a significant impact on the development and commercialization of envafolimab for sarcoma in North America and YH001 for certain sarcoma subtypes in North America. For example, Eucure may pursue clinical trials for YH001 in North America outside of the Initial Indications or Substitute Indications, and also within the Initial Indications or Substitute Indications as part of a combination therapy of YH001 and an additional Eucure product, any of which could have a significant impact on the development and commercialization of YH001 for sarcoma in North America. Additionally, adverse events in clinical trials outside of the United States could cause the FDA to put clinical trials of envafolimab or YH001 in the United States on hold, and negative results of clinical trials of envafolimab in other indications may cast doubt as to the likelihood of positive results of clinical trials in UPS/MFS or other sarcoma indications.

We are subject to a number of other risks associated with these collaboration and clinical trial agreements, including:

- we and our corporate partners could disagree as to future development plans which could delay initiation of clinical trials or stop a future clinical trial;
- there may be disputes between us and our corporate partners, including disagreements regarding the terms of the collaboration and clinical trial agreement, that may result in the delay of or failure to achieve development, regulatory and commercial objectives and/or costly litigation or arbitration that diverts our management's attention and resources;
- our corporate partners may not provide us with timely and accurate information regarding development progress and activities outside of sarcoma and North America, which could adversely impact our ability to report progress to our investors and may cause us to make ill-informed decisions with respect to our own development efforts;
- our corporate partners may not properly maintain or defend the intellectual property rights licensed to us in North America or may undertake activities that invite litigation that could jeopardize or invalidate the intellectual property rights licensed to us or expose us to potential litigation; and
- our corporate partners are responsible for conducting CMC activities for envafolimab and YH001 and may not conduct such activities at the quality level required to seek FDA approval.

If we have disagreements with our corporate partners, if they do not perform their obligations under the collaboration and clinical trial agreements or there are negative events with respect to envafolimab or YH001 outside of the licensed indications or North America, there could be material adverse consequences to our ability to successfully develop and commercialize envafolimab and YH001 in North America or to the value of envafolimab and YH001 to us.

Our ability to realize value from any product candidates developed under our agreements with I-Mab will depend in part on I-Mab's activities and willingness to fund future development and the timing and outcome of our dispute with I-Mab of which we cannot predict the outcome and could materially adversely affect our ability to operate our business and financial results.

Pursuant to the terms of our strategic collaboration and clinical trial agreements with I-Mab, we are largely responsible for clinical development activities and I-Mab is responsible for pre-clinical development and manufacturing activities. Consequently, our ability to realize value or generate any revenues from the development of product candidates in collaboration with I-Mab will depend in part on I-Mab's willingness and ability to successfully complete pre-clinical development and manufacturing activities, in addition to funding agreed-upon portions of the costs of clinical development. We have limited control over the amount and timing of resources that I-Mab will dedicate to its respective efforts, and have limited rights in the event that I-Mab determines to cease development or manufacturing activities or funding for any product candidate under the collaboration. We could also encounter disagreements with I-Mab over the timing and scope of development or manufacturing of any product candidates or payments owed under the collaboration or which, if any, BsAb product candidates are selected for development. For example, in March 2020, I-Mab issued a press release announcing a strategic partnership with Kalbe Genexine Biologics (KG Bio), whereby KG Bio received what the press release described as a right of first negotiation outside North America for TJ004309 for up to $340 million in potential payments to I-Mab. In March 2020, we also learned that I-Mab had entered into two license and collaboration agreements with ABL Bio in July 2018 (ABL Bio License 1 and ABL Bio License 2). Under ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I-Mab and ABL agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal after we invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations concerning two strategic collaboration and clinical trial agreements with us entered into in November 2018. Those strategic collaboration and clinical trial agreements relate to the development of TJ004309 and five of I-Mab's proprietary bispecific antibody product candidates to be nominated by I-Mab within a five-year period for development and commercialization in North America. We filed counterclaims in the arbitration seeking to recover over $200 million in damages from I-Mab based on I-Mab's breaches of the two strategic collaboration and clinical trial agreements. In 2021, I-Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is "Complete," as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I-Mab's termination. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking a variety of relief including an order of specific performance requiring us to comply with I-Mab's purported termination of the TJ004309 Agreement. In May 2021, the Delaware Court of Chancery stayed the lawsuit in favor of arbitration. The Tribunal held a hearing on the merits in February 2022, and final post-hearing briefs were submitted by us and I-Mab in May 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties submitted their respective cost submissions for attorney fees reimbursement in January 2023. The Tribunal did not indicate when it expects to render its final decision; however, it did note that it was far along in its deliberations and preparation of a final award. We expect the Tribunal to render its final decision in the first quarter of 2023. Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal's discretion. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, which could materially adversely affect our ability to operate our business and our financial results, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. The dispute with I-Mab has caused, and could continue to cause, us to incur significant costs, as well as distract our management over an extended period. Until these disputes are concluded, we will be unable to provide a timeline as to when or if we will file an IND for a BsAb under the Bispecific Agreement. Furthermore, our ability to license bispecific product candidates from I-Mab may be more limited than we previously believed.

We may not be successful in establishing and maintaining additional collaborations, which could adversely affect our ability to develop and commercialize our existing product candidates or to leverage our clinical development capabilities.

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional licensing and collaboration agreements, including potentially with major biotechnology or pharmaceutical companies. In particular, we are actively seeking additional corporate partnerships in which we would share in the cost and risk of clinical development and commercialization of innovative product candidates of third parties. We face significant competition in seeking appropriate partners, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as having the requisite potential to demonstrate safety and efficacy and as being economically valuable in light of the terms that we are seeking and other available products for licensing by other companies. With respect to additional partnerships whereby we would develop third party product candidates, we will need to identify promising product candidates where the owner of the development and commercial rights could benefit from our clinical development capabilities. Under our collaboration and clinical trial agreement with I-Mab for TJ004309, we are prohibited from developing other biologic product candidates targeting the same indications for which TJ004309 is being developed, which increases our reliance on the success of I-Mab's activities with respect to TJ004309 and could limit our ability to collaborate with others with respect to biologic product candidates in certain indications. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any inability or delay in entering into new collaboration agreements related to our product candidates, in particular in foreign countries where we do not have and do not intend to establish significant capabilities, could delay the development and commercialization of our product candidates and reduce their market potential. If we are unable to enter into additional collaborations that leverage our clinical development capabilities, we may be forced to reduce these capabilities, which could lower the value of our company and make it less likely that third parties will seek to collaborate with us to develop their product candidates.

We rely on third parties to conduct preclinical studies and clinical trials of product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for product candidates.

We do not have our own capabilities to perform preclinical testing of product candidates, and therefore rely entirely on third party contractors and laboratories to conduct these studies for us. In addition, while we intend to continue designing, monitoring and managing our clinical trials of product candidates using our clinical operations and regulatory team, we still depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials at their sites under agreements with us. We will compete with many other companies for the resources of these third-party contractors, laboratories, investigators and collaborators, and the initiation and completion of our preclinical studies and clinical trials may be delayed if we encounter difficulties in engaging these third parties or need to change service providers during a preclinical study or clinical trial.

We control only certain aspects of the activities conducted for us by the third parties on which we currently rely and on which we will rely in the future for our preclinical studies and clinical trials. Nevertheless, we are responsible for ensuring that each of our clinical trials and certain of our preclinical studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. With respect to clinical trials, we and these third parties are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with product candidates produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state health care laws, including, among others, fraud and abuse, false claims, privacy and security, and physician payment transparency laws. Any third parties conducting our preclinical studies and clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical development programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties 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 protocols or regulatory requirements or for other reasons, our preclinical studies and clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize product candidates. As a result, our financial results and the commercial prospects for our product candidates or those of our partners would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies which could do harm to our business and affect our ability to be profitable. In particular, our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. Additionally, we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Any disclosure or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market.

The patent position of biotechnology companies is generally uncertain because it involves complex legal and factual considerations in a legal framework that is constantly evolving. The standards applied by the United States Patent and Trademark Office (USPTO) and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. There is a substantial amount of prior art in the biotechnology and pharmaceutical fields, including scientific publications, patents and patent applications. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidate that we may develop. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate.

For applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the claims of our applications and patents. As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. It is not yet clear, what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Furthermore, due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all our product candidates or methods involving these product candidates in the parent patent application.

In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords is limited. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic and biosimilar products.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including delays as a result of the COVID-19 pandemic impacting our or our licensors' operations.

Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products.

We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely impact our business and operations.

Specific to the development of YH001 in North America, we hold an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment, through administration of YH001 by intravenous or subcutaneous means, of multiple human indications, including the Initial Indications or one or more of the Substitute Indications, which may be substituted for Initial Indications at our discretion. As it relates to the development of envafolimab for the treatment of sarcoma in North America, we hold an exclusive license from 3D Medicines and Alphamab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering envafolimab. We also hold a non-exclusive license for the conduct of clinical trials in the EU in support of the development of envafolimab for the treatment of sarcoma in North America. Regarding the development of TJ004309 in North America, we hold a non-exclusive license from I-Mab to any and all intellectual property rights, including patents, copyrights, trademarks and know-how, claiming or covering any pharmaceutical composition or preparation comprising or containing TJ004309.

As a licensee of third parties, we rely on these third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

Third party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination and review proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we and our partners are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product candidates or methods of use of our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use or manufacture of our product candidates.

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also, in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If any third party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we or our partner obtain a license. These licenses may not be available on acceptable terms, if at all. Even if we or our partner were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we or our partner could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our partner are unable to enter into licenses on acceptable terms.

Parties making claims against us or our partner may obtain injunctive or other equitable relief, which could effectively block our or our partner’s ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Third parties may submit applications for patent term extensions in the United States and/or supplementary protection certificates in the EU member states seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our products.

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party’s trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patent of our licensors, which could be expensive and time consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. In addition, one or more of our third party collaborators may have submitted, or may in the future submit, a patent application to the USPTO without naming a lawful inventor that developed the subject matter in whole or in part while under an obligation to execute an assignment of rights to us. As a result, we may be required to file infringement or inventorship claims to stop third party infringement, unauthorized use, or to correct inventorship. This can be expensive, particularly for a company of our size, and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation or other proceedings brought at the USPTO or any foreign patent authority may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party, or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or collaborators, to prevent misappropriation of our trade secrets, confidential information or proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

We have in-licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. YH001 and associated intellectual property have been licensed from Eucure and Biocytogen, envafolimab and associated intellectual property have been licensed from 3D Medicines and Alphamab, and TJ004309 and associated intellectual property have been licensed from I-Mab.

Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment or diligence obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our and our partners' ability to utilize the affected intellectual property in our drug development efforts, and our ability to enter into collaboration or marketing agreements for a product candidate, may be adversely affected.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims 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 or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

Obtaining and maintaining 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 non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. 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. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.

Risks Related to Commercialization of Product Candidates

Even if we obtain regulatory approval of product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors and others in the medical community.

Factors that will influence whether product candidates are accepted in the market include:

- the clinical indications for which product candidates are approved, if any;
- physicians, hospitals, cancer treatment centers and patients considering product candidates as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by governmental and commercial third party payors;
- the willingness of patients to pay out-of-pocket in the absence of coverage by governmental and commercial third party payors;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If, for any of these or other reasons, product candidates fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, third party payors or others in the medical community, we will not be able to generate significant revenue. Even if our products 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 products, are more cost effective or render our products obsolete.

Off-label use of approved drugs could adversely impact peak sales of our product candidates if approved, including Keytruda's off-label use in UPS/MFS.

While no PD-(L)1 treatments are currently FDA approved in UPS/MFS or any other sarcoma subtype, Keytruda (pembrolizumab, marketed by Merck & Co.) has a compendia listing in UPS and is reimbursed for off-label use in UPS. The off-label use of Keytruda in UPS/MFS may adversely affect the peak net sales of envafolimab in UPS/MFS and other sarcoma subtypes, if envafolimab is approved by the FDA and commercialized in the United States. Similarly, while no CTLA-4 therapy is approved by the FDA for the treatment of soft tissue sarcoma, if YH001 is approved, it may nevertheless compete with the currently marketed CTLA-4 inhibitor ipilimumab (Yervoy, marketed by Bristol Myers Squibb), which is approved by the FDA in multiple indications other than soft tissue sarcoma.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are more advanced or effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize product candidates.

We face competition both in the United States and internationally, including from major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing product candidates against competitors.

Under the terms of our license agreement with Case Western, we obtained an exclusive, worldwide license to certain patents, know-how and other intellectual property controlled by Case Western related to TRC102. Despite our exclusive license, Case Western retained the right to grant non-exclusive licenses to third parties in the same field of use as our exclusive license as a means to settle any intellectual property disputes Case Western may have in the future with such third parties. While Case Western has not made us aware of any present intent to exercise this right, there can be no guarantee that Case Western will not do so in the future or that it would not grant such a non-exclusive license to a competitor of ours seeking to develop and commercialize a product that is identical to TRC102 in the same field of use that we are pursuing. If this were to occur, and we did not have other intellectual property outside of the Case Western license agreement to prevent competitive products for the same indications, we may face competition much earlier than we currently anticipate and the value of TRC102 may decline substantially.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from "biosimilars" due to the changing regulatory environment. In the United States, the Biologics Price Competition and Innovation Act created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or "biosimilar," to or "interchangeable" with an FDA-approved biological product. This pathway could allow competitors to reference data from biological products already approved after 12 years from the time of approval. Future FDA standards or criteria for determining biosimilarity and interchangeability, and FDA discretion to determine the nature and extent of product characterization, non-clinical testing and clinical testing on a product-by-product basis, may further facilitate the approval of biosimilar products and their ability to compete with our product candidates or those of our partners. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. Any such event or further changes in the law could decrease the period for which we have exclusivity and consequently negatively impact our business and competitive position. Expiration or successful challenge of our applicable patent rights could also trigger competition from other products, assuming any relevant exclusivity period has expired.

Finally, as a result of the expiration or successful challenge of our patent rights, we could face litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

Coverage and reimbursement may be limited or unavailable in certain market segments for product candidates, which could make it difficult for us to sell product candidates profitably.

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third party payors. In addition, because our product candidates and those of our partners represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from these product candidates.

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. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and other third party payors, such as commercial health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third party payor may depend upon a number of factors, including, but not limited to, the third party payor's determination that use of a product 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.

In the United States, no uniform policy of coverage and reimbursement for products exists among third party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Obtaining coverage and reimbursement approval of a product from a government or other third party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data to each payor separately for the use of our products, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of product candidates. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, 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.

We intend to seek approval to market product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of product candidates will depend significantly on the availability of coverage and adequate reimbursement from third party payors for product candidates.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Third party payors, whether domestic or foreign, or governmental or commercial, and governments are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, was enacted in the United States. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 (Tax Act) includes a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the

"donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative changes to the statute will remain in effect until 2031 unless additional Congressional action is taken. However, COVID-19 pandemic relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, former U.S. President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been heightened governmental scrutiny over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain market acceptance in the medical community;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business in the future, or the effect any future legislation or regulation will have on us.

If we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If any product candidates are approved for commercialization, we expect that we or our partners will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- different payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- reduced protection for intellectual property rights;

- unexpected changes in tariffs, trade barriers and regulatory requirements, including the significant sanctions and export controls imposed against Russia, Russian banks and certain Russian individuals by the United States, United Kingdom and EU, along with others;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If we or our partners outside of the United States are unable to successfully manage these risks associated with international operations, the market potential for our product candidates or those of our partners outside the United States will be limited and our results of operations may be harmed.

Risks Related to Our Business and Industry

If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

We do not have internal new drug discovery capabilities or a technology platform with which to develop novel product candidates. Unless we develop or acquire these capabilities or a technology platform, our only means of expanding our product pipeline will be to acquire or in-license product candidates that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. In addition, part of our corporate strategy is to leverage our existing internal clinical development and regulatory capabilities by entering into collaborations where we conduct development activities related to third party product candidates in exchange for commercialization and payment rights, such as our collaborations with Eucure and Biocytogen with respect to YH001, 3D Medicines and Alphamab with respect to envafolimab, and I-Mab with respect to TJ004309 and potential BsAb candidates. Identifying, selecting and acquiring or licensing promising product candidates requires substantial technical, financial and human resources. Efforts to do so may not result in the actual development, acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. With respect to TJ004309, if I-Mab licenses rights to TJ004309 to a third party, while we would be entitled to receive varying portions of royalty and non-royalty payments from I-Mab, we would have no further rights to develop, commercialize or realize value from TJ004309. With respect to envafolimab, 3D Medicines and Alphamab retain certain rights to reacquire the rights for sarcoma in North America in connection with an arm's length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications. While we and 3D Medicines and Alphamab must negotiate in good faith and agree to fair compensation be paid to us for the value of and opportunity represented by the reacquired rights, we cannot guarantee that any compensation paid to us would adequately cover our investments in the program, the present value of the rights to us or our opportunity costs as a result of having advanced the program prior to reacquisition. Also, in the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace us as the party responsible for commercialization, and we do not co-market envafolimab for sarcoma in North America, then 3D Medicine and Alphamab will be required to compensate us for our costs associated with preparing for and conducting commercial activities. However, we may not be able to agree with 3D Medicines and Alphamab on adequate compensation and cannot guarantee that any agreed-upon compensation would adequately cover our investments in commercializing envafolimab in North America or our lost opportunity costs in pursuing commercialization. If we are unable to retain existing product candidates and add additional product candidates to our pipeline, we may not be able to execute on an important part of our business strategy and our long-term business and prospects will be limited.

We and our partners are subject to extensive federal, state, and foreign regulation, and our failure to comply with healthcare laws could harm our business.

Although we do not currently have any products on the market, we and our partners are subject to healthcare regulation and enforcement by the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws that may affect our ability to operate include:

- the federal anti-kickback statute, which applies to our business activities, including our research, marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things,

knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs;

- federal civil and criminal false claims laws, including the federal False Claims Act, and federal civil monetary penalty law that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other governmental healthcare programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, imposes certain regulatory and contractual requirements on covered entities, and their business associates that create, receive, maintain or transmit individually identifiable health information for or on their behalf, as well as their covered subcontractors, regarding the privacy, security and transmission of individually identifiable health information;
- federal "sunshine" requirements imposed by the ACA on certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information regarding any payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members; and
- state or foreign law equivalents of each of the above federal laws that may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information relating to drug and biologic pricing; state and local laws that require the registration of pharmaceutical sales representatives; 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 may not have the same effect, thus complicating compliance efforts.

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 certain of these laws. For example, the ACA, among other things, amended the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them 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 federal False Claims Act.

We are also subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and/or may in the future, be subject. For example, the collection and use of personal health data in the EU is governed by the General Data Protection Regulation, or the EU GDPR. The EU GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The EU GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The EU GDPR requirements apply not only to third party transactions, but also to transfers of information within our company, including employee information. The EU GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third party vendors process, including in clinical trials conducted in the United States and EU. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, significant administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, imprisonment, exclusion from governmental health care programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates or those of our partners. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize product candidates; and
- decreased demand for product candidates, if approved for commercial sale.

We currently carry product liability insurance covering our clinical trials with limits we believe are customary for other companies in our field and stage of development. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

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

As of December 31, 2022, we had federal and California NOL carryforwards of $194.3 million and $144.5 million, respectively. The federal and California NOL carryforwards will begin to expire in 2030 and 2033, respectively, if not utilized. The federal NOL generated after 2017 of $111.1 million will carryforward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. As of December 31, 2022, we also had federal research and development and Orphan Drug tax credit carryforwards of $13.7 million and California research and development tax credit carryforwards of $3.0 million. The federal research and development and Orphan Drug tax credit carryforwards will begin expiring in 2031 and 2036, respectively, if not utilized. The California research credit will carry forward indefinitely under current law. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended (Code), if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We believe we have experienced certain ownership changes in the past and have reduced our deferred tax assets related to NOLs and research and development tax credit carryforwards accordingly. In the event we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

New or future changes to tax laws could materially adversely affect us.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) modified certain provisions of the Tax Act and the recently enacted IRA, includes provisions that will impact the U.S. federal income taxation of corporations, including imposing a minimum tax on the book income of certain large corporations and an excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the IRA or any newly enacted federal tax legislation. The impact of such legislation and any future changes in tax laws on holders of our common stock is also uncertain and could be adverse.

If we fail to attract and keep senior management and key clinical operations and regulatory personnel, we may be unable to successfully develop product candidates and execute our business strategy.

We are highly dependent on members of our senior management, including Charles Theuer, M.D., Ph.D., our President and Chief Executive Officer. Our clinical development strategy and ability to directly manage or oversee our on-going and planned clinical trials are also dependent on the members of our clinical operations and regulatory team. The loss of the services of any of these persons could impede the development of product candidates and our ability to execute our business strategy. We may be particularly impacted by the unexpected loss of employees due to our small employee base and limited ability to quickly shift responsibilities to other employees in our organization. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining other qualified employees for our business, including scientific, quality assurance and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue, making recruitment and retention competitive. This competition has become exacerbated by the increase in employee resignations currently taking place throughout the United States as a result of the COVID-19 pandemic, which is commonly referred to as the “great resignation.” We may also experience employee turnover as a result of the ongoing “great resignation.” As a result, competition for skilled personnel is intense, particularly in the San Diego, California area, and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our development and strategic objectives. In response to competition, rising inflation rates and labor shortages, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count and cause dilution to existing shareholders.

Unfavorable U.S. and global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the U.S. and global economies, the U.S. and global financial markets and adverse macroeconomic and geopolitical developments. U.S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including the ongoing COVID-19 pandemic, material shortages and related supply chain challenges, geopolitical developments such as the conflict between Ukraine and Russia, and higher inflation rates and the responses by central banking authorities to control such inflation, among others. General business and economic conditions that could affect business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our collaborators, our manufacturers and our suppliers operate.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply and clinical trial disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. In response to the invasion, the United States, United Kingdom and EU, along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability and/or supply chain continuity in both Europe and globally, and has introduced significant uncertainty into global markets. In particular, the Russia-Ukraine conflict has contributed to rapidly rising costs of living (driven largely by higher energy prices) in Europe and other advanced economies. Further, a weak or declining economy could strain our suppliers, manufacturers and collaborators, possibly resulting in additional supply disruption for our product candidates and delays to our clinical trials. As a result, our business and results of operations may be adversely affected by the ongoing conflict between Ukraine and Russia, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict. If economic conditions in Europe and other key markets for our business and the business of our suppliers, manufacturers and collaborators remain uncertain or deteriorate further, including as a result of the COVID-19 pandemic or otherwise, we could experience adverse effects on our business, financial condition or results of operations.

Risks Related to Our Common Stock

The market price of our common stock may be highly volatile, and our stockholders may not be able to resell their shares at a desired market price and could lose all or part of their investment.

Even though our common stock trades on the Nasdaq Capital Market, we cannot assure you that an active, liquid trading market for our shares will develop or persist. Our stockholders may not be able to sell their shares quickly or at a recently reported market price if trading in our common stock is not active. The trading price of our common stock has been, and is likely to continue to be, volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- adverse results or delays in clinical trials;
- inability to obtain additional funding;
- any delay in submitting a BLA or an NDA for any product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that marketing application;
- failure to successfully develop and commercialize product candidates;
- changes in laws or regulations applicable to product candidates;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for product candidates, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed product development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, collaborations, joint ventures or capital commitments by us or our competitors;
- failure to maintain our collaboration and clinical trial agreements;
- failure of 3D Medicines or Alphamab to perform their obligations under our collaboration and clinical trial agreements, or the actions of 3D Medicines or Alphamab or their other partners with respect to envafolimab in other indications or outside North America;
- failure of Eucure and Biocytogen to perform their obligations under our collaborative development and commercialization agreement, or the actions of Eucure or Biocytogen or their other partners with respect to YH001 in other indications or outside North America, or within North America in combination with other Eucure product candidates;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- the results of our dispute with I-Mab;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- the impact of macroeconomic and geopolitical events, such as general political, health and economic conditions, including the COVID-19 pandemic, economic slowdowns, recessions, inflation, rising interest rates and tightening of credit markets on our business;
- sales of our common stock by us or our stockholders in the future, in particular any sales by significant stockholders or our affiliates; and
- trading volume of our common stock.

In addition, the stock market in general, and the Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations, and we have in the past experienced volatility that has been unrelated or disproportionate to our operating performance. From January 1, 2022 through March 3, 2023, the closing price of our common stock has ranged between $1.22 and $3.00 per share. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from the Nasdaq Capital Market, which could have an adverse impact on the liquidity and market price of our common stock.

Our common stock is currently listed on the Nasdaq Capital Market, which has qualitative and quantitative listing criteria. If we are unable to meet all of the Nasdaq continued listing requirements and at least one of the Nasdaq continued listing standards in the future, including if the closing bid price for our common stock falls below $1.00 per share for 30 consecutive trading days, or if we are unable to maintain at least $2.5 million in stockholders' equity or a market capitalization of at least $35 million, Nasdaq could determine to delist our common stock. For example, on December 30, 2022, we received a letter from the Nasdaq Stock Market LLC (Nasdaq) notifying us that for 30 consecutive business days prior to the date of such letter, the market value of our common stock was less than $35.0 million, which did not meet the requirement for continued listing on the Nasdaq Capital Market, as required by Nasdaq Listing Rule 5550(b)(2) (the "Market Value Rule").

On January 20, 2023, Nasdaq notified us that we had regained compliance with the Market Value Rule because the market value of our common stock was $35.0 million or greater for the ten consecutive business days from January 5, 2023 to January 19, 2023. Although we have regained compliance with Nasdaq continued listing requirements, if we fail to satisfy another Nasdaq requirement for continued listing, Nasdaq staff could provide notice that our common stock may become subject to delisting. If that were to happen, we may not be able to regain compliance. If we cannot regain compliance after any such notice and if our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Additionally, the RGC Loan Agreement contains covenants that restrict our ability to pay dividends or make other distributions. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our development processes that involve proprietary know-how or information that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

General Risk Factors

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations, reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information (collectively, sensitive data) .

Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the California Consumer Privacy Act of 2018(CCPA), applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties for noncompliance (up to $7,500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, it the California Privacy Rights Act of 2020 (CPRA), expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law.

Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon which we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) and the United Kingdom's GDPR (UK GDPR) impose strict requirements for processing personal data

For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Obligations related to data privacy and security are quickly changing becoming increasingly stringent, and creating regulatory uncertainty Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations. If we or the third parties upon which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or our operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to interruptions to our operations such as our clinical trials; regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences..

In the ordinary course of our business, we and the third parties upon which we rely, process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including, but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Third party sites that take part in clinical trials we sponsor or third parties that are also sponsoring clinical trials involving our product candidates or those of our partners, such as NCI and Case Western, face similar threats and any security breach of their systems could adversely affect us. Security breaches could be particularly harmful to our business due to our reliance on internal clinical development functions and systems to conduct our clinical trials. For example, for clinical trials that we conduct, we rely on third party hosted software to manage the resulting clinical data. While the third party vendor is obligated to back up our clinical data on its servers, we do not independently back up our clinical data, and a loss of our clinical data by the third party vendor could result in delays in our development programs, cause us to breach our obligations to our third party collaborators, and significantly increase our costs to recover or reproduce the data.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon which we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon which we rely) to provide our clinical development activities.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities , but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon which we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

Our operations, and those of our contractors, consultants and collaborators, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. To the extent our collaborators are unable to comply with their obligations under our agreements with them or they are otherwise unable to complete or are delayed in completing development activities due to business disruptions, our ability to advance development in the United States may become impaired. In addition, NCI may be affected by government shutdowns in the United States or withdrawn funding, which may lead to suspension or termination of ongoing NCI-sponsored clinical development of our product candidates. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. In addition, our ability and the ability of our partners to obtain clinical supplies of product candidates could be disrupted if the operations of our third party manufacturers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are located in San Diego, California near major earthquake faults and fire zones. The ultimate impact on us and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

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

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and commercial partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate:

- FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state fraud and abuse laws and other healthcare laws;
- laws governing the conduct of business abroad; or
- laws that require the reporting of true and accurate financial information or data.

Additionally, these parties may fail to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third 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 be in compliance with such laws. 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 civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, contractual damages, integrity oversight and reporting obligations, 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.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with additional third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with partners, consultants, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management, including having to divert a disproportionate amount of its attention away from day-to-day operating activities to implement and manage future growth. Our future financial performance and our ability to commercialize product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

If our third party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability, including through obligations to indemnify our third party manufacturers, or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our development and production efforts or those of our third party manufacturers, which could harm our business, prospects, financial condition or results of operations.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our principal executive offices are located at 4350 La Jolla Village Drive, Suite 800, San Diego, California 92122 in a facility we lease encompassing 6,724 square feet of office space pursuant to our August 2021 lease amendment. Our lease expires in April 2027.

Item 3. Legal Proceedings.

Except with respect to our dispute and related proceedings with I-Mab referenced below, we are not currently a party to any material legal proceedings. From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. For a description of our dispute and related proceedings with I-Mab, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 of this Annual Report.

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 Information

Our common stock is listed on the Nasdaq Capital Market under the ticker symbol "TCON".

Holders of Common Stock

As of March 3, 2023, there were approximately 107 holders of record of our common stock. Certain shares of our common stock are held in "street" name and thus the actual number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid any dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. In addition, pursuant to our RGC Loan Agreement, we are prohibited from paying cash dividends or making any distributions or payments in respect of our equity interests, subject to limited exceptions. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 11 of Part III of this Annual Report.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Recent Sales of Unregistered Securities.

None.

Item 6. Reserved.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, timing of future events and future financial performance, includes forward-looking statements that are based upon current beliefs, plans and expectations and involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause our actual results and the timing of selected events to differ materially from those described in or implied by the forward-looking statements contained in the following discussion and analysis. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this Annual Report or to reflect actual outcomes. Please also see the section within Part I of this Annual Report entitled "Forward-Looking Statements."

Overview

We are a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer and utilizing our cost efficient, contract research organization (CRO) independent product development platform to partner with other life science companies to develop and commercialize innovative products in the United States.

In December 2019, we entered into a collaboration and clinical trial agreement (the Envafolimab Collaboration Agreement) with 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) for the development of envafolimab, also known as KN035, an investigational PD-L1 single-domain antibody (sdAb) administered by rapid subcutaneous injection for the treatment of sarcoma in North America. The ENVASARC Phase 2 pivotal trial (the ENVASARC trial) is enrolling a total of 160 patients at 600mg of envafolimab, with 80 patients enrolling at 600mg of envafolimab every three weeks in cohort C, and 80 patients enrolling at 600mg of envafolimab every three weeks in combination with Yervoy® at 1mg/kg every three weeks for four doses in cohort D, in the sarcoma subtypes of undifferentiated pleomorphic sarcoma (UPS) and myxofibrosarcoma (MFS). Nine of 80 responses by blinded independent central review (BICR) in either cohort are needed to satisfy the primary objective of the trial which is to statistically exceed the known 4% objective response rate (ORR) of Votrient® (pazopanib), the only U.S. Food and Drug Administration (FDA)-approved treatment for patients with refractory UPS or MFS. Achieving the primary endpoint of exceeding the known 4% ORR could be the basis for accelerated approval of envafolimab by the FDA as a single agent and/or in combination with Yervoy. The trial will provide at least 86% power to demonstrate the lower bound of the 95% confidence interval is greater than 5% in each cohort, which would be greater than the 4% ORR of Votrient reported in soft tissue sarcoma in its package insert. Votrient is the only approved treatment for refractory soft tissue sarcoma, which includes UPS and MFS.

In August and October 2022, we announced that the ENVASARC trial will proceed as planned after the independent data monitoring committee (IDMC) reviewed three and twelve weeks of safety data, respectively, from more than 20 patients enrolled in the trial as of June 30, 2022. The safety data reviewed included data from more than 10 patients enrolled into cohort C of treatment with single agent envafolimab at 600mg every three weeks and more than 10 patients enrolled into cohort D of treatment with envafolimab at 600mg every three weeks in combination with Yervoy (ipilimumab).

In December 2022, we announced the IDMC recommended continued accrual as planned in both cohorts at the first planned interim efficacy analysis. The IDMC reviewed interim safety and efficacy data from 18 patients enrolled into each cohort who completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans). The double-digit ORR assessed by BICR in each cohort exceeded the prespecified futility rule that required at least one response among the initial 18 patients enrolled at 600mg into each cohort. Envafolimab monotherapy (cohort C) and in combination with Yervoy (cohort D) was well tolerated, with only a single related serious adverse event reported in 36 patients. A second interim efficacy analysis is planned following the 12-week efficacy scan in the 92nd dosed patient, to allow for determination of the preliminary ORR, which we expect in the third quarter of 2023. There must be at least three responses among the initial 46 patients enrolled at 600mg into each cohort to continue enrollment in that cohort per the futility rule of the trial.

In September 2022, we announced that the FDA had granted us fast track designation for the development of envafolimab for patients with locally advanced, unresectable or metastatic UPS and MFS who have progressed on one or two prior lines of chemotherapy. We are also eligible to apply for breakthrough therapy designation based on data from the ENVASARC clinical trial. We expect to complete enrollment by the end of 2023, have final response assessment data including duration of response in all patients from the ENVASARC trial in mid-2024, and, assuming positive data, to submit a biologics license application (BLA) to the FDA seeking accelerated approval in 2024. At any time that we reach nine responses in each cohort and meet the endpoint, we expect to discuss the submission process with the FDA.

Our other clinical stage oncology product candidates include YH001, which is a monospecific investigational cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) antibody, that we licensed from Eucure (Beijing) Biopharma Co., Ltd. (Eucure) and Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen) in October 2021, TRC102, which is a small molecule that has been studied in Phase 1 and Phase 2 trials for the treatment of mesothelioma, lung cancer, glioblastoma and solid tumors, and TJ004309, which is a CD73 antibody in Phase 1 clinical development for the treatment of solid tumors, that we licensed from I-Mab Biopharma (I-Mab) in November 2018.

YH001 is an investigational humanized CTLA-4 IgG1 monoclonal antibody that completed dosing in two Phase 1 trials sponsored by Eucure for the treatment of various cancer indications. CTLA-4 is a protein expressed on T-cells and expressed at high levels specifically on regulatory T-cells that act as a checkpoint to inhibit effector T-cell immune responses to cancer cells. The CTLA-4 inhibitor Yervoy (ipilimumab) marketed by BMS has been approved as a single agent in melanoma and approved in combination with other therapies in multiple indications including non-small cell lung cancer, renal cell carcinoma (RCC) and microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer. Data from the Phase 1 dose escalation trial in Australia of YH001 in combination with the PD-1 antibody, toripalimab, were presented at the American Society of Clinical Oncology 2022 Annual Meeting. YH001 was well tolerated up to 4 mg/kg when combined with toripalimab in the 24 patients as of the December 31, 2021 data cut-off date. The Phase 1 dose escalation trial in China of YH001 as a single agent, recently completed enrollment and determined a recommended Phase 2 dose. We expect data to be presented in the second half of 2023. No CTLA-4 therapy is approved by the FDA for the treatment of soft tissue sarcoma.

In August 2022, we announced that the FDA had approved the Investigational New Drug (IND) application for the initiation of a Phase 1/2 clinical trial of YH001 in combination with envafolimab and doxorubicin, an approved treatment for soft tissue sarcoma, for the treatment of sarcoma patients and in December 2022, we initiated dosing in the Phase 1/2 clinical trial. The Phase 1/2 trial will assess the safety and efficacy of the triplet combination of YH001, envafolimab and doxorubicin in the common sarcoma subtypes of leiomyosarcoma and dedifferentiated liposarcoma, and we expect Phase 1 data in the second half of 2023. In addition, the trial will assess the safety and efficacy of the doublet combination of YH001 and envafolimab in patients with the rare sarcoma subtypes of alveolar soft part sarcoma and chondrosarcoma. Additionally, we plan to initiate trials of YH001 as a single agent or in combination with immunotherapies in other tumor types.

TRC102 is a small molecule in clinical development to reverse resistance to specific chemotherapeutics by inhibiting DNA base excision repair (BER). In initial clinical trials of more than 100 patients, TRC102 has shown good tolerability and we believe promising anti-tumor activity in combination with alkylating and antimetabolite chemotherapy for the treatment of cancer patients. TRC102 has been studied in Phase 1 or Phase 2 trials in mesothelioma patients in combination with the approved chemotherapeutic Alimta® (pemetrexed), in glioblastoma, ovarian cancer, lung and colorectal cancer patients in combination with the approved chemotherapeutic Temodar® (temozolomide) and in lung cancer patients in combination with the approved chemotherapeutics Alimta and cisplatin as well as external beam radiation (i.e., chemoradiation). All current TRC102 trials are sponsored and funded by the National Cancer Institute (NCI). We retain global rights to develop and commercialize TRC102 in all indications. In October 2020, we received orphan drug designation (ODD) from the FDA for TRC102 for the treatment of patients with malignant glioma, including glioblastoma. O6-methylguanine DNA methyltransferase (MGMT) deficiency is observed in about one-third of glioblastoma patients, and a prior study of Temodar and TRC102 reported at the Society for Neuro-Oncology in 2018 demonstrated that two MGMT deficient glioblastoma patients had prolonged survival when treated with Temodar and TRC102 after progressing previously on Temodar and radiation therapy. A December 2020 publication in Cancer Cell also demonstrated Temodar and TRC102 were active in MGMT deficient patients with colorectal cancer. Based on these data, we believe a trial in first line glioblastoma patients of Temodar, radiation therapy and TRC102 is warranted and are discussing further development with investigators at this time. In addition, based on data presented at the ASCO 2020 virtual meeting that the combination of chemoradiation and TRC102 produced objective responses in all 15 evaluable patients with advanced localized lung cancer treated in a Phase 1 trial, in January 2022, the NCI initiated a randomized Phase 2 trial of chemoradiation with or without TRC102, followed by consolidative durvalumab treatment. The primary objective is to improve the 56% one-year progression free survival (PFS) rate with current standard of care to 75% with current standard of care plus TRC102. The trial began enrollment in June 2022 and is expected to be complete in 2025.

TJ004309, also known as TJD5 or ulileDlimab, is a novel humanized antibody against CD73 expressed on stromal cells and tumors that converts extracellular adenosine monophosphate (AMP) to the immunosuppressive metabolite adenosine. We are developing TJ004309 in collaboration with I-Mab under a strategic collaboration and clinical trial agreement that we entered into in November 2018 (the TJ004309 Agreement). In July 2019, we began enrollment in a Phase 1 clinical trial to assess safety and preliminary efficacy of TJ004309 as a single agent and when combined with the PD-L1 checkpoint inhibitor Tecentriq® in patients with advanced solid tumors, and in June 2021 we presented data from the ongoing Phase 1 trial at the ASCO 2021 virtual meeting. In a poster presentation titled “The safety, pharmacokinetics (PK), pharmacodynamics (PD) and clinical efficacy of ulileDlimab (TJ004309), a differentiated CD73 antibody, in combination with atezolizumab in patients with advanced cancer,” ulileDlimab was found to be well-tolerated up to 20mg/kg every three weeks and 15mg/kg once weekly as a monotherapy and in combination therapy with atezolizumab 1200mg every three weeks and no dose limiting toxicity (DLT) was observed and the maximum tolerated dose (MTD) was not reached. There was one complete response in a PD-(L)1 naïve patient, two partial responses (PRs) with one PR in a PD-(L)1 naïve patient and one PR in a PD-(L)1 refractory patient, and three cases of stable disease (SD) following treatment with ulileDlimab and atezolizumab.

We entered into a separate strategic collaboration and clinical trial agreement (the Bispecific Agreement) which allows for the development of up to five of I-Mab’s proprietary bispecific antibody (the BsAb) product candidates to be nominated by I-Mab within a five-year period for development and commercialization in North America, with the option to opt-in and acquire product rights outside of Greater China and Korea prior to completing the first pivotal clinical trial for any bispecific product candidate.

In March 2020, I-Mab issued a press release announcing a strategic partnership with Kalbe Genexine Biologics (KG Bio), whereby KG Bio received what the press release described as a right of first negotiation outside North America for TJ004309 for up to $340 million in potential payments to I-Mab. In March 2020, we also learned that I-Mab had entered into two license and collaboration agreements with ABL Bio in July 2018 (ABL Bio License 1 and ABL Bio License 2). Under ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I-Mab and ABL agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio’s proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce (the ICC) before an arbitration tribunal seated in New York City (the Tribunal) after we invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations concerning two strategic collaboration and clinical trial agreements with us entered into in November 2018. Those strategic collaboration and clinical trial agreements relate to the development of TJ004309 and five of I-Mab's proprietary bispecific antibody product candidates to be nominated by I-Mab within a five-year period for development and commercialization in North America. We filed counterclaims in the arbitration seeking to recover over $200 million in damages from I-Mab based on I-Mab's breaches of the two strategic collaboration and clinical trial agreements. In 2021, I-Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is "Complete," as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I-Mab's termination. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking a variety of relief including an order of specific performance requiring us to comply with I-Mab's purported termination of the TJ004309 Agreement. In May 2021, the Delaware Court of Chancery stayed the lawsuit in favor of arbitration. The Tribunal held a hearing on the merits in February 2022, and final post-hearing briefs were submitted by us and I-Mab in May 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties submitted their respective cost submissions for attorney fees reimbursement in January 2023. The Tribunal did not indicate when it expects to render its final decision; however, it did note that it was far along in its deliberations and preparation of a final award. We expect the Tribunal to render its final decision in the first quarter of 2023.

Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal's discretion. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. The dispute with I-Mab has caused, and could continue to cause, us to incur significant costs.

The following table summarizes key information regarding ongoing and planned development of our clinical stage product candidates:

	Phase	Data Expected
Envafolimab		
Soft Tissue Sarcoma (UPS and MFS)	Pivotal Phase 2	Interim Data – Q3 2023 Final Data – mid-2024
Envafolimab + YH001		
Multiple Soft Tissue Sarcoma Subtypes	Phase 1/2 (planned)	Second half of 2023 and 2024
TRC102		
Lung Cancer	Randomized Phase 2	2025

We utilize a CRO-independent product development platform that emphasizes capital efficiency. Our experienced clinical operations, data management, quality assurance, product development and regulatory affairs groups manage significant aspects of our clinical trials with internal resources. We use these internal resources to reduce the costs associated with utilizing CROs to conduct clinical trials. In our experience, this model has resulted in capital efficiencies and improved communication with clinical trial sites, which can expedite patient enrollment and improve the quality of patient data as compared to a CRO-managed model. We have leveraged this platform in all of our sponsored clinical trials. We have also leveraged our product development platform to diversify our product pipeline without payment of upfront license fees through license agreements with Eucure and Biocytogen, 3D Medicines and Alphamab, I-Mab, and Janssen. We continue to evaluate life science companies that would benefit from a rapid and capital-efficient U.S. drug development solution that includes U.S. and European Union (EU) clinical development expertise. We believe we will continue to be recognized as a preferred U.S. clinical development partner through a cost- and risk-sharing partnership structure, which may include U.S. commercialization.

Our goal is to be a leader in the development of targeted therapies for patients with cancer and other diseases of high unmet medical need.

Since our inception in 2004, we have devoted substantially all of our resources to research and development efforts relating to our product candidates, including conducting clinical trials, in-licensing related intellectual property, providing general and administrative support for these operations, and protecting our intellectual property. To date, we have not generated any revenue from product sales and instead, have funded our operations from the sales of equity securities, payments received in connection with our collaboration agreements, and commercial bank debt. At December 31, 2022, we had cash and cash equivalents totaling $17.5 million, of which $0.1 million is pledged as collateral for our obligations under our corporate headquarters facility lease.

We do not own or operate, nor do we expect to own or operate, facilities for product manufacturing, storage, distribution or testing. We contract with third parties or our collaboration partners for the manufacture of our product candidates and we intend to continue to do so in the future.

We have incurred losses from operations in each year since our inception. Our net losses were $29.1 million and $28.7 million for the fiscal years ended December 31, 2022 and 2021, respectively. At December 31, 2022, we had an accumulated deficit of $236.9 million.

We expect to continue to incur significant expenses and operating losses for at least the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our current level of research and development expenses to increase in 2023 as we:

- continue to enroll the ENVASARC trial and Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes;
- continue our research and development efforts;
- in-license additional product candidates for development and commercialization; and
- seek regulatory approvals for product candidates that successfully complete clinical trials.

We do not expect to generate any revenues from product sales until we successfully complete development and obtain regulatory approval for one or more product candidates, which we expect will take a number of years. If we obtain regulatory approval for any product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, and distribution. Accordingly, we will need to raise substantial additional capital. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts, developments under our collaboration agreements, including whether and when we receive milestone and other potential payments, the outcome of our dispute with I-Mab, and the timing and nature of the regulatory approval process for product candidates. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources. Debt financing, if available, may involve covenants further restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Further, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. As a result of the COVID-19 pandemic and actions taken to slow its spread, as well as adverse macroeconomic and geopolitical developments, such as the ongoing military conflict between Ukraine and Russia, actual and anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and ability to develop product candidates.

Collaboration and License Agreements

Collaboration Agreement with 3D Medicines and Alphamab

In December 2019, we, 3D Medicines, and Alphamab entered into the Envafolimab Collaboration Agreement for the development of envafolimab, an investigational PD-L1 sdAb, or nanobody, administered by rapid subcutaneous injection, for the treatment of sarcoma in North America.

Pursuant to the Envafolimab Collaboration Agreement, we were granted an exclusive license to develop and commercialize envafolimab for the treatment of sarcoma in North America. We are responsible for conducting and will bear the costs of any Phase 1, Phase 2, and Phase 3 or post-approval clinical trial in North America for envafolimab in the indications of refractory and first line treatment of sarcoma. 3D Medicines and Alphamab are responsible for conducting and will bear the costs of investigational new drug (IND)-enabling studies (other than those specific to the sarcoma indication) and the preparation of the chemistry, manufacturing and controls (CMC) activities sections of an IND application for envafolimab. 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third-party manufacturer to manufacture and supply, envafolimab to us at pre-negotiated prices that vary based on clinical or commercial use. 3D Medicines and Alphamab retained the right to develop envafolimab in all territories outside of North America as well as within North America for all indications other than sarcoma.

We will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue, unless (a) envafolimab is first approved in North America for an indication other than sarcoma and launched in North America, or (b) envafolimab is first approved in North America for sarcoma and subsequently approved in North America for an additional non-orphan indication and sold commercially by 3D Medicines and/or Alphamab, or licensee, in which case 3D Medicines and Alphamab will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue. If 3D Medicines and Alphamab become responsible for commercialization under the Envafolimab Collaboration Agreement, we have the option to co-market envafolimab for sarcoma in North America. In the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace us as the party responsible for commercialization, and we elect and 3D Medicines and Alphamab agree for us to not co-market envafolimab for sarcoma in North America, then 3D Medicines and Alphamab will be required to compensate us for our costs associated with preparing for and conducting commercial activities.

If we have the responsibility for commercialization under the Envafolimab Collaboration Agreement, we will owe 3D Medicines and Alphamab tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits. If 3D Medicines and Alphamab have responsibility for commercialization under the Envafolimab Collaboration Agreement, we will be entitled to (a) tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if we have elected to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if we have chosen to co-market envafolimab in sarcoma. Payment obligations under the Envafolimab Collaboration Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

3D Medicines and Alphamab retain the right to reacquire the rights to envafolimab for sarcoma in North America in connection with an arm's length sale to a third party of the rights to develop and commercialize envafolimab in North America for all indications, provided that the sale may not occur prior to completion of a pivotal trial of envafolimab in sarcoma without our written consent and the parties must negotiate in good faith and agree to fair compensation be paid to us for the value of and opportunity represented by the reacquired rights.

Each party agreed that during the term of the Envafolimab Collaboration Agreement, it would not develop or license from any third party a monospecific inhibitor to PD-L1 or PD-1 in sarcoma.

The term of the Envafolimab Collaboration Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in North America or the expiration of all payment obligations. The Envafolimab Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab. In the event we elect, or a joint steering committee (JSC) determines, to cease further development or commercialization of envafolimab, or if we fail to use commercially reasonable efforts to develop (including progress in clinical trials) and commercialize envafolimab and do not cure such failure within a specified time period, then our rights and obligations under the Envafolimab Collaboration Agreement will revert to 3D Medicines and Alphamab.

Collaboration Agreement with Eucure and Biocytogen

In October 2021, we, Eucure and Biocytogen entered into a collaborative development and commercialization agreement (the YH001 Collaboration Agreement) for the development of YH001, a monospecific investigational CTLA-4 antibody. Pursuant to the YH001 Collaboration Agreement, we were granted an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment, through administration of YH001 by intravenous or subcutaneous means, of multiple human indications, including sarcoma, microsatellite stable colorectal cancer, RCC, and K-ras positive non-small cell lung cancer (collectively, the Initial Indications) or one or more of bladder cancer, endometrial cancer, and melanoma as substitute indications, which may be substituted for Initial Indications at our discretion (each upon such substitution, a Substitute Indication). We are responsible for, and will bear the costs of, preparing and filing all regulatory submissions and conducting any Phase 1, Phase 2, Phase 3, or post-approval clinical trials in North America for YH001 in the Initial Indications and potentially the Substitute Indications, while Eucure is responsible for conducting, and will bear the costs of, the preparation of CMC activities for YH001. Eucure has agreed to manufacture and supply, or to arrange for a third-party manufacturer to manufacture and supply, YH001 to us for clinical trials pursuant to the terms of a clinical supply and quality agreement that will be separately negotiated and agreed in good faith between the parties.

Eucure may pursue clinical trials for YH001 in North America outside of the Initial Indications or Substitute Indications, and also within the Initial Indications or Substitute Indications as part of a combination therapy of YH001 and an additional Eucure product. During a specified period, we have the option, subject to Eucure's prior written approval, to expand the license to include the development and commercialization of YH001 for the treatment, through administration by intravenous or subcutaneous means, of all human and veterinary therapeutic indications in North America for a payment to Eucure in the low single digit millions (the Company Option).

Pursuant to the YH001 Collaboration Agreement, we granted Eucure an irrevocable, perpetual, royalty-free, exclusive license, with the right to grant sublicenses to develop, register, sell, offer to sell, have sold, market and distribute YH001 in all territories outside of North America as well as within North America for all indications other than the Initial Indications and the Substitute Indications.

We will be responsible for commercializing YH001 in North America, including booking of sales revenue in the Initial and Substitute Indications. We will owe Eucure escalating double digit royalties on net sales of YH001 in North America ranging from the mid-twenties to mid-double digits; provided that until the end of the first full calendar year following the first commercial sale of YH001, royalties will range from the lower double digits to the mid-double digits. If sales of YH001 exceed a pre-determined sales threshold in the first full year of sales following first commercial sale, we will owe a milestone to Eucure in the high single digit millions. Payment obligations under the YH001 Collaboration Agreement continue on a country-by-country basis until the latest of (i) expiration of the last to expire licensed patent covering YH001, (ii) expiration of marketing or regulatory exclusivity covering YH001 and (iii) 10 years from the first commercial sale of YH001 in such country in North America. Eucure has agreed to manufacture and supply, or to arrange for a third-party manufacturer to manufacture and supply, YH001 to us at cost plus a low double-digit markup for commercial sales pursuant to the terms of a commercial supply and quality agreement that will be separately negotiated and agreed in good faith between the parties within 180 days prior to the anticipated first commercial sale in North America.

Pursuant to the YH001 Collaboration Agreement, each party agreed that during the term of the YH001 Collaboration Agreement, it would not develop, manufacture, commercialize or license from any third party a monospecific inhibitor to CTLA-4.

The term of the YH001 Collaboration Agreement continues until the earlier of (i) the date that the parties cease further development and commercialization of YH001 in North America or (ii) on a country-by-county basis, the expiration of the royalty obligations in such country. The YH001 Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to YH001. In the event of a termination of the YH001 Collaboration Agreement, other than by us as a result of Eucure's material uncured breach or bankruptcy, (i) our license shall terminate and (ii) we would be obligated to grant Eucure an irrevocable, perpetual, royalty-free, non-exclusive license with the right to grant sublicenses under its rights in all development data and intellectual property to develop, register, sell, offer to sell, have sold, market and distribute YH001 in North America. In the event of a termination of the YH001 Collaboration Agreement by us as a result of Eucure's material uncured breach or bankruptcy, the license shall continue in the Initial Indications in North America, provided that (i) such license shall remain exclusive during the royalty term and non-exclusive thereafter; (ii) we shall have the right to have YH001 manufactured for its development and commercialization requirements in the Initial Indications in North America; and (iii) the license shall terminate in the event of an uncured material breach by us of any provision (including payment obligations) that survives termination of the YH001 Collaboration Agreement. In the event the YH001 Collaboration Agreement terminates for safety reasons related to YH001, by mutual agreement of the parties or by Eucure in the event of an uncured material breach or bankruptcy by us, then our rights and obligations under the YH001 Collaboration Agreement will revert to Eucure. In the event Eucure does not approve the Company Option, we may terminate the YH001 Collaboration Agreement for convenience with a 30-day notice to Eucure, provided that such termination is given within 12 months of the effective date of the YH001 Collaboration Agreement (the Company Option Termination). In the event of a Company Option Termination, Eucure would be obligated to reimburse us for all costs and expenses that we incurred in performing the development activities.

Collaboration Agreements with I-Mab Biopharma

In November 2018, we entered into two separate strategic collaboration and clinical trial agreements with I-Mab for the development of multiple immuno-oncology programs, including I-Mab's proprietary CD73 antibody TJ004309 as well as up to five proprietary bispecific antibodies currently under development by I-Mab.

In the TJ004309 Agreement, we are collaborating with I-Mab on developing TJ004309, and will bear the costs of filing an IND application and for Phase 1 clinical trials, share costs equally for Phase 2 clinical trials, and we will bear 40% and I-Mab 60% of the costs for pivotal clinical trials. I-Mab will also be responsible for the cost of certain non-clinical activities and the supply of TJ004309 and any reference drugs used in the development activities. We also agreed with I-Mab for a specified period of time to not develop or license to or from a third party any monoclonal antibody targeting CD73 or any other biologic for certain indications that a JSC, as set up under the TJ004309 Agreement, selects for TJ004309 development.

In the event that I-Mab licenses rights to TJ004309 to a third party, we would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to territories outside of Greater China. In the event that I-Mab commercializes TJ004309, we would be entitled to receive a royalty on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the EU and Japan in the mid-single digits. The portions of certain third party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which we would be entitled escalate based on the phase of development and relevant clinical trial obligations we complete under the TJ004309 Agreement, ranging from a high-single digit to a mid-teen percentage of non-royalty consideration as well as a double digit percentage of royalty consideration. In March 2020, I-Mab issued a press release announcing a strategic partnership with KG Bio, whereby KG Bio received what the press release described as a right of first negotiation outside North America for TJ004309 for up to $340 million in potential payments to I-Mab. On April 8, 2020, we issued a notice of dispute regarding possible breach of the TJ004309 Agreement, which resulted in a binding arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal. The latest developments in the dispute with I-Mab are discussed in more detail below following the discussion of the Bispecific Agreement.

The TJ004309 Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to TJ004309. I-Mab may also terminate the TJ004309 Agreement if we cause certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJ004309 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical trial, in which case we would be entitled to a minimum termination fee of $9.0 million, or following the completion of the first Phase 2 clinical trial, in which case we would be entitled to a pre-specified termination fee of $15.0 million and either a percentage of non-royalty consideration I-Mab may receive as part of a license to a third party or an additional payment if TJ004309 is approved for marketing outside Greater China before a third party license is executed, in addition to a double digit percentage of royalty consideration. In 2021, I-Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is “Complete,” as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I-Mab’s termination. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking an order of specific performance requiring us to comply with I-Mab’s effort to terminate the agreement. We disagreed with I-Mab’s position and in May 2021, the Delaware Court of Chancery stayed the lawsuit filed by I-Mab and subsequently this matter was remanded and included in the proceeding before the Tribunal.

Pursuant to the Bispecific Agreement, we and I-Mab may mutually select through a JSC up to five of I-Mab’s BsAb product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, we will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical trials, and we will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical trials, in each case within North America. Subject to I-Mab’s right to co-promote an approved product candidate, we will be responsible for commercializing any approved product candidates in North America, and we will share profits and losses equally with I-Mab in North America. We would also be entitled to receive tiered low single digit royalties on net sales of product candidates in the EU and Japan.

At any time prior to completing the first pivotal clinical trial for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical trial costs for a product candidate or the JSC decides to cease development over our objections after initiating Phase 3 clinical trials, we will have an option to obtain an exclusive license to such product candidate in all territories except Greater China and Korea and any other territories in which I-Mab previously licensed rights to a third party subject to our right of first refusal for any licenses I-Mab may grant to third-parties.

If we exercise our licensing option, we would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, we would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time we obtained the exclusive license as follows: (i) if before IND-enabling studies and the preparation of the CMC activities of the collaborative product, we would owe I-Mab a one-time upfront payment of $10.0 million, development and regulatory based milestone payments totaling up to $90.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the mid-single digits on annual net sales; (ii) if after IND submission but before completion of a Phase 1a clinical trial of the collaborative product, we would owe I-Mab a one-time upfront payment of $25.0 million, development and regulatory based milestone payments totaling up to $125.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the high single digits on annual net sales; (iii) if after completion of a Phase 1a clinical trial but before completion of a Phase 2 proof of concept clinical trial for the collaborative product, we would owe I-Mab a one-time upfront payment of $50.0 million, development and regulatory based milestone payments totaling up to $250.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the low double digits on annual net sales; and (iv) if after completion of a Phase 2 proof of concept clinical trial and before completion of a pivotal trial for the collaborative product, we would owe I-Mab a one-time upfront payment of $80.0 million, development and regulatory based milestone payments totaling up to $420.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the high-teens on annual net sales.

Each party agreed that for a specified period of time, it would not develop or license to or from any third party any bispecific monoclonal antibody targeting the same two biological targets as those of any selected product candidates under the Bispecific Agreement.

If development of any selected product candidates is terminated by a decision of the JSC, all rights to the product candidate will revert to I-Mab, subject to our rights to obtain an exclusive license in certain circumstances. If development is terminated after submission of an IND and prior to initiating Phase 3 clinical studies or after initiating Phase 3 clinical studies and with our concurrence, we would be entitled to tiered low single digit royalties on net sales of the product candidate in North America, the EU and Japan.

The Bispecific Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or with respect to any selected product candidate, for safety reasons related to that product candidate.

In March 2020, we learned that I-Mab had entered into two license and collaboration agreements with ABL Bio in July 2018. Under ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I-Mab and ABL agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal after we invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations concerning the TJ004309 Agreement and Bispecific Agreement. We filed counterclaims in the arbitration seeking to recover over $200 million in damages from I-Mab based on I-Mab's breaches of the two strategic collaboration and clinical trial agreements. In 2021, I-Mab sent us notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing us a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is "Complete," as that term is defined in the TJ004309 Agreement, and we responded by disputing the basis for I-Mab's termination. However, we believe we "completed" the TJ004309 Phase 1 trial in November 2022. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking a variety of relief including an order of specific performance requiring us to comply with I-Mab's purported termination of the TJ004309 Agreement. In May 2021, the Delaware Court of Chancery stayed the lawsuit in favor of arbitration. The Tribunal held a hearing on the merits in February 2022, and final post-hearing briefs were submitted by us and I-Mab in May 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties submitted their respective cost submissions for attorney fees reimbursement in January 2023. The Tribunal did not indicate when it expects to render its final decision; however, it did note that it was far along in its deliberations and preparation of a final award. Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal's discretion. As of the date of this Annual Report, the TJ004309 Agreement and Bispecific Agreement disputes remain under consideration by the Tribunal, and we expect the Tribunal to render its final decision in the first quarter of 2023. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. The dispute with I-Mab has caused, and could continue to cause, us to incur significant costs.

License Agreement with Case Western

Under our license agreement with Case Western, we may be required to pay up to an aggregate of approximately $9.8 million in milestone payments, of which $0.7 million relates to the initiation of certain development activities ($0.2 million of which has been paid) and approximately $9.1 million relates to the submission of certain regulatory filings and receipt of certain regulatory approvals. If products utilizing certain intellectual property licensed from Case Western (the TRC102 Technology) are successfully commercialized, we will be required to pay Case Western a single-digit royalty on net sales, subject to adjustments in certain circumstances. Beginning on the earlier of a specified number of years from the effective date of the agreement and the anniversary of the effective date following the occurrence of a specified event, we will be required to make a minimum annual royalty payment of $75,000, which will be credited against our royalty obligations. In the event we sublicense any of our rights under the agreement relating to the TRC102 Technology, we will be obligated to pay Case Western a portion of certain fees we may receive under the sublicense. Our royalty obligations will continue on a country-by-country basis through the later of the expiration of the last valid claim under the TRC102 Technology or 14 years after the first commercial sale of a product utilizing the TRC102 Technology in a given country.

Financial Operations Overview

Revenue

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing of any additional collaboration agreements and recognition of associated upfront and milestone payments, and the extent to which any of our products are approved and successfully commercialized by us or our partners. If we or our partners fail to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues, our results of operations and our financial position could be adversely affected.

Research and Development Expenses

Research and development expenses consist of costs associated with the preclinical and clinical development of product candidates. These costs consist primarily of:

- salaries and employee-related expenses, including stock-based compensation and benefits for personnel in research and development functions;
- costs incurred under clinical trial agreements with investigative sites;
- costs to acquire preclinical study and clinical trial materials;
- costs associated with conducting our preclinical, development and regulatory activities, including fees paid to third party professional consultants, service providers and our scientific advisory board;
- payments related to licensed products and technologies; and
- facilities, depreciation and other expenses, including allocated expenses for rent and maintenance of facilities.

Research and development costs, including third party costs reimbursed in connection with our collaboration agreements, are expensed as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received.

The following table summarizes our research and development expenses by product candidate for the periods indicated:

	Years Ended December 31,		
	2022	2021	2020
	(in thousands)		
Third-party research and development expenses:			
Envafolimab	$ 7,570	$ 5,704	$ 1,107
YH001	390	3	—
TRC102	379	142	197
TJ004309	320	825	1,553
Total third-party research and development expenses	8,659	6,674	2,857
Unallocated expenses	5,229	4,472	5,341
Total research and development expenses	$ 13,888	$ 11,146	$ 8,198

Unallocated expenses consist primarily of our internal personnel and facility related costs.

We expect our current level of research and development expenses to increase in 2023 primarily due to the continued enrollment of the ENVASARC trial and Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes.

We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

The costs of clinical trials to us and the timing of such costs may vary significantly based on factors such as:

- the extent to which costs for comparator drugs are borne by third parties;
- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the effects of macroeconomic and geopolitical developments;
- the phase of development of the product candidate;
- the efficacy and safety profile of the product candidate; and
- the extent to which costs are borne by third parties such as the NCI.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance and administration, corporate development and administrative support functions, including stock-based compensation expenses and benefits. Other significant general and administrative expenses include legal services, including those associated with the TJ004309 Agreement and Bispecific Agreement arbitration, insurance, occupancy costs, accounting services, and the cost of various consultants.

We anticipate that our general and administrative expenses will decrease in 2023; however, there may be increases to the extent we have to expend additional legal fees in connection with enforcing and collecting any arbitration award from I-Mab.

Other Income (Expense)

Other income (expense) primarily consists of interest related to our loan agreements with SVB, which was terminated in June 2022, and RGC offset in part by interest income from our cash equivalents and investing activities.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, as well as the reported revenues and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience and on various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies related to revenue recognition, expense accruals, and stock-based compensation are most critical to understanding and evaluating our reported financial results.

Revenue Recognition

We did not recognize any revenue during the year ended December 31, 2022. Our revenue during the year ended December 31, 2021 was derived from our 2021 license and supply agreement with Enviro and Kairos. The terms of this arrangement included payments to us for the following: a non-refundable, up-front license fee; equity ownership in Enviro; financing milestone payments; and royalties on net sales of the licensed product. In accordance with Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, we perform the following five steps in determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of these agreements: (i) identification of the contract(s) with a customer; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services transferred to the customer. Once a contract is determined to be within the scope of Accounting Standards Codification 606, Revenue from Contracts with Customers, at contract inception, we assess the goods or services promised within the contract to determine those that are performance obligations and assess whether each promised good is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied.

As part of the accounting for these types of arrangements, we develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

Licenses of intellectual property: If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, we evaluate whether the achievement of the milestones is considered probable and estimate the amount to be included in the transaction price using the most likely amount method. Performance milestone payments represent a form of variable consideration. If it is probable that a significant revenue reversal would not occur, the associated milestone payment is included in the transaction price. Achievement of milestones that are not within our control or the licensee, such as regulatory approvals, are not considered probable until the approvals are achieved. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achieving such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the outset of the arrangement.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our out-licensing arrangements.

We receive payments from our collaborators based on billing schedules established in each contract. Up-front payments and fees may require deferral of revenue recognition to a future period until we perform our obligations under the collaboration arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Clinical Trial Expense Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate expenses resulting from our obligations under contracts with vendors, clinical sites, and consultants in connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

Our objective is to reflect the appropriate trial expenses in our consolidated financial statements by recording those expenses in the period in which services are performed and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials. During the course of a clinical trial, we adjust the clinical expense recognition if actual results differ from our estimates. We make estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical accruals are dependent upon accurate reporting by third-party vendors. Although we do not expect our estimates to differ materially from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period. For the three years ended December 31, 2022, there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

Other Company Information

Net Operating Loss and Research and Development Tax Credit Carryforwards

As of December 31, 2022, we had federal and California NOL carryforwards of $194.3 million and $144.5 million, respectively. The federal and California NOL carryforwards will begin to expire in 2030 and 2033, respectively, if not utilized. The federal NOL generated after 2017 of $111.1 million will carryforward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. As of December 31, 2022, we also had federal research and development and Orphan Drug tax credit carryforwards of $13.7 million and California research and development tax credit carryforwards of $3.0 million. The federal research and development and Orphan Drug tax credit carryforwards will begin expiring in 2031 and 2036, respectively, if not utilized. The California research credit will carry forward indefinitely under current law.

Pursuant to Sections 382 and 383 of the Code, our annual use of our NOL and research and development credit carryforwards may be limited in the event that a cumulative change in ownership of more than 50% occurs within a three-year period. We completed a Section 382/383 analysis regarding the limitation of our NOL and research and development credit carryforwards as of December 31, 2018 and did not identify a cumulative change in ownership of more than 50% within the proceeding three-year period. Future ownership changes, including changes during the year ended December 31, 2022, may limit our ability to utilize our remaining NOL and research and development tax credit carryforwards. As of December 31, 2022, we had a full valuation allowance against our deferred tax assets.

Results of Operations

This section discusses our results of operations for the year ended December 31, 2022 as compared to the year ended December 31, 2021. For a discussion and analysis of the year ended December 31, 2021 compared to the year ended December 31, 2020 please refer to the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations included in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 15, 2022.

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	Years Ended December 31,		
	2022	2021	Change
	(in thousands)		
License revenue	$ —	$ 346	$ (346)
Research and development expenses	13,888	11,146	2,742
General and administrative expenses	14,006	17,547	(3,541)
Total other expense	(1,241)	(320)	(921)

License revenue. License revenue was $0.3 million for the year ended December 31, 2021 and related to revenue recognized under the Enviro license agreement with no corresponding revenue in the comparable period in 2022.

Research and development expenses. Research and development expenses were $13.9 million and $11.1 million for the years ended December 31, 2022 and 2021, respectively. The increase of $2.7 million was primarily due to the continued enrollment of the ENVASARC trial. We expect research and development expenses to continue to increase in future periods primarily due to our continued enrollment of the ENVASARC trial and Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes.

General and administrative expenses. General and administrative expenses were $14.0 million and $17.5 million for the years ended December 31, 2022 and 2021, respectively. The decrease of $3.5 million was primarily due to legal expenses incurred in 2021 in connection with the arbitration proceeding of our dispute with I-Mab regarding the TJ004309 Agreement and Bispecific Agreement. We expect continued decreases from legal expenses in future periods as we and I-Mab submitted our arbitration post-hearing briefs in May 2022. However, there may be increases to the extent we must expend additional legal fees in connection with enforcing and collecting any arbitration award from I-Mab.

Other expense. Other expense was $1.2 million and $0.3 million for the years ended December 31, 2022 and 2021, respectively. The increase of $0.9 million was primarily due to noncash interest expense incurred associated with the RGC Loan Agreement and the impairment of our investment in a privately held company which was received as partial consideration under the 2021 Enviro license agreement.

Liquidity and Capital Resources

Our sources of cash liquidity include our cash and cash equivalents. We believe that our cash and cash equivalents as of December 31, 2022 will be sufficient to fund the current requirements of working capital and other financial commitments, including our long-term debt and operating lease obligations, into mid-2023. Based on our current business plan, we believe that there is substantial doubt as to whether our existing cash and cash equivalents will be sufficient to meet our obligations as they become due within one year from the date the consolidated financial statements are issued.

We may fund our future liquidity needs by selling shares of our common stock under our existing Capital on Demand™ sales agreement with JonesTrading Institutional Services LLC (JonesTrading). In addition, we periodically consider various other financing alternatives, including debt financings, in order to meet our liquidity needs and may, from time to time, seek to take advantage of favorable interest rate environments, if any, or other market conditions.

We have incurred losses and negative cash flows from operations since our inception. As of December 31, 2022, we had an accumulated deficit of $236.9 million, and we expect to continue to incur net losses for the foreseeable future. We expect our current level of research and development expenses to increase in 2023 primarily due to the continued enrollment of the ENVASARC trial and Phase 1/2 clinical trial of YH001 in combination with envafolimab in certain sarcoma subtypes. Given we do not anticipate any revenues from product sales in the foreseeable future, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third-party funding, and licensing or collaboration arrangements.

As of the date of this Annual Report, the TJ004309 Agreement and Bispecific Agreement dispute with I-Mab remain under consideration by the Tribunal, and we expect their final decision in the first quarter of 2023. The claims under the arbitration are complex; accordingly, we cannot predict the outcome of the arbitration, and we are unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal. If the Tribunal does decide to award us certain amounts in the arbitration and we were able to recover some or all of that award, such award and subsequent recovery may materially increase our liquidity.

Arbitration Financing Investment Agreement

In December 2022, we entered into a non-recourse financing agreement (the Investment Agreement) with certain investors (collectively the Investors) pursuant to which the Investors will pay us a maximum aggregate amount (Maximum Capital) equal to $30.0 million or a lesser amount based on the amount awarded (Award), if any, to us in connection with our ongoing arbitration proceeding with I-Mab (the Arbitration). Of the Maximum Capital, (i) $3.5 million (Initial Capital) was paid to us shortly after execution, (ii) 25% will be paid to us within 15 business days of issuance of an Award, subject to the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement, and (iii) the remainder will be paid to us in tranches over a multi-year period, subject again to the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement.

Subject to and contingent on our actual recovery of proceeds from an Award or any contemporaneously resolved settlements with I-Mab and following the payment of applicable attorney's fees (the Proceeds), we shall pay the Investors an amount (Repayment Amount) equal to the sum of (i) all amounts paid by the Investors to or on behalf of us pursuant to the Investment Agreement, plus (ii) a low sub-single digit to low single digit multiple calculated on each tranche of Maximum Capital actually paid by the Investors to or on behalf of us with the applicable multiple being based on the timing of payment from us and whether certain events relating to the Arbitration occur, plus (iii) a mid-teen percentage annual rate of return on the amounts set forth in clauses (i) and (ii) that begins to accrue if the amounts are not paid by us to the Investors within a multi-month period specified in the Investment Agreement. If the amount of Proceeds are less than the Repayment Amount, then we shall only be required to pay to the Investors the Proceeds recovered (other than in circumstances in which we accept a settlement offer that resolves the Arbitration for an amount less than the Repayment Amount without the prior written consent of the Investors), and in the circumstance in which there are no Proceeds then we shall not be required to pay the Investors any Repayment Amounts and the Investors shall have no right of recourse or right of action against us.

The Investment Agreement contains customary representations, warranties and covenants and also includes customary events of default, including payment defaults, breaches of representations or covenants and a bankruptcy default. The Investment Agreement also contains customary covenants that require us to, among other things, (i) use commercially reasonable efforts to pursue its claims in connection with the Arbitration and recover amounts awarded to it in connection with an Award, (ii) pay costs and expenses in connection with enforcing an Award, (iii) keep the Investors informed regarding the Arbitration and its collection and enforcement efforts and (iv) not incur liens (other than permitted liens) on or transfer any portion of its assets related to its claims in connection with the Arbitration, any Award, the Proceeds and related assets.

We may terminate the obligation of the Investors to pay all or certain tranches of the Maximum Capital by providing advance written notice to the Investors as set forth in the Investment Agreement. If we fail to pay amounts owed to the Investors when due, such overdue amounts bear interest at a default rate set forth in the Investment Agreement. Upon certain remedy events, including our breach of the Investment Agreement, the Investors may exercise all of their rights and remedies as set forth in the Investment Agreement and under applicable law, including, without limitation, termination of their obligations to pay additional amounts under the Investment Agreement. Pursuant to the Investment Agreement, we will also grant to the Investors a security interest in our interest in our claims in connection with the Arbitration, any Award, the Proceeds and related assets (Specific Collateral), as further described in the Investment Agreement, as security for the payment of our obligations under the Investment Agreement.

As of December 31, 2022, the $3.5 million Initial Capital was funded. The arbitration financing arrangement is a non-recourse financing agreement whereby repayment of all capital amounts funded under the Investment Agreement, including the Initial Capital, and the amount that which is required to be repaid is contingent upon our actual recovery of proceeds from an Award. In the event in which there is no recovery of proceeds from an Award, we are not required to repay the $3.5 million Initial Capital.

Runway Growth Finance Corp. Loan and Security Agreement

In September 2022, as amended December 2022, we entered into a loan and security agreement (the RGC Loan Agreement) with Runway Growth Finance Corp. (RGC or the Lender) that provides a term loan commitment in an aggregate principal amount of up to $35.0 million in three tranches: (i) a Term A loan in an aggregate principal amount of $10.0 million, with the full amount funded on the closing of the RGC Loan Agreement and repaid in January 2023 in connection with the execution of our arbitration financing arrangement; (ii) a Term B loan in an aggregate principal amount of up to $15.0 million to be funded in one or more disbursements at our request on or prior to June 30, 2024, subject to certain conditions being met; and (iii) a Term C loan in an aggregate principal amount of up to $10.0 million that may be disbursed in a single disbursement in the lender's sole discretion upon our request at any time from closing of the RGC Loan Agreement through and including December 31, 2024. Pursuant to the December 2022 amendment (the RGC Loan Amendment): (i) we repaid all amounts of principal and accrued but unpaid interest in respect of the Term A Loan (as defined in the RGC Loan Agreement) on January 3, 2023 without the obligation for us to pay the final payment fee or the prepayment fee described in the RGC Loan Agreement; (ii) on or before March 31, 2023, at our request, if we have raised at least $25.0 million in net cash proceeds from certain equity or debt transactions (including amounts raised in connection with our arbitration financing arrangement) prior to making such request, Lender will loan to us an aggregate principal amount of $10.0 million, with the full amount funded in a single disbursement; (iii) we will not issue an additional warrant to Lender in connection with the loan, if any, described in clause (ii) above; and (iv) Lender's security interest in specific collateral will be subordinated to the arbitration financing investors' security interest in the specific collateral. If the loan described in clause (ii) above is not made by March 31, 2023, the RGC Loan Agreement will terminate on that date, and we will not be obligated to pay the prepayment fee described in the RGC Loan Agreement but the final payment fee described in the RCG Loan Agreement will become immediately due and payable.

Borrowings under the term loan facility bear interest at a variable annual rate equal to the sum of (i) the greater of (a) the rate of interest noted in The Wall Street Journal, Money Rates section, as the "Prime Rate" or (b) 3.5%, plus (ii) 5.0%. We are obligated to make interest-only payments monthly in arrears through and including September 30, 2024 and thereafter monthly payments in arrears through the maturity date of September 1, 2026 equal to 1/24th of all outstanding principal plus accrued and unpaid interest.

We were obligated to pay a closing fee in the amount of (i) $50,000, which was paid upon the funding of the Term A loan, and (ii) an amount equal to 0.50% of the Term B loan and the Term C loan advanced to us , if any, due and payable on the applicable funding date of such Term B loan and Term C loan.

We are also obligated to pay a final payment fee equal to 4.25% of the aggregate principal amount of the funded term loans at the earlier to occur of (i) the maturity date, (ii) acceleration of the term loans and (iii) prepayment under the RGC Loan Agreement.

We have the option to prepay all, but not less than all, of the amounts of outstanding principal, accrued and unpaid interest and any other amounts due and payable under the RGC Loan Agreement, including a final payment fee. If we exercise our right to prepay the term loan(s) prior to the maturity date, we are obligated to pay a prepayment fee equal to (a) 3.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs on or prior to the first anniversary date, (b) 2.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs after the first anniversary date but on or prior to the second anniversary date and (c) 1.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs after the second anniversary date but prior to the maturity date.

Our obligations under the RGC Loan Agreement are collateralized by a first priority security interest in substantially all of our assets other than our intellectual property. The RGC Loan Agreement also contains customary representations, warranties and covenants that limit, among other things, our ability to (i) incur indebtedness, (ii) incur liens on our property, (iii) pay dividends or make other distributions, (iv) sell our assets, (v) make certain loans or investments, (vi) merge or consolidate, (vii) voluntarily repay or prepay certain indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions. Upon the occurrence and during the continuance of an event of default, a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balances, and the lender may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the RGC Loan Agreement and under applicable law, including, without limitation, termination of its obligations to extend credit to us. The RGC Loan Agreement contains customary representations, warranties and covenants, including financial covenants, and also includes customary events of default, including payment defaults, breaches of covenants, change in control and a material adverse effect default.

In connection with the funding of the Term A loan, we issued Runway Growth Finance Corp. warrants to purchase 150,753 shares of our common stock (the RGC Term A Warrants) at an exercise price of $1.99 per underlying share of our common stock. The RGC Term A Warrants are fully exercisable in whole or in part at the option of the holder, payable in cash or on a cashless basis according to the formula set forth in the RGC Term A Warrants, and expire September 2, 2032. In addition, in connection with the RGC Loan Agreement, additional warrants will be issued upon funding of the other term loan tranches, if any.

As of December 31, 2022, the total outstanding balance owed under the RGC Loan Agreement was $10.0 million and pursuant the December 2022 RGC Loan Amendment, future minimum principal and interest payments, including the final payment fee, were $10.5 million for each of the next 12 and 24 months, respectively.

Registered Direct Offering

In June 2022, we issued and sold 841,989 shares of our common stock at a purchase price of $1.32 per share and pre-funded warrants to purchase 2,205,018 shares of our common stock at a purchase price of $1.31 per share of underlying common stock with an exercise price of $0.01 per share of underlying common stock (the 2022 Pre-Funded Warrants) for net proceeds of approximately $3.9 million in a registered direct offering (the Offering) with an accredited institutional healthcare-focused fund. In accordance with their terms, the 2022 Pre-Funded Warrants may not be exercised if the holder's ownership of our common stock would exceed 19.99% of the shares of our common stock outstanding immediately after giving effect to such exercise. In connection with the Offering, we amended two existing pre-funded warrants to purchase shares of our common stock held by the same institutional healthcare-focused fund to extend the exercise periods and to permit exercise in excess of a similar 19.99% limit following approval of our stockholders of such exercise.

ATM Facility

In December 2020, as amended in March 2022, we entered into a Capital on Demand™ Sales Agreement (the Sales Agreement) with JonesTrading pursuant to which we could sell from time to time, at our option, up to an aggregate of $50.0 million of shares of our common stock through JonesTrading, as sales agent or principal, $45.7 million of which remains available for sale as of December 31, 2022. Sales of our common stock made pursuant to the Sales Agreement, if any, will be made on the Nasdaq Capital Market under our effective registration statement on Form S-3 subject to limitations on the amount of securities the Company may sell pursuant to its effective registration statement on Form S-3 within any 12 month period, by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, we may also sell shares of our common stock through JonesTrading, on the Nasdaq Capital Market or otherwise, at negotiated prices or at prices related to the prevailing market price. JonesTrading will use its commercially reasonable efforts to sell our common stock from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We are required to pay JonesTrading 2.5% of gross proceeds from the common stock sold through the Sales Agreement.

Operating Lease Obligations

Our operating lease obligations relate to our corporate headquarters in San Diego, California, which expires in April 2027. As of December 31, 2022, future minimum lease payments under this lease were $0.3 million and $0.7 million for each of the next 12 and 24 months, respectively.

Other Obligations

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturing organizations and with vendors for preclinical safety and research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts.

Cash Flows

The following table summarizes our net cash flow activity for each of the periods set forth below:

	Years Ended December 31,	
	2022	2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (26,239)	$ (22,571)
Investing activities	(17)	3,952
Financing activities	19,684	10,560
Change in cash, cash equivalents, and restricted cash	$ (6,572)	$ (8,059)

Operating activities. Net cash used in operating activities was $26.2 million and $22.6 million for the years ended December 31, 2022 and 2021, respectively, and was primarily due to our net loss for the respective year, adjusted for noncash items and offset by changes in our working capital.

Investing activities. Net cash used in investing activities was $17,000 for the year ended December 31, 2022. Net cash provided by investing activities was $4.0 million for the year ended December 31, 2021 and was due to maturities of short-term investments.

Financing activities. Net cash provided by financing activities was $19.7 million for the year ended December 31, 2022 and primarily resulted from our $10.0 million debt financing with RGC, $3.4 million in net proceeds from our arbitration financing arrangement, and $7.9 million in net proceeds received from the Offering and periodic issuances and sales of our common stock under the Sales Agreement with JonesTrading, partially offset by $1.7 million in SVB loan repayments. Net cash provided by financing activities was $10.6 million for the year ended December 31, 2021 and primarily resulted from $13.4 million in net proceeds raised in connection with an underwritten public offering in July 2021, offset by $2.8 million in net repayments on borrowings under the 2018 Amended SVB Loan.

Funding Requirements

At December 31, 2022, we had cash and cash equivalents totaling $17.5 million, of which $0.1 million is pledged as collateral for our obligations under our corporate headquarters facility lease. We believe that our cash and cash equivalents as of December 31, 2022, will be sufficient to fund our obligations into mid-2023. We will need additional funding to complete the development and commercialization of our product candidates or those of our partners. In addition, we may evaluate in-licensing and acquisition opportunities to gain access to new product candidates that fit with our strategy. Any such transaction will likely increase our future funding requirements. These uncertainties raise substantial doubt about our ability to continue as a going concern for a period of 12 months following the date that the accompanying audited consolidated financial statements were issued.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Our future capital requirements are difficult to forecast and will depend on many factors, including:

- our ability to initiate, and the progress and results of, our ongoing and planned clinical trials;
- the ability and willingness of our collaboration partners and licensees to continue clinical development of product candidates;
- our ability to enter into and maintain our collaborations;
- our ability to achieve, and our obligations to make, milestone payments under our collaboration and license agreements;
- the outcome of our disputes with I-Mab with respect to the TJ004309 and Bispecific Agreements, our ability to recover any award resulting from that dispute and the timing of any termination of the TJ004309 Agreement;
- the costs and timing of procuring supplies of product candidates for clinical trials and regulatory submissions;
- the scope, progress, results and costs of preclinical development, and clinical trials of our product candidates;
- the extent to which macroeconomic and geopolitical developments, including as a result of the COVID-19 pandemic, delay our clinical development activities or those of our collaborators;
- the costs, timing and outcome of regulatory review of product candidates;
- the revenue, if any, received from commercial sales of our product candidates for which we or any of our partners, including Eucure and Biocytogen, 3D Medicines and Alphamab, and I-Mab, may receive marketing approval;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any product candidates for which we receive marketing approval and do not partner for commercialization; and
- the extent to which we acquire or in-license other products and technologies.

Until we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, and licensing arrangements. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. As a result of macroeconomic and geopolitical developments, such as the COVID-19 pandemic and actions taken to slow its spread, the ongoing military conflict between Ukraine and Russia, actual or anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans or programs which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve our intended business objectives. Any of these actions could materially harm our business, results of operations and future prospects.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of
TRACON Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TRACON Pharmaceuticals, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Clinical Trial Expense Accruals

Description of the Matter	During 2022, the Company incurred $13.9 million for research and development expense and as of December 31, 2022, the Company accrued $6.1 million for clinical trial expenses. As described in Note 1 of the financial statements, the Company records accruals for estimated research and development costs relating to clinical trials comprising payments for work performed by third party vendors and consultants, participating clinical trial sites, and others. The Company accounts for the expenses based upon the progress of the clinical trial as measured by patient progression through the trial. Auditing the Company's accounting for clinical trial expense accruals was especially challenging as evaluating the progress or patient progression through the clinical trials is dependent upon a high volume of data which is tracked in spreadsheets.

How We Addressed the Matter in Our Audit	To test the completeness of the Company's accrued clinical trial expenses, among other procedures, we obtained supporting evidence of the research and development activities performed for significant clinical trials. We inquired of internal clinical trial project managers to understand the status of significant clinical trial activities. To assess the appropriate measurement of accrued clinical trial costs, our audit procedures included, among others, obtaining and inspecting significant agreements and agreement amendments, evaluating the Company's documentation of key milestones and completion terms, activities, timing, and costs of clinical trials, and testing a sample of transactions by comparing the costs against related invoices and contracts. We also tested a sample of subsequent payments by agreeing the invoice to the original accrual and the invoice payments to bank statements.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2011.
San Diego, California
March 8, 2023

TRACON Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share data)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 17,433	$ 24,072
Prepaid and other assets	795	864
Total current assets	18,228	24,936
Property and equipment, net	51	50
Restricted cash	67	—
Other assets	1,123	1,571
Total assets	$ 19,469	$ 26,557
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 11,107	$ 10,753
Accrued compensation and related expenses	1,457	1,532
Long-term debt, current portion	9,807	1,391
Total current liabilities	22,371	13,676
Other long-term liabilities	969	1,167
Arbitration financing payable	3,280	—
Commitments and contingencies (Note 5)		
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value, authorized shares — 10,000,000 at December 31, 2022 and December 31, 2021; issued and outstanding shares — none	—	—
Common stock, $0.001 par value; authorized shares — 40,000,000 at December 31, 2022 and December 31, 2021; issued and outstanding shares — 23,125,250 and 19,445,903 at December 31, 2022 and December 31, 2021, respectively	23	19
Additional paid-in capital	229,737	219,471
Accumulated deficit	(236,911)	(207,776)
Total stockholders' (deficit) equity	(7,151)	11,714
Total liabilities and stockholders' equity (deficit)	$ 19,469	$ 26,557

See accompanying notes.

TRACON Pharmaceuticals, Inc.

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Years Ended December 31,		
	2022	2021	2020
License revenue	$ —	$ 346	$ —
Operating expenses:			
Research and development	13,888	11,146	8,198
General and administrative	14,006	17,547	8,025
Total operating expenses	27,894	28,693	16,223
Loss from operations	(27,894)	(28,347)	(16,223)
Other expense:			
Interest expense, net	(994)	(318)	(545)
Other expense	(247)	(2)	(7)
Total other expense	(1,241)	(320)	(552)
Net loss	$ (29,135)	$ (28,667)	$ (16,775)
Net loss per share, basic and diluted	$ (1.39)	$ (1.66)	$ (1.87)
Weighted-average shares outstanding, basic and diluted	20,919,118	17,252,637	8,984,148

See accompanying notes.

TRACON Pharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity (Deficit)

(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2019	4,051,187	$ 4	$ 165,028	$ (162,334)	$ 2,698
Issuance of common stock under equity plans	6,628	—	2	—	2
Stock-based compensation expense	—	—	1,034	—	1,034
Issuance of common stock and warrants, net of offering costs	11,320,972	11	37,976	—	37,987
Issuance of common stock in exchange for services	100,000	—	126	—	126
Net loss	—	—	—	(16,775)	(16,775)
Balance at December 31, 2020	15,478,787	15	204,166	(179,109)	25,072
Issuance of common stock under equity plans	40,414	—	149	—	149
Stock-based compensation expense	—	—	1,775	—	1,775
Issuance of common stock, net of offering costs	3,926,702	4	13,381	—	13,385
Net loss	—	—	—	(28,667)	(28,667)
Balance at December 31, 2021	19,445,903	19	219,471	(207,776)	11,714
Issuance of common stock under equity plans	56,261	—	95	—	95
Stock-based compensation expense	—	—	2,041	—	2,041
Issuance of common stock and warrants, net of offering costs	3,232,418	3	7,871	—	7,874
Issuance of common stock upon cashless exercise of pre-funded warrants	390,668	1	—	—	1
Issuance of common stock warrants in connection with debt financing	—	—	259	—	259
Net loss	—	—	—	(29,135)	(29,135)
Balance at December 31, 2022	23,125,250	$ 23	$ 229,737	$ (236,911)	$ (7,151)

See accompanying notes.

TRACON Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Years Ended December 31,		
	2022	2021	2020
Cash flows from operating activities			
Net loss	$ (29,135)	$ (28,667)	$ (16,775)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	2,041	1,775	1,034
Common stock issued for services	—	—	126
Depreciation and amortization	16	14	12
Noncash interest	343	61	123
Amortization of debt discount	435	21	43
Amortization of premium/discount on short-term investments	—	(1)	(1)
Lease asset amortization and liability accretion, net	54	(73)	(25)
Equity ownership license revenue	—	(246)	—
Impairment of private company equity ownership	246	—	—
Changes in assets and liabilities:			
Prepaid expenses and other assets	69	(80)	64
Accounts payable and accrued expenses	(233)	4,683	(1,878)
Accrued compensation and related expenses	(75)	(58)	235
Net cash used in operating activities	(26,239)	(22,571)	(17,042)
Cash flows from investing activities			
Purchase of property and equipment	(17)	(48)	(5)
Purchases of available-for-sale short-term investments	—	—	(3,998)
Proceeds from the maturity of available-for-sale short-term investments	—	4,000	—
Net cash (used in) provided by investing activities	(17)	3,952	(4,003)
Cash flows from financing activities			
Proceeds from long-term debt	9,960	—	—
Repayment of long-term debt	(1,680)	(2,800)	(1,400)
Proceeds from arbitration financing	3,430	—	—
Proceeds from sale of common stock and warrants, net of offering costs	7,879	13,211	38,162
Proceeds from issuance of common stock under equity plans, net of tax withholdings	95	149	2
Net cash provided by financing activities	19,684	10,560	36,764
Change in cash, cash equivalents, and restricted cash	(6,572)	(8,059)	15,719
Cash, cash equivalents, and restricted cash at beginning of period	24,072	32,131	16,412
Cash, cash equivalents, and restricted cash at end of period	$ 17,500	$ 24,072	$ 32,131
Supplemental disclosure of cash flow information			
Interest paid	$ 359	$ 266	$ 443
Supplemental schedule of noncash investing and financing activities			
Issuance of common stock warrants in connection with long-term debt	$ 259	$ —	$ —

See accompanying notes.

1. Organization and Summary of Significant Accounting Policies

Organization and Business

TRACON Pharmaceuticals, Inc. (TRACON or the Company) was incorporated in the state of Delaware on October 28, 2004. TRACON is a biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, and utilizes its cost efficient, contract research organization (CRO) independent product development platform to partner with other life science companies to develop and commercialize innovative products in the United States.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, TRACON Pharma Limited and TRACON Pharma International Limited, which were formed in September 2015 and January 2019, respectively, and are currently inactive. All significant intercompany accounts and transactions have been eliminated.

Basis of Presentation

As of December 31, 2022, the Company has devoted substantially all its efforts to product development, raising capital, and building infrastructure and has not realized revenues from its planned principal operations. The Company has incurred operating losses since inception. As of December 31, 2022, the Company had an accumulated deficit of $236.9 million. The Company anticipates that it will continue to incur net losses into the foreseeable future as it continues the development and commercialization of its product candidates and works to develop additional product candidates through research and development programs. At December 31, 2022, the Company had cash and cash equivalents of $17.5 million, of which $0.1 million is classified as restricted cash as it is pledged as collateral for the Company's obligations under its corporate headquarters facility lease. Based on the Company's current business plan, management believes that there is substantial doubt as to whether existing cash and cash equivalents will be sufficient to meet its obligations as they become due within twelve months from the date the consolidated financial statements are issued. The Company's ability to execute its operating plan through 2023 and beyond depends on its ability to obtain additional funding through equity offerings, debt financings, or potential licensing and collaboration arrangements. The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. However, the Company's current working capital, anticipated operating expenses and net losses, and the uncertainties surrounding its ability to raise additional capital as needed, as discussed below, raise substantial doubt about its ability to continue as a going concern for a period of one year following the date that these consolidated financial statements are issued. The consolidated financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company plans to continue to fund its losses from operations through its existing cash and cash equivalents, as well as through future equity offerings, debt financings, other third-party funding, and potential licensing or collaboration arrangements. In addition, the Company may fund its losses from operations through the Capital on Demand™ Sales Agreement (the Sales Agreement) the Company entered into with JonesTrading in December 2020, as amended in March 2022, pursuant to which the Company may sell, at its option, up to an aggregate of $50.0 million of the Company's common stock, $45.7 million of which remained available for sale as of December 31, 2022. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to the Company. As a result of the COVID-19 pandemic and actions taken to slow its spread, as well as adverse macroeconomic and geopolitical developments, such as the ongoing military conflict between Ukraine and Russia, actual or anticipated changes in interest rates, economic inflation and the responses by central banking authorities to control such inflation, the global credit and financial markets have experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets deteriorate in the future, it may make any additional debt or equity financing more difficult, more costly, and more dilutive. Even if the Company raises additional capital, it may also be required to modify, delay or abandon some of its plans, which could have a material adverse effect on the Company's business, operating results and financial condition, and the Company's ability to achieve its intended business objectives. Any of these actions could materially harm the Company's business, results of operations, and future prospects.

Risks and Uncertainties

COVID-19, a novel strain of coronavirus (together with its variants, COVID-19), has become a global pandemic. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. While vaccines have become widely available in certain countries, and businesses and economies have reopened, the status of global economic recovery remains uncertain and unpredictable, and will continue to be impacted by developments in the pandemic including any subsequent waves of outbreak or new variant strains of the COVID-19 virus which may require re-closures or other preventative measures. The COVID-19 pandemic may also have long-term effects on the nature of the office environment and remote working, which may present risks for the Company's strategy, operational, talent recruiting and retention, and workplace culture.

In addition to the ongoing COVID-19 pandemic, global economic and business activities continue to face widespread macroeconomic uncertainties, including labor shortages, inflation and monetary supply shifts, recession risks and potential disruptions from the Russia-Ukraine conflict. The Company continues to actively monitor the impact of these macroeconomic factors on its financial condition, liquidity, operations, and workforce. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact the Company's business.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of the Company's consolidated financial statements requires it to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenue, and expenses. The most significant estimates in the Company's consolidated financial statements relate to expenses incurred for clinical trials. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments and assumptions or a revision of the carrying value of the Company's assets or liabilities as of the date of this filing.

Restricted Cash

Restricted cash consists of money market funds held by the Company's financial institution as collateral for the Company's obligations under its facility lease for the Company's corporate headquarters in San Diego, California.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less at the date of purchase. The carrying amounts approximate fair value due to the short maturities of these investments. Cash and cash equivalents include cash in readily available checking and money market funds.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Property and Equipment

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful life of the related assets, which is generally five years. Leasehold improvements are amortized over the shorter of the lease term or estimated useful life of the related assets. Repairs and maintenance costs are charged to expense as incurred.

Leases

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, operating leases are recorded as other assets, accounts payable and accrued expenses, and other long-term liabilities within the consolidated balance sheet. The Company currently does not have any finance leases.

Operating lease right-of-use (ROU) assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. Lease terms may include options to extend or terminate when the Company is reasonably certain that the option will be exercised. Lease expense is recognized on a straight-line basis over the lease term.

Revenue Recognition

To date, substantially all the Company's revenue has been derived from license agreements. The terms of these arrangements included payments to the Company for the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. In accordance with Accounting Standards Codification 606, *Revenue from Contracts with Customers*, (ASC 606) the Company performs the following five steps in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of these agreements: (i) identification of the contract(s) with a customer; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as, the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services transferred to the customer. Once a contract is determined to be within the scope of ASC 606, at contract inception, the Company assesses the goods or services promised within the contract to determine those that are performance obligations and assesses whether each promised good 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.

As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promised goods or services, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, the Company evaluates whether the achievement of the milestones is considered probable and estimates the amount to be included in the transaction price using the most likely amount method. Performance milestone payments represent a form of variable consideration. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Achievement of milestones that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable until the approvals are achieved. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis and the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achieving such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are generally considered options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the outset of the arrangement.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its out-licensing arrangements.

The Company receives payments from its collaborators based on billing schedules established in each contract. Up-front and other payments may require deferral of revenue recognition to a future period until the Company performs its obligations under its collaboration arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Clinical Trial Expense Accruals

As part of the process of preparing the Company's financial statements, the Company is required to estimate expenses resulting from its obligations under contracts with vendors, clinical sites, and consultants in connection with conducting clinical trials. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

The Company's objective is to reflect the appropriate trial expenses in its consolidated financial statements by recording those expenses in the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with the clinical sites and applicable personnel and outside service providers as to the progress or state of consummation of trials. During a clinical trial, the Company adjusts the clinical expense recognition if actual results differ from its estimates. The Company makes estimates of accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. The Company's clinical trial accruals are dependent upon accurate reporting by clinical sites and other third-party vendors. Although the Company does not expect its estimates to differ materially from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low for any particular period. For each of the three years in the period ended December 31, 2022, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Research and Development Costs

Research and development costs, including license fees, are expensed as incurred.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of employee stock option grants, employee restricted stock unit grants (RSUs), and employee stock purchase plan (ESPP) rights recognized as expense over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The Company estimates the fair value of stock option grants and ESPP rights using the Black-Scholes option pricing model. The fair value of RSUs is based on the closing sales price for such stock on the date of grant. Equity award forfeitures are recorded as they occur.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized as income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and comprehensive loss were the same for all periods presented.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average shares of common stock outstanding for the period, without consideration for common stock equivalents and adjusted for the weighted average number of shares of common stock outstanding that are subject to repurchase. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock method. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	December 31,		
	2022	2021	2020
Warrants to purchase common stock	6,766,246	4,810,409	4,810,409
Common stock options	2,246,310	1,308,360	601,481
ESPP shares	3,387	3,258	5,349
	9,015,943	6,122,027	5,417,239

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

2. Financial Instruments and Fair Value Measurements

Cash equivalents, which are classified as equity securities, and restricted cash consisted of the following (in thousands):

	December 31, 2022				December 31, 2021			
	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Money market funds	$ 10,150	$ —	$ —	$ 10,150	$ 5,003	$ —	$ —	$ 5,003
Equity securities[1]	—	—	—	—	246	—	—	246
	$ 10,150	$ —	$ —	$ 10,150	$ 5,249	$ —	$ —	$ 5,249
Classified as:								
Cash equivalents				$ 10,083				$ 5,003
Restricted cash				67				—
Other assets				—				246
Total cash equivalents, restricted cash, and other assets				$ 10,150				$ 5,249

[1] The Company's equity securities included in other assets as of December 31, 2021 consisted of its investment in a privately held company obtained as partial consideration under the 2021 Enviro license agreement. The Company recognizes its private company equity securities at cost minus impairments, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. The $0.2 million investment was fully impaired during the year ended December 31, 2022 and recorded within other expense on the consolidated statements of operations.

The Company had no short-term investments at December 31, 2022 and 2021. The Company classifies all investments as available-for-sale securities, as the sale of such investments may be required prior to maturity to implement management strategies. These investments are carried at amortized cost which approximates fair value. A decline in the market value of any short-term investment below cost that is determined to be other-than-temporary will result in a revaluation of its carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. No such impairment charges were recorded for any period presented.

Realized gains and losses from the sale of short-term investments, if any, are determined on a specific identification basis. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense on the consolidated statements of operations. Realized and unrealized gains and losses during the periods presented were immaterial. Premiums and discounts are amortized or accreted over the life of the related security as an adjustment to yield using the straight-line method and are included in interest income on the consolidated statements of operations. Interest and dividends on securities classified as available-for-sale are included in interest income on the consolidated statements of operations.

The carrying amounts of cash and cash equivalents, prepaid and other assets, accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, which is considered a Level 2 input, the Company believes that the fair value of long-term debt approximates its carrying value.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements.

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

The fair values of the Company's assets and liabilities, which are measured at fair value on a recurring basis, were determined using the following inputs (in thousands):

		Fair Value Measurements at Reporting Date Using		
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
At December 31, 2022				
Money market funds	$ 10,150	$ —	$ 10,150	$ —
At December 31, 2021				
Money market funds	$ 5,003	$ —	$ 5,003	$ —

3. Balance Sheet Details

Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31,	
	2022	2021
Computer and office equipment	$ 203	$ 186
Furniture and fixtures	19	19
Leasehold improvements	21	21
	243	226
Less accumulated depreciation and amortization	(192)	(176)
	$ 51	$ 50

Depreciation expense related to property and equipment totaled approximately $16,000, $14,000 and $12,000 for the years ended December 31, 2022, 2021 and 2020, respectively.

Accounts payable and accrued expenses

Accounts payable and accrued expenses consisted of the following (in thousands):

	December 31,	
	2022	2021
Accounts payable	$ 3,923	$ 4,943
Accrued clinical related expenses	6,091	4,461
Accrued legal and accounting	299	842
Accrued long-term debt terminal interest	425	280
Current portion of operating lease liability	198	147
Other accruals	171	80
	$ 11,107	$ 10,753

4. Long-Term Debt

Arbitration Financing Investment Agreement

In December 2022, the Company entered into a non-recourse financing agreement (the Investment Agreement) with certain investors (collectively the Investors) pursuant to which the Investors will pay the Company a maximum aggregate amount (Maximum Capital) equal to $30.0 million or a lesser amount based on the amount awarded (Award), if any, to the Company in connection with its ongoing arbitration proceeding (the Arbitration) with I-Mab Biopharma (I-Mab). Of the Maximum Capital, (i) $3.5 million (Initial Capital) was paid to the Company shortly after execution, (ii) 25% will be paid to the Company within 15 business days of issuance of an Award, subject to the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement, and (iii) the remainder will be paid to the Company in tranches over a multi-year period, subject to the issuance of an Award and the Award size exceeding a prespecified threshold and satisfaction of other conditions set forth in the Investment Agreement. In connection with the execution of the Investment Agreement and funding of the Initial Capital amount, the Company paid a closing fee in the amount of 2%.

Subject to and contingent on the Company's actual recovery of proceeds from an Award or any contemporaneously resolved settlements with I-Mab and following the payment of applicable attorney's fees (the Proceeds), the Company shall pay the Investors an amount (Repayment Amount) equal to the sum of (i) all amounts paid by the Investors to or on behalf of the Company pursuant to the Investment Agreement, plus (ii) a low sub-single digit to low single digit multiple calculated on each tranche of Maximum Capital actually paid by the Investors to or on behalf of the Company with the applicable multiple being based on the timing of payment from the Company and whether certain events relating to the Arbitration occur, plus (iii) a mid-teen percentage annual rate of return on the amounts set forth in clauses (i) and (ii) that begins to accrue if the amounts are not paid by the Company to the Investors within a multi-month period specified in the Investment Agreement. If the amount of Proceeds are less than the Repayment Amount, then the Company shall only be required to pay to the Investors the Proceeds recovered (other than in circumstances in which the Company accepts a settlement offer that resolves the Arbitration for an amount less than the Repayment Amount without the prior written consent of the Investors), and in the circumstance in which there are no Proceeds then the Company shall not be required to pay the Investors any Repayment Amounts and the Investors shall have no right of recourse or right of action against the Company.

The Investment Agreement contains customary representations, warranties and covenants and also includes customary events of default, including payment defaults, breaches of representations or covenants and a bankruptcy default. The Investment Agreement also contains customary covenants that require the Company to, among other things, (i) use commercially reasonable efforts to pursue its claims in connection with the Arbitration and recover amounts awarded to it in connection with an Award, (ii) pay costs and expenses in connection with enforcing an Award, (iii) keep the Investors informed regarding the Arbitration and its collection and enforcement efforts and (iv) not incur liens (other than permitted liens) on or transfer any portion of its assets related to its claims in connection with the Arbitration, any Award, the Proceeds and related assets.

The Company may terminate the obligation of the Investors to pay all or certain tranches of the Maximum Capital by providing advance written notice to the Investors as set forth in the Investment Agreement. If the Company fails to pay amounts owed to the Investors when due, such overdue amounts bear interest at a default rate set forth in the Investment Agreement. Upon certain remedy events, including the Company's breach of the Investment Agreement, the Investors may exercise all of their rights and remedies as set forth in the Investment Agreement and under applicable law, including, without limitation, termination of their obligations to pay additional amounts under the Investment Agreement. Pursuant to the Investment Agreement, the Company will also grant to the Investors a security interest in its interest in its claims in connection with the Arbitration, any Award, the Proceeds and related assets (Specific Collateral), as further described in the Investment Agreement, as security for the payment of the Company's obligations under the Investment Agreement.

In December 2022, the Investors funded the Initial Capital amount of $3.5 million which was recorded as arbitration financing payable on the consolidated balance sheet. The carrying amount of the arbitration financing payable recorded on the consolidated balance sheet is net of debt discount, including the Initial Capital closing fee, which is being amortized over the estimated term of the agreement using the effective interest method. Pursuant to the terms of the Investment Agreement, repayment of all capital amounts funded under the Investment Agreement, including the Initial Capital, and the obligation amount owed is contingent upon the Company's actual recovery of proceeds from an Award, which is uncertain. Accordingly, as of December 31, 2022, the Company has estimated an effective interest rate and term of the agreement over which the related debt discount is being amortized. The Company will re-evaluate this estimate at the end of each subsequent reporting period, with any material changes recorded prospectively using a new effective interest rate based on the updated estimate of the amount of arbitration financing payable owed as of the end of the reporting period. In the event in which there is no recovery of proceeds from an Award, the Company is not required to repay the $3.5 million Initial Capital. As of December 31, 2022, the arbitration financing payable was classified as long-term liabilities as it is considered unlikely the obligation amount owed under the Investment Agreement will be settled prior to December 31, 2023.

Runway Growth Finance Corp. Loan and Security Agreement

In September 2022, the Company entered into a loan and security agreement (the RGC Loan Agreement). with Runway Growth Finance Corp. (RGC). The RGC Loan Agreement is a long-term debt facility that provides a term loan commitment in an aggregate principal amount of up to $35.0 million in three tranches: (i) a Term A loan in an aggregate principal amount of $10.0 million, with the full amount funded in a single disbursement on closing of the RGC Loan Agreement and repaid in January 2023 in connection with the Investment Agreement; (ii) a Term B loan in an aggregate principal amount of up to $15.0 million to be funded in one or more disbursements at the request of the Company on or prior to June 30, 2024, subject to certain conditions being met; and (iii) a Term C loan in an aggregate principal amount of up to $10.0 million that may be disbursed in a single disbursement in the lender's sole discretion upon the Company's request at any time from closing of the RGC Loan Agreement through and including December 31, 2024. In December 2022, the Company and RGC amended the RGC Loan Agreement (the RGC Loan Amendment) under which: (i) the Company repaid all amounts of principal and accrued but unpaid interest in respect of the Term A Loan on January 3, 2023; (ii) on or before March 31, 2023, at the Company's request, if the Company has raised at least $25.0 million in net cash proceeds from certain equity or debt transactions (including amounts raised in connection with the Investment Agreement) prior to making such request, Lender will loan to the Company an aggregate principal amount of $10.0 million, with the full amount funded in a single disbursement; (iii) the Company will not issue an additional warrant to Lender in connection with the loan, if any, described in clause (ii) above; and (iv) Lender's security interest in Specific Collateral was subordinated to the arbitration financing Investors' security interest in the Specific Collateral. If the loan described in clause (ii) above is not made by March 31, 2023, the RGC Loan Agreement will terminate on that date, and the Company will not be obligated to pay the prepayment fee described in the RGC Loan Agreement but the final payment fee described in the RCG Loan Agreement will become immediately due and payable. All other material terms and conditions of the RGC Loan Agreement remained unchanged and the transaction was accounted for as a debt modification.

Borrowings under the term loan facility bear interest at a variable annual rate equal to the sum of (i) the greater of (a) the rate of interest noted in The Wall Street Journal, Money Rates section, as the "Prime Rate" or (b) 3.5%, plus (ii) 5.0%. The Company is obligated to make interest-only payments monthly in arrears through and including September 30, 2024 and thereafter monthly payments in arrears through the maturity date of September 1, 2026 equal to 1/24th of all outstanding principal plus accrued and unpaid interest.

The Company is obligated to pay a closing fee in the amount of (i) $50,000, which was paid upon the funding of the Term A loan, and (ii) an amount equal to 0.50% of the Term B loan and the Term C loan advanced to the Company, if any, due and payable on the applicable funding date of such Term B loan and Term C loan.

The Company is also obligated to pay a final payment fee equal to 4.25% of the aggregate principal amount of the funded term loans at the earlier to occur of (i) the maturity date, (ii) acceleration of the term loans and (iii) prepayment under the RGC Loan Agreement. The closing fee, other related debt issuance costs, and the final payment fee were recorded as a component of the total debt discount and will be recognized as interest expense over the term of the RGC Loan Agreement using the effective interest method.

The Company has the option to prepay all, but not less than all, of the amounts of outstanding principal, accrued and unpaid interest and any other amounts due and payable under the RGC Loan Agreement, including a final payment fee. If the Company exercises its right to prepay the term loan(s) prior to the maturity date, it is obligated to pay a prepayment fee equal to (a) 3.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs on or prior to the first anniversary date, (b) 2.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs after the first anniversary date but on or prior to the second anniversary date and (c) 1.0% of the outstanding principal amount of the applicable term loan(s) prepaid at the time of such prepayment if it occurs after the second anniversary date but prior to the maturity date.

The Company's obligations under the RGC Loan Agreement are collateralized by a first priority security interest in substantially all of its assets other than the intellectual property of the Company and for Specific Collateral that is subordinated to the arbitration financing Investors' security interest. The RGC Loan Agreement also contains customary representations, warranties and covenants that limit, among other things, the ability of the Company to (i) incur indebtedness, (ii) incur liens on its property, (iii) pay dividends or make other distributions, (iv) sell its assets, (v) make certain loans or investments, (vi) merge or consolidate, (vii) voluntarily repay or prepay certain indebtedness and (viii) enter into transactions with affiliates, in each case subject to certain exceptions. Upon the occurrence and during the continuance of an event of default, a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balances, and the lender may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the RGC Loan Agreement and under applicable law, including, without limitation, termination of its obligations to extend credit to the Company. The RGC Loan Agreement contains customary representations, warranties and covenants, including financial covenants, and also includes customary events of default, including payment defaults, breaches of covenants, change in control and a material adverse effect default. As of December 31, 2022, the Company was in compliance with all covenants and conditions of the RGC Loan Agreement.

In connection with the funding of the Term A loan, the Company issued Runway Growth Finance Corp. warrants to purchase 150,753 shares of its common stock (the RGC Term A Warrants) at an exercise price of $1.99 per underlying share of the Company's common stock. The RGC Term A Warrants are fully exercisable in whole or in part at the option of the holder, payable in cash or on a cashless basis according to the formula set forth in the RGC Term A Warrants, and expire September 2, 2032. The fair value of the warrant at the grant date was determined utilizing a Black-Scholes pricing model, recorded as a component of the total debt discount and stockholders' equity (deficit) within additional paid-in capital on the consolidated balance sheets, and will be amortized to interest expense using the effective interest method over the term of the debt.

Long-term debt and unamortized debt discount balances associated with the RGC Loan Agreement entered into in 2022 were as follows (in thousands):

	December 31, 2022
Long-term debt	$ 10,000
Less debt discount, net of current portion	—
Long-term debt, net of debt discount	10,000
Less current portion of long-term debt	(10,000)
Long-term debt, net of current portion	$ —
Current portion of long-term debt	$ 10,000
Current portion of debt discount	(193)
Current portion of long-term debt, net	$ 9,807

As of December 31, 2022, future minimum principal and interest payments, including the final payment, under the RGC Loan Agreement are as follows (in thousands):

2023	$ 10,491
	10,491
Less interest and final payment	(491)
Long-term debt	$ 10,000

Silicon Valley Bank Loan and Security Agreement

In May 2018, the Company entered into a third amendment to its Amended and Restated Loan and Security Agreement with Silicon Valley Bank (the 2018 Amended SVB Loan) under which the Company borrowed $7.0 million, all of which was immediately used to repay the Company's then existing loan with SVB (the 2017 Amended SVB Loan).

As of December 31, 2021, the total principal amount owed under the 2018 Amended SVB Loan was $1.4 million, net of a remaining unamortized debt discount balance of $9,000. The 2018 Amended SVB Loan matured in June 2022 and in accordance with its terms, the Company paid a final payment of $0.3 million associated with the payoff of the 2018 Amended SVB Loan. In August 2022, the Company terminated the Amended and Restated Loan and Security Agreement with SVB.

At December 31, 2022, the Company had the following exercisable outstanding warrants for the purchase of common stock issued in connection with the Company's loan agreements with SVB:

Expiration	Number of shares	Exercise price
November 14, 2023 through June 4, 2024	3,874	$ 77.40
January 25, 2024	4,669	$ 51.40
May 3, 2025	5,363	$ 26.10
	13,906	

5. Commitments and Contingencies

License Agreements

The Company has entered into various license agreements pursuant to which the Company acquired licenses to certain intellectual property. The agreements generally required an upfront license fee and, in some cases, reimbursement of patent costs. Additionally, under each agreement, the Company may be required to pay annual maintenance fees, royalties, milestone payments and sublicensing fees. Each license agreement is generally cancelable by the Company, given appropriate prior written notice. At December 31, 2022, potential future milestone payments under these agreements totaled an aggregate of $9.6 million.

6. Stockholders' Equity

Sale of Common Stock and Pre-Funded Warrants

In June 2022, the Company issued and sold 841,989 shares of its common stock at a purchase price of $1.32 per share and pre-funded warrants to purchase 2,205,018 shares of its common stock at a purchase price of $1.31 per share of underlying common stock with an exercise price of $0.01 per share of underlying common stock (the 2022 Pre-Funded Warrants) for net proceeds of approximately $3.9 million in a registered direct offering (the Offering) with an accredited institutional healthcare-focused fund. In accordance with their terms, the 2022 Pre-Funded Warrants may not be exercised if the holder's ownership of the Company's common stock would exceed 19.99% of the shares of the Company's common stock outstanding immediately after giving effect to such exercise. The 2022 Pre-Funded Warrants were recorded as a component of stockholders' equity (deficit) within additional paid-in capital on the consolidated balance sheets. In connection with the Offering, the Company amended two existing pre-funded warrants to purchase shares of the Company's common stock held by the same institutional healthcare-focused fund to extend the exercise periods and to permit exercise in excess of a similar 19.99% limit following approval of the Company's stockholders of such exercise.

In July 2021, the Company completed an underwritten public offering of 3,926,702 shares of its common stock at an offering price of $3.82 per share. The Company received net proceeds of approximately $13.4 million, after deducting underwriting discounts, commissions and offering-related expenses.

At-The-Market Issuance Sales Agreement

In December 2020, as amended in March 2022, the Company entered into a Capital on Demand™ Sales Agreement (the Sales Agreement) with JonesTrading, pursuant to which it may sell from time to time, at its option, up to an aggregate of $50.0 million of the Company's common stock through JonesTrading, as sales agent or principal, $45.7 million of which remains available for sale as of December 31, 2022. Sales of the Company's common stock made pursuant to the Sales Agreement with JonesTrading, if any, will be made on the Nasdaq Capital Market under the Company's effective registration statement on Form S-3, subject to limitations on the amount of securities the Company may sell pursuant to its effective registration statement on Form S-3 within any 12-month period, by means of ordinary brokers' transactions at market prices. Additionally, under the terms of the Sales Agreement, the Company may also sell shares of its common stock through JonesTrading, on the Nasdaq Capital Market or otherwise, at negotiated prices or at prices related to the prevailing market price. JonesTrading will use its commercially reasonable efforts to sell the Company's common stock from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). The Company is required to pay JonesTrading 2.5% of gross proceeds for the common stock sold through the Sales Agreement.

Common Stock Warrants

As of December 31, 2022, the Company had the following outstanding warrants for the purchase of common stock:

Expiration	Number of shares	Exercise price
November 14, 2023 through June 4, 2024	3,874	$ 77.40
January 25, 2024	4,669	$ 51.40
March 27, 2024	1,369,602	$ 27.00
May 3, 2025	5,363	$ 26.10
August 27, 2030	1,889,513	$ 0.01
August 31, 2030	1,137,454	$ 0.01
June 21, 2032	2,205,018	$ 0.01
September 2, 2032	150,753	$ 1.99
	6,766,246	

During the year ended December 31, 2022, the Company issued 390,668 shares of its common stock upon the cashless exercise of 398,093 pre-funded warrants. During the year ended December 31, 2021, no warrants were exercised.

Stock Compensation Plans

Effective January 1, 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan (2015 Plan). Under the 2015 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then employees, officers, non-employee directors or consultants of the Company or its subsidiaries. Initially, a total of 80,103 shares of common stock were reserved for issuance under the 2015 Plan. In addition, pursuant to the June 10, 2021 amendment, the number of shares of common stock available for issuance under the 2015 Plan will be annually increased on the first day of each fiscal year during the term of the 2015 Plan, as amended, beginning with the 2022 fiscal year until (and including) January 1, 2031, by an amount equal to 5% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year or such other amount as the Company's board of directors may determine. The maximum term of the options granted under the 2015 Plan is no more than ten years. Grants generally vest at 25% one year from the vesting commencement date and ratably each month thereafter for a period of 36 months, subject to continuous service. In addition, pursuant to a June 2021 amendment, the 2015 Plan was amended to allow an additional aggregate 200,000 shares of common stock to be used exclusively for the grant of equity awards as a material inducement for individuals to commence employment at the Company in compliance with Nasdaq Listing Rule 5635(c)(4).

Stock Options

Stock option activity under all Plans is summarized as follows:

	Number of Options	Weighted-Average Exercise Price
Balance at December 31, 2021	1,308,360	$ 13.99
Granted	937,950	2.20
Exercised	—	—
Forfeited	—	—
Balance at December 31, 2022	2,246,310	$ 9.07

Information about the Company's outstanding stock options as of December 31, 2022 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding	2,246,310	$ 9.07	8.00	$ 23,168
Options vested and expected to vest	2,246,310	$ 9.07	8.00	$ 23,168
Options exercisable	860,683	$ 17.36	6.75	$ 1,480

The weighted-average grant date fair value per share of employee option grants during the years ended December 31, 2022, 2021 and 2020 was $1.65, $6.05, and $2.62, respectively. The aggregate intrinsic value used in the above table of options at December 31, 2022 is based on the Company's closing market price per common share on December 30, 2022, the last business day of the 2022 fiscal year, of $1.49. No stock options were exercised during the year ended December 31, 2022 and 3,727 stock options were exercised during the year ended December 31, 2021 for proceeds of $21,000. The total intrinsic value of options exercised was $4,000 during the year ended December 31, 2021. The total grant-date fair value of options that vested during the years ended December 31, 2022, 2021 and 2020 was $2.6 million, $0.8 million and $1.0 million, respectively.

***Employee Stock Purchase* Plan (ESPP)**

On January 1, 2015, the Company's board of directors adopted the ESPP, which became effective upon the pricing of the Company's initial public offering on January 29, 2015. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. Initially, a total of 18,346 shares of common stock was reserved for issuance under the ESPP. In addition, pursuant to the June 10, 2021 amendment, the number of shares of common stock available for issuance under the ESPP will be annually increased on the first day of each fiscal year during the term of the ESPP, beginning with the 2022 fiscal year, by an amount equal to the lessor of: (i) 250,000 shares; (ii) 1% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year; or (iii) such other amount as the Company's board of directors may determine. Stock compensation expense for the years ended December 31, 2022, 2021 and 2020 related to the ESPP was immaterial.

Stock-Based Compensation Expense

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee stock option grants were as follows:

	Years Ended December 31,		
	2022	2021	2020
Risk-free interest rate	1.9%	0.8%	1.2%
Expected volatility	89.8%	90.3%	85.8%
Expected term (in years)	6.2	6.2	6.2
Expected dividend yield	—	—	—

Risk-free interest rate. The Company bases the risk-free interest rate assumption on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

Expected volatility. The Company considers its historical volatility when determining the expected volatility.

Expected term. The expected term represents the period of time that options are expected to be outstanding. Because the Company does not have historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period.

Expected dividend yield. The Company bases the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

The allocation of stock-based compensation expense was as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Research and development	$ 830	$ 628	$ 386
General and administrative	1,211	1,147	648
	$ 2,041	$ 1,775	$ 1,034

As of December 31, 2022 and 2021, the unrecognized compensation cost related to outstanding time-based options was $3.6 million and $4.0 million, respectively, and is expected to be recognized as expense over approximately 2.5 years and 2.7 years, respectively.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance was as follows:

	December 31,	
	2022	2021
Common stock warrants	6,766,246	4,810,409
Common stock options granted and outstanding	2,246,310	1,308,360
Awards available under the 2015 Plan	150,335	115,990
Shares available under the Employee Stock Purchase Plan	243,817	105,619
	9,406,708	6,340,378

7. Collaborations

Eucure and Biocytogen Collaborative Development and Commercialization Agreement

In October 2021, the Company, Eucure (Beijing) Biopharma Co., Ltd. (Eucure) and Biocytogen Pharmaceuticals (Beijing) Co., Ltd. (Biocytogen), Eucure's controlling affiliate, entered into a collaborative development and commercialization agreement (the YH001 Collaboration Agreement) for the development of YH001, a monospecific investigational CTLA-4 antibody.

Pursuant to the YH001 Collaboration Agreement, the Company was granted an exclusive (including with respect to Eucure and its affiliates), nontransferable, license to develop and commercialize YH001 in North America for the treatment, through administration of YH001 by intravenous or subcutaneous means, of multiple human indications, including sarcoma, microsatellite stable colorectal cancer, renal cell carcinoma (RCC), and K-ras positive non-small cell lung cancer (collectively, the Initial Indications) or one or more of bladder cancer, endometrial cancer, and melanoma as substitute indications, which may be substituted for Initial Indications at the Company's discretion (each upon such substitution, a Substitute Indication). The Company is responsible for, and will bear the costs of, preparing and filing all regulatory submissions and conducting any Phase 1, Phase 2, Phase 3, or post-approval clinical trials in North America for YH001 in the Initial Indications and potentially the Substitute Indications, while Eucure is responsible for conducting, and will bear the costs of, the preparation of chemistry, manufacturing and controls activities for YH001. Eucure has agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, YH001 to the Company for clinical trials pursuant to the terms of a clinical supply and quality agreement to be separately negotiated.

During a specified period, the Company has the option, subject to Eucure's prior written approval, to expand the license to include the development and commercialization of YH001 for the treatment, through administration by intravenous or subcutaneous means, of all human and veterinary therapeutic indications in North America for a payment to Eucure in the low single digit millions.

The Company will be responsible for commercializing YH001 in North America, including booking of sales revenue in the Initial and Substitute Indications. The Company will owe Eucure escalating double digit royalties on net sales of YH001 in North America ranging from the mid-twenties to mid-double digits; provided that until the end of the first full calendar year following the first commercial sale of YH001, royalties will range from the lower double digits to the mid-double digits. If sales of YH001 exceed a pre-determined sales threshold in the first full year of sales following first commercial sale, the Company will owe a milestone to Eucure in the high single digit millions. Payment obligations under the YH001 Collaboration Agreement continue on a country-by-country basis until the latest of (i) expiration of the last to expire licensed patent covering YH001, (ii) expiration of marketing or regulatory exclusivity covering YH001 and (iii) 10 years from the first commercial sale of YH001 in such country in North America. Eucure has agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, YH001 to the Company at cost plus a low double digit markup for commercial sales pursuant to the terms of a commercial supply and quality agreement to be separately negotiated.

3D Medicines and Alphamab Collaboration and Clinical Trial Agreement

In December 2019, the Company, 3D Medicines Co., Ltd. (3D Medicines), and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab) entered into a collaboration and clinical trial agreement (the Envafolimab Collaboration Agreement) for the development of envafolimab, also known as KN035, an investigational PD-L1 single-domain antibody (sdAb), or nanobody, administered by subcutaneous injection, for the treatment of sarcoma in North America. No consideration was exchanged in the Envafolimab Collaboration Agreement. Given no consideration was exchanged, no value was assigned to the Envafolimab Collaboration Agreement in the accompanying consolidated balance sheets.

Pursuant to the Envafolimab Collaboration Agreement, the Company was granted an exclusive license to develop and commercialize envafolimab for the treatment of sarcoma in North America. The Company is responsible for conducting, and will bear the costs of Phase 1, Phase 2, and Phase 3 or post-approval clinical trials in North America for envafolimab in the indications of refractory and first line treatment of sarcoma. 3D Medicines and Alphamab are responsible for conducting, and will bear the costs of, investigational new drug (IND)-enabling studies (other than those specific to the sarcoma indication) and the preparation of chemistry, manufacturing and controls (CMC) activities sections of an IND application for envafolimab. 3D Medicines and Alphamab have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to the Company at pre-negotiated prices that vary based on clinical or commercial use. 3D Medicines and Alphamab retained the right to develop envafolimab in all territories outside of North America as well as within North America for all indications other than sarcoma.

The Company will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue, unless (a) envafolimab is first approved in North America for an indication other than sarcoma and launched in North America, or (b) envafolimab is first approved in North America for sarcoma and subsequently approved in North America for an additional non-orphan indication and sold commercially by 3D Medicines and/or Alphamab, or a licensee, in which case 3D Medicines and Alphamab will be responsible for commercializing envafolimab for sarcoma in North America, including booking of sales revenue. If 3D Medicines and Alphamab become responsible for commercialization under the Envafolimab Collaboration Agreement, the Company has the option to co-market envafolimab for sarcoma in North America. In the event that envafolimab is first approved in North America for sarcoma and within three years of the commercial launch of envafolimab in North America for sarcoma 3D Medicines and Alphamab replace the Company as the party responsible for commercialization, and the Company elects and 3D Medicines and Alphamab agree for the Company to not co-market envafolimab for sarcoma in North America, then 3D Medicine and Alphamab will be required to compensate the Company for its costs associated with preparing for and conducting commercial activities.

If the Company has the responsibility for commercialization under the Envafolimab Collaboration Agreement, the Company will owe 3D Medicines and Alphamab tiered double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits. If 3D Medicines and Alphamab have responsibility for commercialization under the Envafolimab Collaboration Agreement, the Company will be entitled to (a) escalating double digit royalties on net sales of envafolimab for sarcoma in North America ranging from the teens to mid-double digits if the Company has chosen to not co-market envafolimab in sarcoma or (b) a 50% royalty on net sales of envafolimab for sarcoma in North America if the Company has chosen to co-market envafolimab in sarcoma. Payment obligations under the Envafolimab Collaboration Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

3D Medicines and Alphamab retain the right to reacquire the rights to envafolimab for sarcoma in North America in connection with an arm's length sale to a third party, provided that the sale may not occur prior to completion of a pivotal trial of envafolimab in sarcoma without the Company's written consent and the parties must negotiate in good faith and agree to fair compensation to be paid to the Company for the value of and opportunity represented by the required rights.

Each party agreed that during the term of the Envafolimab Collaboration Agreement, it would not develop or license from any third party a monospecific inhibitor to PD-L1 or PD-1 in sarcoma.

The term of the Envafolimab Collaboration Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in North America or the expiration of all payment obligations. The Envafolimab Collaboration Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab. In the event the Company elects, or a joint steering committee determines, to cease further development or commercialization of envafolimab, or if the Company fails to use commercially reasonable efforts to develop (including progress in clinical trials) and commercialize envafolimab and does not cure such failure within a specified time period, then the Company's rights and obligations under the Envafolimab Collaboration Agreement will revert to 3D Medicines and Alphamab.

I-Mab Collaboration Agreements

In November 2018, the Company and I-Mab Biopharma (I-Mab) entered into separate strategic collaboration and clinical trial agreements (the I-Mab Collaboration Agreements) for the development of programs for multiple immuno-oncology product candidates, including I-Mab's proprietary CD73 antibody TJ004309 (the TJ004309 Agreement) as well as up to five proprietary bispecific antibodies currently under development by I-Mab (the Bispecific Agreement).

No consideration was exchanged in the I-Mab Collaboration Agreements. Given the early preclinical stage of development of these assets as of the agreement date, no value was assigned to the I-Mab Collaboration Agreements in the accompanying consolidated balance sheets.

TJ004309 Agreement

Pursuant to the TJ004309 Agreement, the Company and I-Mab are collaborating on developing the TJ004309 antibody, with the Company bearing the costs of filing an IND and for Phase 1 clinical trials, with the parties sharing costs equally for Phase 2 clinical trials, and with the Company and I-Mab bearing 40% and 60%, respectively, of the costs for pivotal clinical trials. I-Mab will be responsible for the cost of certain non-clinical activities, the drug supply of TJ004309, and any reference drugs used in the clinical trials. Each of the parties also agreed for a specified period of time to not develop or license to or from a third party any monoclonal antibody targeting CD73 or any other biologic for certain indications that a joint steering committee (JSC), as set up under the TJ004309 Agreement, selects for TJ004309 development.

In the event that I-Mab licenses rights to TJ004309 to a third party, the Company would be entitled to receive escalating portions of royalty and non-royalty consideration received by I-Mab with respect to territories outside of Greater China. In the event that I-Mab commercializes TJ004309, the Company would be entitled to receive a royalty on net sales by I-Mab in North America ranging from the mid-single digits to low double digits, and in the EU and Japan in the mid-single digits. The portions of certain third-party royalty and non-royalty consideration and the royalty from net sales by I-Mab to which the Company would be entitled escalate based on the phase of development and relevant clinical trial obligations the Company completed under the TJ004309 Agreement, ranging from a high-single digit to a mid-teen percentage of non-royalty consideration as well as a double digit percentage of royalty consideration. In March 2020, I-Mab issued a press release announcing a strategic partnership with KG Bio, whereby KG Bio received what the press release described as a right of first negotiation outside North America for TJ004309 for up to $340 million in potential payments to I-Mab. On April 8, 2020, the Company issued a notice of dispute regarding possible breach of the TJ004309 Agreement, which resulted in a binding arbitration proceeding under the Rules of Arbitration of the ICC before the Tribunal. The latest developments in the dispute with I-Mab are discussed in more detail below following the discussion of the Bispecific Agreement.

The TJ004309 Agreement may be terminated by either party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to TJ004309. I-Mab may also terminate the TJ004309 Agreement if the Company causes certain delays in completing a Phase 1 clinical trial. In addition, I-Mab may terminate the TJ004309 Agreement for any reason within 90 days following the completion of the first Phase 1 clinical trial, in which case the Company would be entitled to a minimum termination fee of $9.0 million, or following the completion of the first Phase 2 clinical trial, in which case the Company would be entitled to a pre-specified termination fee of $15.0 million and either a percentage of non-royalty consideration I-Mab may receive as part of a license to a third party or an additional payment if TJ004309 is approved for marketing outside Greater China before a third-party license is executed, in addition to a double digit percentage of royalty consideration. In 2021, I-Mab sent the Company notices purporting to terminate the TJ004309 Agreement, which would result in I-Mab owing the Company a prespecified termination fee of $9.0 million. However, I-Mab does not have an option to terminate the TJ004309 Agreement without cause until the ongoing Phase 1 clinical trial of TJ004309 is "Complete," as that term is defined in the TJ004309 Agreement, and the Company responded by disputing the basis for I-Mab's termination. In March 2021, I-Mab filed a lawsuit in the Delaware Court of Chancery seeking an order of specific performance requiring the Company to comply with I-Mab's effort to terminate the agreement. The Company disagreed with I-Mab's position and in May 2021, the Delaware Court of Chancery stayed the lawsuit filed by I-Mab and subsequently this matter was remanded and included in the proceeding before the Tribunal.

Bispecific Agreement

Pursuant to the Bispecific Agreement, the Company and I-Mab may mutually select through a joint steering committee (JSC) up to five of I-Mab's bispecific antibody (BsAb) product candidates within a five-year period for development and commercialization in North America.

For each product candidate selected by the JSC for development under the Bispecific Agreement, I-Mab will be responsible and bear the costs for IND-enabling studies and establishing manufacturing for the product candidate, while the Company will be responsible for and bear the costs of filing an IND and conducting Phase 1 and Phase 2 clinical trials, and the Company will be responsible for and will share equally with I-Mab in the costs of conducting Phase 3 or pivotal clinical trials, in each case within North America. Subject to I-Mab's right to co-promote an approved product candidate, the Company will be responsible for commercializing any approved product candidates in North America and will share profits and losses equally with I-Mab in North America. The Company would also be entitled to tiered low single digit royalties on net sales of product candidates in the EU and Japan.

At any time prior to completing the first pivotal clinical trial for a product candidate or if I-Mab ceases to support development costs or pay its portion of Phase 3 clinical trial costs for a product candidate or the JSC decides to cease development over the Company's objections after initiating Phase 3 clinical trials, the Company will have an option to obtain an exclusive license to such product candidate in all territories except Greater China and Korea, and any other territories in which I-Mab previously licensed rights to a third party subject to the Company's right of first refusal for any licenses I-Mab may grant to third-parties.

If the Company exercises the option, it would assume sole responsibility for developing and commercializing the product candidate in the licensed territory, and in lieu of profit or loss sharing with I-Mab with respect to such product candidate, the Company would owe I-Mab pre-specified upfront and milestone payments and royalties on net sales, with the payments and royalties escalating depending on the phase of development the product candidate reached at the time the Company obtained the exclusive license as follows: (i) if before IND-enabling studies and the preparation of the CMC activities of the collaborative product, the Company would owe I-Mab a one-time upfront payment of $10.0 million, development and regulatory based milestone payments totaling up to $90.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the mid-single digits on annual net sales; (ii) if after IND submission but before completion of a Phase 1a clinical trial of the collaborative product, the Company would owe I-Mab a one-time upfront payment of $25.0 million, development and regulatory based milestone payments totaling up to $125.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the high single digits on annual net sales; (iii) if after completion of a Phase 1a clinical trial but before completion of Phase 2 proof of concept clinical trial for the collaborative product, the Company would owe I-Mab a one-time upfront payment of $50.0 million, development and regulatory based milestone payments totaling up to $250.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the low double digits on annual net sales; and (iv) if after completion of Phase 2 proof of concept clinical trial and before completion of pivotal trial for the collaborative product, the Company would owe I-Mab a one-time upfront payment of $80.0 million, development and regulatory based milestone payments totaling up to $420.0 million that begin upon completion of a pivotal trial, sales milestones totaling up to $250.0 million, and royalties in the high-teen double digits on annual net sales.

Each party agreed that for a specified period of time, it would not develop or license to or from any third party any bispecific monoclonal antibody targeting the same two biological targets as those of any selected product candidates under the Bispecific Agreement.

If development of any selected product candidates is terminated by a decision of the JSC, all rights to the product candidate will revert to I-Mab, subject to the Company's right to obtain an exclusive license in certain circumstances. If development is terminated after submission of an IND and prior to initiating Phase 3 clinical trials or after initiating Phase 3 clinical trials and with the Company's concurrence, the Company would be entitled to tiered low single digit royalties on net sales of the product candidate in North America, the EU, and Japan.

The Bispecific Agreement may be terminated by either party in the event of an uncured material breach by the other party, bankruptcy of the other party, or with respect to any selected product candidate, for safety reasons related to that product candidate.

In March 2020, the Company learned that I-Mab had entered into two license and collaboration agreements with ABL Bio in July 2018. Under ABL Bio License 1, I-Mab granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a BsAb using certain monoclonal antibody sequences. Under ABL License 2, I-Mab and ABL agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include China, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

In June 2020, I-Mab commenced an arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce (the ICC) before an arbitration tribunal seated in New York City (the Tribunal) after the Company invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations concerning the TJ004309 Agreement and Bispecific Agreement. The Tribunal held a hearing on the merits in February 2022, and final post-hearing briefs were submitted by the Company and I-Mab in May 2022. On November 8, 2022, the Tribunal invited the parties to submit additional, limited briefing on two discrete issues by December 9, 2022. Following that submission, the parties submitted their respective cost submissions for attorney fees reimbursement in January 2023. The Tribunal did not indicate when it expects to render its final decision; however, it did note that it was far along in its deliberations and preparation of a final award. Under the applicable rules of the arbitration, the prevailing party may be awarded attorneys' fees at the Tribunal's discretion. As of the date of this Annual Report, the TJ004309 Agreement and Bispecific Agreement disputes remain under consideration by the Tribunal, and the Company expects the Tribunal to render its final decision in the first quarter of 2023. The claims under the arbitration are complex; accordingly, the Company cannot predict the outcome of the arbitration, and is unable to estimate the amount of recovery or damages, if any, that may be awarded by the Tribunal.

8. Leases

The Company's operating lease obligations relate to its corporate headquarters as the Company leases its office space under a non-cancelable operating lease. The Company amended its lease in August 2021 extending the lease term to April 2027. The lease is subject to base lease payments and additional charges for common area maintenance and other costs and includes certain lease incentives and tenant improvement allowances. Operating lease expense was $0.4 million for each of the three years ended December 31, 2022, 2021 and 2020. As of December 31, 2022, the Company does not have any finance leases, nor any other operating leases.

Supplemental cash flow information related to operating leases was as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Cash paid within operating cash flows	$ 285	$ 461	$ 442
ROU assets recognized in exchange for new lease obligations	$ —	$ 1,117	$ —

Supplemental balance sheet information related to operating leases was as follows (in thousands, except lease term and discount rate):

	December 31,	
	2022	2021
Reported as:		
Other assets (ROU asset)	$ 1,123	$ 1,325
Accounts payable and accrued expenses (lease liability)	$ 198	$ 147
Other long-term liabilities (lease liability)	969	1,167
Total lease liabilities	$ 1,167	$ 1,314
Weighted average remaining lease term	4.3	5.3
Weighted average discount rate	11.3%	11.3%

As of December 31, 2022, the maturities of the Company's operating lease liabilities are as follows (in thousands):

2023	$ 320
2024	334
2025	349
2026	365
2027	123
Total lease payments	1,491
Less imputed interest	(324)
Total operating lease liabilities	$ 1,167

Under the terms of the lease agreement, the Company provided the lessor with an irrevocable letter of credit in the amount of $66,949. The lessor is entitled to draw on the letter of credit in the event of any default by the Company under the terms of the lease.

9. Income Taxes

A reconciliation of the Company's effective tax rate and federal statutory tax rate is summarized as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Federal income taxes	$ (6,118)	$ (6,020)	$ (3,523)
State income taxes, net of federal benefit	(1,962)	(1,889)	(1,084)
Permanent items	81	93	104
Uncertain tax positions	2,477	494	1,224
Research and development credits	(2,119)	(1,661)	(555)
Other, net	125	28	—
Stock compensation	78	203	113
Change in valuation allowance	7,438	8,752	3,721
Provision for income taxes	$ —	$ —	$ —

Significant components of the Company's deferred tax assets and deferred tax liabilities are summarized as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 50,779	$ 47,633
Research and development and Orphan Drug credits	11,928	10,472
Depreciation and amortization	236	247
Right-of-use liability	245	276
Section 174 capitalized research expense	2,503	—
Other, net	1,906	1,573
Total deferred tax assets	67,597	60,201
Right-of-use asset	(236)	(278)
Total deferred tax liabilities	(236)	(278)
Total net deferred	67,361	59,923
Valuation allowance	(67,361)	(59,923)
Net deferred tax assets	$ —	$ —

The Company has net deferred tax assets relating primarily to net operating loss (NOL) carryforwards and research and development and Orphan Drug credit carryforwards. Beginning in 2022, the Tax Cuts and Jobs Act of 2017 requires taxpayers to capitalize and amortize research and development expenditures over five years for domestic research and 15 years for foreign research pursuant to Section 174 of the Internal Revenue Code (Code). Subject to certain limitations, the Company may use these deferred tax assets to offset taxable income in future periods. Due to the Company's history of losses and uncertainty regarding future earnings, a full valuation allowance has been recorded against the Company's deferred tax assets, as it is more likely than not that such assets will not be realized. The net change in the total valuation allowance for the years ended December 31, 2022, 2021 and 2020 was $7.4 million, $8.8 million and $3.7 million, respectively.

As of December 31, 2022, the Company had federal and California NOL carryforwards of $194.3 million and $144.5 million, respectively. The federal and California NOL carryforwards will begin to expire in 2030 and 2033, respectively, if not utilized. The federal NOL generated after 2017 of $111.1 million will carryforward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. As of December 31, 2022, the Company also had federal research and development and Orphan Drug tax credit carryforwards of $13.7 million and California research and development tax credit carryforwards of $3.0 million. The federal research and development and Orphan Drug tax credit carryforwards will begin expiring in 2031 and 2036, respectively, if not utilized. The California research credit will carry forward indefinitely under current law.

Pursuant to Sections 382 and 383 of the Code, the annual use of the Company's NOL and research and development credit carryforwards may be limited in the event that a cumulative change in ownership of more than 50% occurs within a three-year period. The Company previously completed a Section 382/383 analysis regarding the limitation of NOL and research and development credit carryforwards as of December 31, 2018 and did not identify any change in ownership of more than 50% within the preceding three-year period since an ownership change was determined to have occurred at the time of the Company's initial public offering in January 2015. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since December 31, 2018. If the Company has experienced an ownership change at any time since December 31, 2018, utilization of the NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382 of the Code. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance with no net effect on income tax expense or the effective tax rate.

The Inflation Reduction Act of 2022, which incorporates a Corporate Alternative Minimum Tax (CAMT), was signed on August 16, 2022. The changes will become effective for the tax years beginning after December 31, 2022. The new tax will require companies to compute two separate calculations for federal income tax purposes and pay the greater of the new minimum tax or their regular tax liability. The act is not expected to have a significant impact on the Company's financial position, results of operations or cash flows.

The changes in the Company's unrecognized tax benefits are summarized as follows (in thousands):

Balance at December 31, 2019	$	5,092
Change related to prior year positions		—
Increase related to current year positions		1,518
Balance at December 31, 2020		6,610
Change related to prior year positions		1
Increase related to current year positions		506
Balance at December 31, 2021		7,117
Change related to prior year positions		(5)
Increase related to current year positions		2,984
Balance at December 31, 2022	$	10,096

The Company's policy is to include interest and penalties related to unrecognized income tax benefits as a component of income tax expense. The Company has no accruals for interest or penalties in the accompanying consolidated balance sheets as of December 31, 2022 and 2021 and has not recognized interest or penalties in the accompanying consolidated statements of operations for the three years in the period ended December 31, 2022.

Due to the valuation allowance recorded against the Company's deferred tax assets, future changes in unrecognized tax benefits will not impact the Company's effective tax rate. The Company does not expect its unrecognized tax benefits to change significantly in the next 12 months.

The Company is subject to taxation in the United States and California. Due to the net operating loss carryforwards, the U.S. federal and California returns are open to examination for all years since inception. The Company has not been, nor is it currently, under examination by the federal or any state tax authority.

10. 401(k) Plan

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company, at its discretion, may make certain matching contributions to the 401(k) plan. Matching contributions for the years ended December 31, 2022, 2021 and 2020 totaled $0.2 million, $0.1 million and $0.1 million, respectively.

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

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) designed to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified and pursuant to the requirements of the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (who are our principal executive officer and principal financial officer, respectively), to allow for timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) promulgated under the Exchange Act, we carried out an evaluation, with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of December 31, 2022, the end of the period covered by this report. Based upon the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control — Integrated Framework.

Based on our assessment, our management has concluded that, as of December 31, 2022, our internal control over financial reporting was effective based on those criteria.

Pursuant to Regulation S-K Item 308(b), this Annual Report on Form 10-K does not include an attestation report of our company's registered public accounting firm regarding internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes. During the quarter ended December 31, 2022, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 and not set forth below will be set forth in our definitive proxy statement to be filed with the Securities and Exchange Commission on Schedule 14A in connection with our 2023 Annual Meeting of Stockholders (the Proxy Statement), which is expected to be filed by May 1, 2023, under the headings “Executive Officers,” “Proposal 1 – Election of Directors,” “Class II Director Nominees,” Governance – Board of Directors,” “Continuing Directors,” “Information Regarding the Board of Directors and Corporate Governance,” and “Delinquent Section 16(a) Reports,” if any, and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to our directors and employees (including our principal executive officer, principal financial officer, principal accounting officer and controller), and have posted the text of the policy on our website (www.traconpharma.com). In addition, we intend to promptly disclose on our website in the future (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver, to the extent any such waiver is required to be disclosed pursuant to the rules and regulations of the SEC.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation is incorporated by reference to the information set forth in the sections titled “Executive Compensation” in our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth in the section titled “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement.

The information required by Item 201(d) of Regulation S-K is incorporated by reference to the information set forth in the section titled “Executive Compensation” in our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item regarding certain relationships and related transactions and director independence is incorporated by reference to the information set forth in the sections titled “Transactions with Related Parties” and “Information Regarding the Board of Directors and Corporate Governance,” respectively, in our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item regarding principal accountant fees and services is incorporated by reference to the information set forth in the section titled “Principal Accountant Fees and Services” in our Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this report.

1. Financial Statements

The consolidated financial statements of TRACON Pharmaceuticals, Inc. listed below are set forth in Item 8 of this Annual Report for the year ended December 31, 2022:

2. Financial Statement Schedules

These schedules have been omitted because the required information is included in the consolidated financial statements or notes thereto or because they are not applicable or not required.

3. Exhibits

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of TRACON Pharmaceuticals, Inc.
3.3(1)	Amended and Restated Bylaws.
4.1(3)	Form of Common Stock Certificate of the Registrant.
4.2(4)	Form of Pre-Funded Warrant dated March 27, 2018 (attached as Exhibit B-1 to the Securities Purchase Agreement).
4.3(4)	Form of Common Warrant dated March 27, 2018 (attached as Exhibit B-2 to the Securities Purchase Agreement).
4.4(12)	Description of Capital Stock.
4.5(7)	Form of Pre-Funded Warrant dated June 21, 2022.
4.6(7)	Form of Amended and Restated Pre-Funded Warrant 1 dated June 21, 2022.
4.7(7)	Form of Amended and Restated Pre-Funded Warrant 2 dated June 21, 2022.
4.8(3)	Warrant to Purchase Stock issued to Silicon Valley Bank on November 14, 2013.
4.9(3)	Warrant to Purchase Stock issued to Silicon Valley Bank on June 4, 2014.
4.10(3)	Warrant to Purchase Stock issued to Silicon Valley Bank on May 13, 2015.
4.11(9)	Warrant to Purchase Stock issued to Silicon Valley Bank on January 25, 2017.
4.12(10)	Warrant to Purchase Stock issued to Silicon Valley Bank on May 3, 2018.
4.13(8)	Form of Warrant to Purchase Common Stock dated September 2, 2022.
10.1+(3)	Form of Indemnity Agreement by and between the Registrant and its directors and officers.
10.2+(3)	TRACON Pharmaceuticals, Inc. 2011 Equity Incentive Plan and Forms of Stock Option Agreement and Notice of Exercise thereunder.

Exhibit Number	Description of Document
10.3+(11)	TRACON Pharmaceuticals, Inc. 2015 Equity Incentive Plan and Forms of Stock Option Grant Notice, Stock Option Agreement, Notice of Exercise and Restricted Stock Unit Agreement thereunder, as amended June 28, 2021.
10.4+	TRACON Pharmaceuticals, Inc. Non-Employee Director Compensation Policy, as amended February 1, 2023.
10.5+(12)	TRACON Pharmaceuticals, Inc. Amended and Restated 2015 Employee Stock Purchase Plan, as amended June 10, 2021.
10.6+(13)	TRACON Pharmaceuticals, Inc. Bonus Plan, as amended January 29, 2021.
10.7+(14)	Amended and Restated Employment Agreement by and between the Registrant and Charles P. Theuer, M.D., Ph.D., dated February 5, 2019.
10.8+	Employment Agreement by and between the Registrant and Bonne Adams, dated February 27, 2017.
10.9+	Severance Agreement by and between the Registrant and Bonne Adams, dated September 27, 2017.
10.10+(5)	Employment Agreement by and between the Registrant and Scott Brown, dated January 28, 2020.
10.11+(5)	Severance Agreement by and between the Registrant and Scott Brown, dated December 4, 2019.
10.12+(3)	TRACON Pharmaceuticals, Inc. Severance Plan and Summary Plan Description.
10.13*#(5)	Collaboration and Clinical Trial Agreement by and among the Registrant, 3D Medicines (Beijing) Co., LTD. and Jiangsu Alphamab Biopharmaceuticals Co., LTD. dated December 20, 2019.
10.14(2)	Capital on Demand™ Sales Agreement, dated as of December 9, 2020, by and between the Registrant and JonesTrading Institutional Services LLC.
10.15 (6)	Amendment to the Capital on Demand™ Sales Agreement, dated as of March 15, 2022, by and between the Registrant and JonesTrading Institutional Services LLC.
10.16*#(15)	Collaborative Development and Commercialization Agreement by and among the Registrant, Eucure (Beijing) Biopharma Co., Ltd. and Biocytogen Pharmaceuticals (Beijing) Co., Ltd. dated October 8, 2021.
10.17(7)	Securities Purchase Agreement, between the Registrant and Opaleye L.P., dated June 21, 2022.
10.18*#	Investment Agreement, dated December 22, 2022, by and between the Registrant and Batiste Investments LLC.
10.19(8)*#	Loan and Security Agreement by and among the Registrant, each other party thereto as a borrower from time to time, the lenders from time to time party thereto and Runway Growth Finance Corp., dated as of September 2, 2022.
10.20*#	First Amendment to Loan and Security Agreement, dated December 22, 2022, by and between the Registrant and Runway Growth Finance Corp.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
32.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document

Exhibit Number	Description of Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page for the Registrant’s Annual Report on Form 10-K has been formatted in Inline XBRL and contained in Exhibit 101

+ Indicates management contract or compensatory plan.

* Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by “[***]”) because the Registrant has determined that the information is both not material and is the type that the Registrant treats as private or confidential.

Schedules (or similar attachments, including exhibits) to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission or its staff upon request.

(1) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on February 4, 2015.

(2) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on December 9, 2020.

(3) Incorporated by reference to the Registrant’s Registration Statement on Form S-1 (File No. 333-201280), as amended.

(4) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on March 23, 2018.

(5) Incorporated by reference to Registrant's Annual Report on Form 10-K, filed with the SEC on February 28, 2020.

(6) Incorporated by reference to the Registrant’s Registration Statement on Form S-3, filed with the SEC on March 16, 2022.

(7) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on June 21, 2022.

(8) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on September 6, 2022.

(9) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on January 31, 2017.

(10) Incorporated by reference to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 10, 2018.

(11) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on June 30, 2021.

(12) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on June 11, 2021

(13) Incorporated by reference to the Registrant's Annual Report on Form 10-K, filed with the SEC on February 25, 2021.

(14) Incorporated by reference to the Registrant’s Annual Report on Form 10-K, filed with the SEC on March 1, 2019.

(15) Incorporated by reference to the Registrant’s Annual Report on Form 10-Q, filed with the SEC on November 3, 2021.

(16) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed with the SEC on August 27, 2020

(17) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on August 31, 2020.

Signatures

Pursuant to the requirements of the Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TRACON Pharmaceuticals, Inc.

Date: March 8, 2023

By: /s/ CHARLES P. THEUER, M.D., PH.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dr. Charles P. Theuer, M.D., Ph.D. and Scott B. Brown, CPA, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this report, 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 requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Charles P. Theuer, M.D., Ph.D. Charles P. Theuer, M.D., Ph.D.	President, Chief Executive Officer and Member of the Board of Directors *(Principal Executive Officer)*	March 8, 2023
/s/ Scott B. Brown, CPA Scott B. Brown, CPA	Chief Financial Officer (*Principal Financial and Accounting Officer*)	March 8, 2023
/s/ Lisa Johnson-Pratt, M.D. Lisa Johnson-Pratt, M.D.	Member of the Board of Directors	March 8, 2023
/s/ Carol C. Lam, J.D. Carol C. Lam. J.D.	Member of the Board of Directors	March 8, 2023
/s/ William R. LaRue William R. LaRue	Member of the Board of Directors	March 8, 2023
/s/ Martin A. Mattingly, Pharm.D. Martin A. Mattingly, Pharm.D.	Member of the Board of Directors	March 8, 2023
/s/ Saundra Pelletier Saundra Pelletier	Member of the Board of Directors	March 8, 2023
/s/ J. Rainer Twiford, J.D., Ph.D. J. Rainer Twiford, J.D., Ph.D.	Member of the Board of Directors	March 8, 2023
/s/ Stephen T. Worland, Ph.D. Stephen T. Worland, Ph.D.	Member of the Board of Directors	March 8, 2023

Exhibit 10.4

TRACON PHARMACEUTICALS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

(Adopted February 1, 2023)

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of TRACON Pharmaceuticals, Inc. (the "***Company***") or any of its subsidiaries (each such member, a "***Non-Employee Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (the "***Director Compensation Policy***") for his or her Board service.

The Director Compensation Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

A Non-Employee Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

Annual Cash Compensation

Each Non-Employee Director will receive the cash compensation set forth below for service on the Board. The annual cash compensation amounts will be payable in equal quarterly installments, in arrears following the end of each quarter in which the service occurred, pro-rated for any partial months of service. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
    a. All Eligible Directors: $40,000
    b. Chairman/Lead Independent Director (as applicable): $60,000 (in lieu of above)

2. Annual Committee Member Service Retainer:
    a. Member of the Audit Committee: $7,500
    b. Member of the Compensation Committee: $5,000
    c. Member of the Nominating and Corporate Governance Committee: $3,750

3. Annual Committee Chair Service Retainer (in lieu of Committee Member Service Retainer):
    a. Chairman of the Audit Committee: $15,000
    b. Chairman of the Compensation Committee: $10,000
    c. Chairman of the Nominating and Corporate Governance Committee: $7,500

Equity Compensation

Equity awards will be granted under the Company's 2015 Equity Incentive Plan or any successor equity incentive plan (the "***Plan***"). All stock options granted under this policy will be Nonqualified Stock Options (as defined in the Plan), with a term of ten years from the date of grant

1.

and an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of the Company on the date of grant.

(a) Automatic Equity Grants.

(i) Initial Grant for New Directors. Without any further action of the Board, on the date of the Non-Employee Director's initial election to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Non-Employee Director will automatically be granted a Nonstatutory Stock Option to purchase 31,500 shares of common stock (the "***Initial Grant***"). Each Initial Grant will vest in a series of 3 successive equal annual installments over the 3-year period measured from the date of grant.

(ii) Annual Grant. Without any further action of the Board, at the close of business on the date of each annual meeting of the Company's stockholders, each person who is then a Non-Employee Director will automatically be granted either (A) a Nonstatutory Stock Option to purchase 18,000 shares of common stock or (B) a restricted stock unit ("***RSU***") covering 7,875 shares of common stock ((A) or (B) as applicable, the "***Annual Grant***"). Whether the Annual Grant for any particular year takes the form of a Nonstatutory Stock Option or an RSU shall be determined prior to each annual meeting of the Company's stockholders by the Board or the Compensation Committee; provided that absent a determination for any given year, the Annual Grant shall take the form of a Nonstatutory Stock Option. Each Annual Grant will vest in full on the earlier of the one-year anniversary of date of grant, or the date of the next annual meeting of the Company's stockholders.

(b) Vesting; Change in Control. All vesting is subject to the Non-Employee Director's "***Continuous Service***" (as defined in the Plan) on each applicable vesting date. Notwithstanding the foregoing vesting schedules, for each Non-Employee Director who remains in Continuous Service with the Company until immediately prior to the closing of a "***Change in Control***" (as defined in the Plan), the shares subject to his or her then-outstanding equity awards that were granted pursuant to this policy will become fully vested immediately prior to the closing of such Change in Control.

(c) Remaining Terms. The remaining terms and conditions of each stock option, including transferability, will be as set forth in the Company's standard Option Agreement, in the form adopted from time to time by the Board. The remaining terms and conditions of each RSU, including transferability, will be as set forth in the Company's standard Restricted Stock Unit Award Agreement, in the form adopted from time to time by the Board.

Expenses

The Company will reimburse Non-Employee Director for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; *provided*, that the Non-Employee Director timely submit to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

TRACON PHARMACEUTICALS, INC. AMENDED AND RESTATED EMPLOYMENT AGREEMENT

For

BONNE ADAMS

This **AMENDED AND RESTATED EMPLOYMENT AGREEMENT** (the ***"Agreement")*** is made and entered into effective as of February 27, 2017 (the ***"Effective Date"),*** by and between TRACON Pharmaceuticals, Inc., a Delaware corporation (the ***"Company"),*** and Bonne Adams (the ***"Executive").*** The Company and Executive are hereinafter collectively referred to as the ***"Parties",*** and individually referred to as a ***"Party".*** From and following the Effective Date, this Agreement along with the Amended and Restated Severance Agreement entered into by and between Executive and the Company concurrently with this Agreement (the ***"Amended Severance Agreement')*** shall replace and supersede that certain Employment Agreement between Executive and Company entered into as of August 23, 2006 and amended as of March 25, 2011 and Severance Agreement between the Company and Executive dated June 2, 2014 (collectively, the ***"Prior Agreement").*** Certain capitalized terms used in this Agreement are defined in Section 11.

RECITALS

WHEREAS, Executive and the Company are currently parties to the Prior Agreement that is superseded and replaced in its entirety by this Agreement and the Amended Severance Agreement;

WHEREAS, the Company desires to continue to employ Executive to provide personal services to the Company in that capacity, and wishes to provide Executive with certain compensation and benefits in return for such services, and Executive wishes to be so employed and to receive such benefits; and

WHEREAS, the Company and Executive wish to enter into this Agreement to define their mutual rights and duties with respect to Executive's compensation and benefits.

Now, THEREFORE, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, the Parties, intending to be legally bound, agree as follows:

AGREEMENT

1. Employment by the Company.

1.1 **Position.** Executive shall continue to serve as the Company's Senior Vice President, Clinical Operations. During the term of Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company, except for approved vacation periods and reasonable periods of illness or other incapacities permitted by the Company's general employment policies.

1.2 Duties and Location. Executive shall continue to report to the Company's Chief Executive Officer (the ***"CEO"),*** and shall have such duties and responsibilities as are customary for the positions of Senior Vice President, Clinical Operations. Executive's primary office location shall continue to be the Company's San Diego, California office. The Company reserves the right to reasonably require Executive to perform Executive's duties at places other than Executive's primary office location from time to time, and to require reasonable business travel.

1.3 Policies and Procedures. The employment relationship between the Parties shall be governed by the general employment policies and practices of the Company, except that when the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. Compensation.

2.1 Salary. Executive shall receive a base salary at the rate of $288,779 per year (the ***"Base Salary"),*** subject to standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule.

2.2 Bonus. Executive will be eligible for an annual discretionary bonus of up to 35% of Executive's Base Salary (the ***"Annual Bonus").*** Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Board (or the Compensation Committee thereof) in its sole discretion based upon the Company's and Executive's achievement of objectives and milestones to be determined on an annual basis by the Company's Board of Directors (the ***"Board")*** (or the Compensation Committee thereof). Executive must remain an active employee through the end of any given calendar year in order to earn an Annual Bonus for that year and any such bonus will be paid prior to March 15 of the year following the year in which Executive's right to such amount became vested. Executive will not be eligible for, and will not earn, any Annual Bonus (including a prorated bonus) if Executive's employment terminates for any reason before the end of the calendar year.

3. Standard Company Benefits. Executive shall be entitled to participate in all employee benefit programs for which Executive is eligible under the terms and conditions of the benefit plans that may be in effect from time to time and provided by the Company to its employees. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time.

4. Vacation. Executive shall be entitled to accrue vacation in accordance with the terms of the Company's vacation policy and practices (including but not limited to maximum vacation accrual caps).

5. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in furtherance or in connection with the

performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

6. Equity.

6.1 Prior Awards. Any stock, stock options, or other equity awards that Executive has already been granted by the Company shall continue to be governed in all respects by the terms of the applicable grant agreements, grant notices, and plan documents, except as otherwise provided in this agreement.

6.2 Additional Awards. The Board (or the Compensation Committee thereof) may grant additional stock, stock options, or other equity awards to Executive in its sole discretion.

7. Termination of Employment.

7.1 At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without cause or advance notice.

7.2 Termination Benefits. In the event that Executive's employment terminates for any reason, including due to Executive's death or disability, no further payments shall be due under this Agreement, except that the Executive shall be entitled to any amounts earned, accrued or owing but not yet paid under Section 2 above, any benefits accrued or earned under the Company's benefit plans and programs or to which Executive is otherwise entitled under applicable law, and any outstanding equity awards vested as of the termination date, which awards must be exercised within 90 days of the termination date or the earlier expiration of such equity award, whichever occurs first. Executive may also be eligible for other post-employment payments and benefits pursuant to the terms of the Amended Severance Agreement.

8. Section 409A. It is intended that all of the benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A.

9. Proprietary Information Obligations.

9.1 Confidential Information Agreement. As a condition of continued employment, Executive acknowledges and reaffirms Executive's obligations to the Company under the Employee Proprietary Information and Inventions Agreement which Executive executed on or about September 18, 2014 (the ***"Confidentiality Agreement")***

9.2 Third-Party Agreements and Information. Executive represents and warrants that Executive's employment by the Company does not conflict with any prior employment or consulting agreement or other agreement with any third party, and that Executive will perform Executive's duties to the Company without violating any such agreement. Executive represents and warrants that Executive does not possess confidential information arising out of prior employment, consulting, or other third party relationships, that would be used in connection with Executive's

employment by the Company, except as expressly authorized by that third party. During Executive's employment by the Company, Executive will use in the performance of Executive's duties only information which is generally known and used by persons with training and experience comparable to Executive's own, common knowledge in the industry, otherwise legally in the public domain, or obtained or developed by the Company or by Executive in the course of Executive's work for the Company.

10. Outside Activities During Employment.

10.1 Non-Company Business. Except with the prior written consent of the Board, Executive will not during the term of Executive's employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of Executive's duties hereunder.

10.2 No Adverse Interests. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

11. Dispute Resolution. To ensure the rapid and economical resolution of disputes that may arise in connection with Executive's employment and services for the Company, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, Executive's employment with and services for the Company, or the termination of Executive's employment with and services for the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §§1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted in San Diego, California (or such other location as mutually agreed by the parties) by JAMS, Inc. ***("JAMS")*** or its successors by a single arbitrator. ***Both Executive and the Company acknowledge that by agreeing to this arbitration procedure, they each waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding***. Any such arbitration proceeding will be governed by JAMS' then applicable rules and procedures for employment disputes, which can be found at http://www.jamsadr.com/rules-clauses/ and which will be provided to Executive upon request. In any such proceeding, the arbitrator shall (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. Executive and the Company each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. Nothing in this Agreement is intended to prevent either the Company or Executive from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. The Company shall pay all filing fees in excess of those that would be required if the dispute were decided in a court of law, and shall pay the arbitrator's fees and any other fees or costs unique to arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

12. General Provisions.

12.1 **Notices.** Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

12.2 **Severability.** Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

12.3 **Waiver.** Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

12.4 **Complete Agreement.** This Agreement, together with the Severance Agreement and Confidentiality Agreement, constitutes the entire agreement between Executive and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the Parties' agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations (including but not limited to the Prior Agreement). It cannot be modified or amended except in a writing signed by a duly authorized officer of the Company and Executive.

12.5 **Counterparts.** This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

12.6 **Headings.** The headings of the paragraphs hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

12.7 **Successors and Assigns.** This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of Executive's duties hereunder and Executive may not assign any of Executive's rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

12.8 **Tax Withholding and Indemnification.** All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made

pursuant to the Agreement.

12.9 **Choice of Law.** All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the day and year first written above.

TRACON PHARMACEUTICALS, INC.

By: /s/ Charles P. Theuer
Charles P. Theuer, M.D., Ph.D
Chief Executive Officer

Executive

/s/ Bonne Adams
Bonne Adams

Exhibit 10.9

TRACON PHARMACEUTICALS, INC. SEVERANCE PLAN AMENDED AND RESTATED SEVERANCE AGREEMENT

This Amended and Restated Severance Agreement (the **"Agreement")** is entered into by and between Bonne Adams **("you"** or **"your")** and TRACON Pharmaceuticals, Inc. (the ***"Company")*** pursuant to the TRACON Pharmaceuticals, Inc. Severance Plan ***("Plan").*** Capitalized terms used herein but not otherwise defined have the meanings set forth in the Plan.

This Agreement has an effective date of September 27, 2017 (the **"Effective Date")** and as of the Effective Date amends, restates and supersedes in its entirety the Severance Agreement between you and the Company dated June 2, 2014. You are a Covered Employee (as defined in the Plan) and participant in the Plan as provided by the Plan. This Agreement is the Severance Agreement described in the Plan and this Agreement enumerates the Plan benefits that may be provided to you as a Covered Employee as referenced in Section II of the Plan. All provisions of this Agreement are subject to and governed by the terms of the Plan. In the event of any conflict in terms between the Plan and this Agreement, the terms of the Plan shall prevail and govern.

In consideration of the mutual covenants and promises made in this Agreement, you and the Company agree as follows:

I. ***Certain Definitions.*** In addition to terms defined elsewhere herein or in the Plan, the following terms have the following meanings when used in this Agreement:

(a) **"Base Salary"** means your then current base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation), at the rate in effect during the last regularly scheduled payroll period immediately preceding the date of your Qualifying Termination, and determined prior to any reduction in base pay that would permit you to voluntarily resign employment for Good Reason or any reduction in your base pay which occurs following a Change in Control.

(b) **"Board"** means the Company's Board of Directors.

(c) **"Cause"** means the occurrence of one or more of the following:

(i) Your commission of fraud or other unlawful conduct in your performance of duties for the Company;

(ii) your conviction of, or a plea of guilty or nolo contendere to, a felony or other crime (except for misdemeanors which are not materially injurious to the business or reputation of the Company or a Company affiliate); or

(iii) your willful refusal to perform in any material respect your duties and responsibilities for the Company or a Company affiliate or your failure to comply in any material respect with the terms of any agreement between you and the Company, including any proprietary information and assignment of inventions agreement or and the policies and procedures of the Company or a Company affiliate at which you are employed or serve as an officer and/or director if such refusal or failure causes or reasonably expects to cause injury to the Company or a Company affiliate;

(iv) fraud or other illegal conduct in your performance of duties for the Company or a Company affiliate;

(v) any conduct by you which is materially injurious to the Company or a Company affiliate or materially injurious to the business reputation of the Company or a Company affiliate.

The foregoing events are an exhaustive list for which your employment can be terminated by the Company for Cause for purposes of this Agreement. Prior to your termination for Cause at any time within 12 months following a Change in Control, you will be provided with written notice from the Company describing the conduct forming the basis for the alleged Cause and to the extent curable as determined by the Board in its good faith discretion, an opportunity of 15 days to cure such conduct before the Company may terminate you for Cause. If the Board determines that the Cause event is curable, you may during this 15 day period present your case to the full Board before any termination for Cause is finalized by the Company. Any termination for "Cause" will not limit any other right or remedy the Company may have under this Agreement or otherwise.

(a) **"Change in Control Related Termination"** means that a Qualifying Termination where your Termination Date occurs on or within 12 months after a Change in Control.

(b) **"Change in Control"** has the meaning as defined in the Company's 2015 Equity Incentive Plan. For purposes of this Agreement, only the first Change in Control occurring after the Effective Date will be a "Change in Control."

(c) **"Company"** shall mean TRACON Pharmaceuticals, Inc., a Delaware corporation, and shall include any successor company following a Change in Control.

(d) **"Good Reason"** means a resignation of your employment after the first occurrence of any one or more of the following events without your written consent.

(i) a material diminution in your responsibilities, duties or authority;

(ii) a material diminution in your Base Salary; or

(iii) a relocation of the Company's principal place of business where you are assigned to work outside of the San Diego metropolitan area;

provided, however that your resignation will only be for Good Reason if each of the following additional conditions is met: (i) you provide the Company with written notice describing in detail the basis and underlying facts supporting your belief that a Good Reason event has occurred within 45 days of the initial existence of such Good Reason event, (ii) the Company has not cured or remedied the Good Reason event within 30 days after its receipt of your written notice, and (iii) your resignation occurs within ninety (90) days of the initial existence of the Good Reason event. This "Good Reason" definition and process is intended to comply with the safe harbor provided under Treasury Regulation Section l.409A-l(n)(2)(ii) and shall be interpreted accordingly.

(e) **"Non-Change in Control Related Termination"** means a Qualifying Termination that is not a Change in Control Related Termination.

(f) **"Qualifying Termination"** means a termination of your employment by the Company without Cause or your resignation of employment for Good Reason. A Qualifying Termination does not include any termination of your employment due to death or disability.

(g) **"Separation Agreement"** means the separation agreement and general release of all claims in substantially the form attached as **Exhibit A** hereto, with such other changes as the Company may reasonably require in order to provide for an effective release of claims, and delivered to you no later than five days following your Termination Date.

(h) **"Target Bonus"** means the applicable percentage of your annual Base Salary that you were eligible to earn as an annual bonus for the year including your Termination Date, and calculated without giving effect to any reduction in your Base Salary that would give rise to your right to resign for Good Reason or any reduction in Base Salary implemented following a Change in Control.

(i) **"Termination Date"** means your last day of employment with the Company.

2. ***Non-Change in Control Related Termination of Employment.*** If your employment is terminated due to a Non-Change in Control Related Termination, you will be eligible to receive the

severance benefits provided in this Section 2, provided that you must: (i) within not later than forty-five (45) days after your Termination Date, execute and deliver to the Company the Separation Agreement and permit it to become effective in accordance with its terms, and (ii) remain in full compliance with the terms of such Separation Agreement. Upon any breach of the terms of your Separation Agreement, severance benefits provided under this Section 2 will immediately cease.

(a) You will receive a severance payment equal to nine months of your Base Salary **("Cash Severance").** The Cash Severance shall be paid to you in substantially equal installments in accordance with the Company's regular payroll practices over the nine month period following your Termination Date; provided, however, the first payment shall be made on the 60th day following your Termination Date and such first installment shall be in an amount to cover the first two months of Cash Severance payments otherwise scheduled to occur following your Termination Date.

(b) Provided that you timely elect COBRA coverage and you continue to timely pay the same portion (if any) of the necessary group health insurance premium that you were responsible to pay as of immediately before your Termination Date, the Company shall continue to pay the Company portion of the premiums for your Company group health insurance coverage for you and your dependents (the ***"COBRA Premiums")*** until the earlier of: (i) nine months following the Termination Date, (ii) the date you are provided with other group health insurance coverage, or (iii) the date you cease to be eligible for COBRA coverage (the ***"COBRA Payment Period").*** For purposes of this Agreement, COBRA Premiums do not include amounts paid by you for coverage under a Section 125 health care reimbursement account plan. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay you on the first day of each calendar month following the Termination Date, a fully taxable cash payment equal to the applicable COBRA Premiums for that month, subject to applicable tax withholdings for the remainder of the COBRA Payment Period.

(c) In addition to the Cash Severance and COBRA Premiums, all of your outstanding equity awards that are subject to vesting solely upon the passage of time and your continued employment with the Company shall be accelerated in accordance with their applicable vesting schedules as if you had completed an additional nine months of employment as of your Termination Date.

3. ***Change in Control Related Termination of Employment.*** If your employment is terminated due to a Change in Control Related Termination, you will be eligible to receive severance benefits provided in this Section 3, provided that you must: (i) within not later than forty-five (45) days after your Termination Date, execute and deliver to the Company the Separation Agreement and permit it to become effective in accordance with its terms, and (ii) remain in full compliance with the terms of such Separation Agreement. Upon any breach of the terms of your Separation Agreement, severance benefits provided under this Section 3 will immediately cease.

(a) You will receive a severance payment equal to your annual Base Salary and Target Bonus **("CIC Cash Severance").** The CIC Cash Severance shall be paid to you in substantially equal installments in accordance with the Company's regular payroll practices over the twelve month period following your Termination Date; provided, however, the first payment shall be made on the 60th day following your Termination Date and such first installment shall be in an amount to cover the first two months of CIC Cash Severance payments otherwise scheduled to occur following your Termination Date.

(b) Provided that you timely elect COBRA coverage and you continue to timely pay the same portion (if any) of the necessary group health insurance premium that you were responsible to pay as of immediately before your Termination Date, the Company shall continue to pay the Company portion of the premiums for your Company group health insurance coverage for you and your dependents (the ***"COBRA Premiums")*** until the earlier of: (i) twelve months following the Termination Date, or (ii) the date you are provided with other group health insurance coverage (the ***"CIC COBRA Payment Period").*** For purposes of this Agreement, COBRA Premiums do not include amounts paid by you for coverage under a Section 125 health care reimbursement account plan. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay you on the first day of each calendar month following the Termination Date, a fully taxable cash payment equal to the applicable COBRA Premiums for that month, subject to applicable tax withholdings for the remainder of the CIC

COBRA Payment Period.

(c) In addition to the Cash Severance and COBRA Premiums, all of your outstanding equity awards that are subject to vesting solely upon the passage of time and your continued employment with the Company shall be accelerated such that 100% of such outstanding equity awards shall be deemed immediately vested and exercisable as of your Termination Date.

4. ***Assignability; Binding Nature.*** Commencing on the Effective Date, this Agreement will be binding upon you and the Company. This Agreement may not be assigned by you except that your rights to compensation and benefits hereunder, subject to the limitations of this Agreement, may be transferred by will or operation of law. No rights or obligations of the Company under this Agreement may be assigned or transferred except in the event of a merger or consolidation in which the Company is not the continuing entity, or the sale or liquidation of all or substantially all of the assets of the Company provided that the assignee or transferee is the successor to all or substantially all of the assets of the Company and assumes the Company's obligations under this Agreement contractually or as a matter of law. The Company will require any such purchaser, successor or assignee to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such purchase, succession or assignment had taken place. Your rights and obligations under this Agreement shall not be transferable by you by assignment or otherwise provided, however, that if you die, all amounts then payable to you hereunder shall be paid in accordance with the terms of this Agreement to your devisee, legatee or other designee or, if there be no such designee, to your estate.

5. ***Governing Law.*** This Agreement is governed by the Employee Retirement Income Security Act of 1974, as amended, and, to the extent applicable, the laws of the State of Delaware, without reference to the conflict of law provisions thereof.

6. **Taxes.** The Company shall have the right to withhold and deduct from any payment hereunder any federal, state or local taxes of any kind required by law to be withheld with respect to any such payment. The Company (including without limitation members of its Board) shall not be liable to you or other persons as to any unexpected or adverse tax consequence realized by you and you shall be solely responsible for the timely payment of all taxes arising from this Agreement that are imposed on you. This Agreement is intended to comply with the applicable requirements of Internal Revenue Code (the **"Code")** Section 409A and shall be limited, construed and interpreted in a manner so as to comply therewith. Each payment made pursuant to any provision of this Agreement shall be considered a separate payment and not one of a series of payments for purposes of Code Section 409A. While it is intended that all payments and benefits provided under this Agreement to you will be exempt from or comply with Code Section 409A, the Company makes no representation or covenant to ensure that the payments under this Agreement are exempt from or compliant with Code Section 409A. The Company will have no liability to you or any other party if a payment or benefit under this Agreement is challenged by any taxing authority or is ultimately determined not to be exempt or compliant. In addition, if upon your Termination Date, you are then a "specified employee" (as defined in Code Section 409A), then solely to the extent necessary to comply with Code Section 409A and avoid the imposition of taxes under Code Section 409A, the Company shall defer payment of "nonqualified deferred compensation" subject to Code Section 409A payable as a result of and within six (6) months following your Termination Date until the earlier of (i) the first business day of the seventh month following your Termination Date or (ii) ten (10) days after the Company receives written confirmation of your death. Any such delayed payments shall be made without interest.

7. ***Section 280G. Limitation on Payments.*** If any payment or benefit you will or may receive from the Company or otherwise (a ***"280G Payment")*** would (i) constitute a "parachute payment" within the meaning of Section 2800 of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the ***"Excise Tax"),*** then any such 2800 Payment pursuant to this Agreement (a ***"Payment")*** shall be equal to the Reduced Amount. The ***"Reduced Amount"*** shall be either
(x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner

(the ***"Reduction Method")*** that results in the greatest economic benefit for you. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the ***"Pro Rata Reduction Method").***

Notwithstanding any provision of the preceding paragraph to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A of the Code that would not otherwise be subject to taxes pursuant to Section 409A of the Code, then the Reduction Method and/or the Pro Rata Reduction Method, as the case maybe, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A of the Code as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for you as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A of the Code shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A of the Code.

Unless you and the Company agree on an alternative accounting firm or law firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting or law firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting or law firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to you and the Company within fifteen (15) calendar days after the date on which your right to a 280G Payment becomes reasonably likely to occur (if requested at that time by you or the Company) or such other time as requested by you or the Company.

If you receive a Payment for which the Reduced Amount was determined pursuant to clause (x) of the first paragraph of this Section 7 and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, you shall promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of the first paragraph of this Section 7 so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of the first paragraph of this Section 7, you shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

8. ***No Change in At-Will Status.*** Your employment with the Company is and shall continue to be at-will, as defined under applicable law. If your employment terminates for any reason, you shall not be entitled to any payments, benefits, damages, awards or compensation other than as provided by this Agreement or required by applicable law, or as may otherwise be established under the Company's then existing employee benefit plans or policies at the time of termination. Nothing in this Agreement modifies your at-will employment status and either you or the Company can terminate the employment relationship at any time, with or without Cause.

9. ***Entire Agreement.*** Except as otherwise specifically provided in this Agreement, the Plan and this Agreement (and the agreements referenced herein) contain all the legally binding understandings and agreements between you and the Company pertaining to the subject matter of this Agreement and supersedes all such agreements, whether oral or in writing, previously discussed or entered into between the parties.

10. ***Covenants*** (a) As a condition of this Agreement and to your receipt of any post- employment benefits, you agree that you will fully and timely comply with all of the covenants set forth in this Section 1O(a) (which shall survive your termination of employment and termination or expiration of this Agreement):

(i) You will fully comply with all obligations under the proprietary information and inventions agreement between you and the Company (as amended from time to time, the **"Confidentiality Agreement")** and further agree that the provisions of the Confidentiality Agreement shall survive any termination or expiration of this Agreement or termination of your employment or any subsequent service relationship with the Company;

(ii) Within five (5) days of the Termination Date, you shall return to the Company all Company confidential information including, but not limited to, intellectual property, etc. and you shall not retain any copies, facsimiles or summaries of any Company proprietary information;

(iii) You will not at any time during or following your employment with the Company, make (or direct anyone to make) any disparaging statements (oral or written) about the Company, or any of its affiliated entities, officers, directors, employees, stockholders, representatives or agents, or any of the Company's products or services or work-in-progress, that are harmful to their businesses, business reputations or personal reputations;

(iv) You agree that, upon the Company's request and without any payment therefore, you shall reasonably cooperate with the Company (and be available as necessary) after the Termination Date in connection with any matters involving events that occurred during your period of employment with the Company.

(b) You also agree that you will fully and timely comply with all of the covenants set forth in this Section 1O(b) (which shall survive your termination of employment and termination or expiration of this Agreement):

(i) You will fully pay off any outstanding amounts owed to the Company no later than their applicable due date or within thirty days of your Termination Date (if no other due date has been previously established);

(ii) Within five (5) days of the Termination Date, you shall return to the Company all Company property including, but not limited to, computers, cell phones, pagers, keys, business cards, etc.;

(iii) Within fifteen (15) days of the Termination Date, you will submit any outstanding expense reports to the Company on or prior to the Termination Date; and

(iv) As of the Termination Date, you will no longer represent that you are an officer, director or employee of the Company and you will immediately discontinue using your Company mailing address, telephone, facsimile machines, voice mail and e-mail.

(c) You acknowledge that (i) upon a violation of any of the covenants contained in Section 10 of this Agreement or (ii) if the Company is terminating your employment for Cause, the Company would as a result sustain irreparable harm, and, therefore, you agree that in addition to any other remedies which the Company may have, the Company shall be entitled to seek equitable relief including specific performance and injunctions restraining you from committing or continuing any such violation; and

11. ***Offset.*** Any Severance or other payments or benefits made to you under this Agreement may be reduced, in the Company's discretion, by any amounts you owe to the Company provided that any such offsets do not violate Code Section 409A. To the extent you receive severance or similar payments and/or benefits under any other Company plan, program, agreement, policy, practice, or the like, or under the WARN Act or similar state law, the payments and benefits due to you under this Agreement will be correspondingly reduced on a dollar-for-dollar basis (or vice-versa) in a manner that complies with Code Section 409A.

12. ***Notice.*** Any notice that the Company is required to or may desire to give you shall be given by personal delivery, recognized overnight courier service, email, telecopy or registered or certified mail, return receipt requested, addressed to you at your address of record with the Company, or at such other place as you may from time to time designate in writing. Any notice that you are required or may desire to give to the Company hereunder shall be given by personal delivery, recognized overnight courier service, email, telecopy or by registered or certified mail, return receipt requested, addressed to the

Company's Chief Executive Officer at its principal office, or at such other office as the Company may from time to time designate in writing. The date of actual delivery of any notice under this Section 1O shall be deemed to be the date of delivery thereof.

13. ***Waiver; Severability.*** No provision of this Agreement may be amended or waived unless such amendment or waiver is agreed to by you and the Company in writing. No waiver by you or the Company of the breach of any condition or provision of this Agreement will be deemed a waiver of a similar or dissimilar provision or condition at the same or any prior or subsequent time. Except as expressly provided herein to the contrary, failure or delay on the part of either party hereto to enforce any right, power, or privilege hereunder will not be deemed to constitute a waiver thereof. In the event any portion of this Agreement is determined to be invalid or unenforceable for any reason, the remaining portions shall be unaffected thereby and will remain in full force and effect to the fullest extent permitted by law.

14. ***Voluntary Agreement.*** You acknowledge that you have been advised to review this Agreement with your own legal counsel and other advisors of your choosing and that prior to entering into this Agreement, you have had the opportunity to review this Agreement with your attorney and other advisors and have not asked (or relied upon) the Company or its counsel to represent you or your counsel in this matter. You further represent that you have carefully read and understand the scope and effect of the provisions of this Agreement and that you are fully aware of the legal and binding effect of this Agreement. This Agreement is executed voluntarily by you and without any duress or undue influence on the part or behalf of the Company.

By signing below, you expressly acknowledge that you (i) have received a copy of the Plan and its Summary Plan Description, (ii) understand the terms of the Plan and this Agreement, (iii) are voluntarily entering into this Agreement and (iv) are agreeing to be bound by the terms of the Plan and this Agreement.

Please acknowledge your acceptance and understanding of this Agreement by signing and returning it to the undersigned. A copy of this signed Agreement will be sent to you for your records.

ACKNOWLEDGED AND AGREED:

TRACON PHARMACEUTICALS, INC.

BY: /s/ Charles P. Theuer
Charles P. Theuer, President and CEO

/s/ Bonne Adams
Bonne Adams

EXHIBIT A

SEPARATION AGREEMENT AND GENERAL RELEASE OF ALL CLAIMS

This Separation Agreement and General Release, dated [DATE] (the **"Agreement"),** is made pursuant to that certain Amended and Restated Severance Agreement dated [DATE], 2017 (the **"Severance Agreement")** entered into by and between Bonne Adams **("Employee")** on the one hand, and TRACON Pharmaceuticals, Inc. (the **"Company"),** on the other. This Agreement is entered into in consideration for and as condition precedent to the Company providing separation benefits to Employee pursuant to the Severance Agreement. It is understood and agreed that the Company is not otherwise obligated to

provide such benefits under the terms of the Severance Agreement and that the Company is doing so as a direct result of Employee's willingness to agree to the terms hereof. Collectively, Employee and the Company shall be referred to as the **"Parties."**

1. Employee was formerly employed by the Company. Employee's employment with the Company ended effective [DATE] (the **"Termination Date").**

2. The purpose of this Agreement is to resolve any and all disputes relating to Employee's employment with the Company, and the termination thereof (the **"Disputes").** The Parties desire to resolve the above-referenced Disputes, and all issues raised by the Disputes, without the further expenditure of time or the expense of contested litigation. Additionally, the Parties desire to resolve any known or unknown claims as more fully set forth below. For these reasons, they have entered into this Agreement.

3. Employee acknowledges and agrees that Employee has received all wages due to Employee through the Termination Date, including but not limited to all accrued but unused vacation, bonuses, commissions, options, benefits, and monies owed by the Company to Employee. Employee further agrees and acknowledges that Employee has been fully paid and reimbursed for any and all business expenses which Employee incurred during his/her employment with the Company.

4. The Company expressly denies any violation of any federal, state or local statute, ordinance, rule, regulation, policy, order or other law. The Company also expressly denies any liability to Employee. This Agreement is the compromise of disputed claims and nothing contained herein is to be construed as an admission of liability on the part of the Company hereby released, by whom liability is expressly denied. Accordingly, while this Agreement resolves all issues referenced herein, it does not constitute an adjudication or finding on the merits of the allegations in the Disputes and it is not, and shall not be construed as, an admission by the Company of any violation of federal, state or local statute, ordinance, rule, regulation, policy, order or other law, or of any liability alleged in the Disputes.

5. In consideration of and in return for the promises and covenants undertaken by the Company and Employee herein and the releases given by Employee herein:

a. [The Company has previously granted to Employee the following options (collectively, the **"Options")** to purchase shares of the Company's common stock (the **"Shares")** under the Company's 2015 Equity Incentive Plan (the **"Plan"):** [List all Option Grants]. As of the Termination Date of [DATE], a total of [ ] shares underlying Employee's stock options are vested (collectively, the **"Vested Stock Options").** The remaining shares underlying Employee's stock options are unvested and have been forfeited and canceled as of the Termination Date. Employee has until the date that is ninety (90) days after the Termination Date to exercise any or all of the Vested Options (the **"Option Termination Date").** Any portion of Employee's Vested Stock Options that remain unexercised as of the Option Termination Date shall be forfeited and canceled as of such date.]

b. In addition to any compensation otherwise due Employee for actual work performed up to and including the Termination Date, Employee shall receive severance compensation as

outlined in Section
of the Severance
Agreement. Pursuant to
Section

of the Severance

Agreement, Employee will receive a total sum of$, less standard withholdings, representing
[J month[s] of Employee's base salary [and Employee's target bonus] (the **"Severance Pay").** The Severance Pay shall be paid to Employee in cash, in substantially equal monthly installments, payable over the[ ] month period following the Termination Date; provided, however, the first payment shall be made on the 60"' day following the Termination Date and such first installment shall be in an amount to cover the first two months following the Termination Date. As a condition to receiving and continuing to receive the Severance Pay, Employee must (i) within but not later than forty-five (45) days after the Termination Date, execute and deliver to the Company this Agreement, (ii) permit this Agreement to become effective, and (iii) remain in full compliance with this Agreement and the Severance Agreement. Employee shall not be entitled to accrue any additional leave or other benefits subsequent to the Termination Date.

c. Provided Employee timely elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 **("COBRA")** of the Company's group health plan, the Company shall pay the entire applicable premiums to continue Employee's existing medical and dental benefits through [DATE], which represents [ ] month[sJ following the Termination Date. Thereafter, Employee shall be eligible to continue his or her medical and dental benefits at his or her own cost in accordance with COBRA. If at any time subsequent to the Termination Date, Employee obtains medical and dental benefits through another employer, Employee shall immediately notify the Company that he or she has obtained such medical and dental benefits and the Company shall no longer be required to pay any premiums for Employee's medical and dental benefits as of the date that Employee's new medical and dental benefits begin coverage.

d. Any tax liabilities resulting from or arising out of the benefits to Employee referred to in paragraphs Sa, Sb and Sc, above, shall be the sole and exclusive responsibility of Employee. Employee agrees to indemnify and hold the Company and the others released herein harmless from and for any tax liability (including, but not limited to, assessments, interest, and penalties) imposed on the Company by any taxing authority on account of the Company failing to withhold for tax purposes any amount from the benefits made as consideration of this Agreement.

6. Except for any rights created by this Agreement, in consideration of and in return for the promises and covenants undertaken herein by the Company, and for other good and valuable consideration, receipt of which is hereby acknowledged:

a. Employee does hereby acknowledge full and complete satisfaction of and does hereby release, absolve and discharge the Company, and each of its parents, subsidiaries, divisions, related companies and business concerns, past and present, as well as each of its partners, trustees, directors, officers, agents, attorneys, servants and employees, past and present, and each of them (hereinafter collectively referred to as **"Releasees")** from any and all claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, grievances, wages, vacation payments, severance payments, obligations, commissions, overtime payments, debts, profit sharing claims, expenses, damages, judgments, orders and liabilities of whatever kind or nature in law, equity or otherwise, whether known or unknown to Employee which Employee now owns or holds or has at any time owned or held as against Releasees, or any of them, including specifically but not exclusively and without limiting the generality of the foregoing, any and all claims, demands, grievances, agreements, obligations and causes of action, known or unknown, suspected or unsuspected by Employee: (1) arising out of or in any way connected with the Disputes; or (2) arising out of Employee's employment with the Company; or (3) arising out of or in any way connected with any claim, loss, damage or injury whatever, known or unknown, suspected

or unsuspected, resulting from any act or omission by or on the part of the Releasees, or any of them, committed or omitted on or before the Effective Date hereof. Additionally, Employee in any future claims may not use against Releasees as evidence any acts or omissions by or on the part of the Releasees, or any of them, committed or omitted on or before the Effective Date hereof, and no such future claims may be based on any such acts or omissions. Also without limiting the generality of the foregoing, Employee specifically releases the Releasees from any claim for attorneys' fees. EMPLOYEE ALSO SPECIFICALLY AGREES AND ACKNOWLEDGES EMPLOYEE IS WANING ANY RIGHT TO RECOVERY BASED ON STATE OR FEDERAL AGE, SEX, PREGNANCY, RACE, COLOR, NATIONAL ORIGIN, MARITAL STATUS, RELIGION, VETERAN STATUS, DISABILITY, SEXUAL ORIENTATION, MEDICAL CONDITION OR OTHER ANTI-DISCRIMINATION LAWS, INCLUDING, WITHOUT LIMITATION, TITLE VII OF THE *CNIL* RIGHTS ACT OF 1964, THE AGE DISCRIMINATION IN EMPLOYMENT ACT, THE EQUAL PAY ACT, THE AMERICANS WITH DISABILITIES ACT, THE CALIFORNIA FAIR EMPLOYMENT AND HOUSING ACT, THE CALIFORNIA FAMILY RIGHTS ACT, CALIFORNIA LABOR CODE SECTION 970, THE FAMILY AND MEDICAL LEAVE ACT, THE EMPLOYEE RETIREMENT INCOME SECURITY ACT, THE WORKER ADWSTMENT AND RETRAINING ACT, THE FAIR LABOR STANDARDS ACT, AND ANY OTHER SECTION OF THE CALIFORNIA LABOR OR GOVERNMENT CODE, ALL AS AMENDED, WHETHER SUCH CLAIM BE BASED UPON AN ACTION FILED BY EMPLOYEE OR BY A GOVERNMENTAL AGENCY. This release does not release claims that cannot be released as a matter of law.

7. Employee agrees and understands as follows: It is the intention of Employee in executing this instrument that it shall be effective as a bar to each and every claim, demand, grievance and cause of action hereinabove specified. In furtherance of this intention, Employee hereby expressly waives any and all rights and benefits conferred upon Employee by the provisions of Section 1542 of the California Civil Code and expressly consents that this Agreement shall be given full force and effect according to each and all of its express terms and provisions, including those relating to unknown and unsuspected claims, demands and causes of action, if any, as well as those relating to any other claims, demands and causes of action hereinabove specified. Section 1542 provides:

> "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."

Having been so apprised, Employee nevertheless hereby voluntarily elects to and does waive the rights described in Civil Code section 1542 and elects to assume all risks for claims that now exist in Employee's favor, known or unknown, that are released under this Agreement.

8. Employee agrees: (1) the fact of and the terms and conditions of this Agreement; and (2) any and all actions by Releasees taken in accordance herewith, are confidential, and shall not be disclosed, discussed, publicized or revealed by the parties or their attorneys to any other person or entity, including but not limited to radio, television, press media, newspapers, magazines, professional journals and professional reports, excepting only the Parties' accountants, lawyers, immediate family members (mother, father, brother, sister, child, spouse), the persons necessary to carry out the terms of this Agreement or as required by law. Should Employee be asked about the Disputes or this Agreement, Employee shall limit Employee's response, if any, by stating that the matters have been amicably resolved.

9. In the event a government agency files or pursues a charge or complaint relating to Employee's employment with the Company and/or the Disputes, Employee agrees not to accept any monetary or other benefits arising out of the charge or complaint.

10. Employee agrees not to make any derogatory, disparaging or negative comments about the Company, its products, officers, directors, or employees.

11. If any provision of this Agreement or application thereof is held invalid, the invalidity shall not affect other provisions or applications of the Agreement which can be given effect without the invalid provision or application. To this end, the provisions of this Agreement are severable.

12. Employee agrees and understands that this Agreement may be treated as a complete defense to any legal, equitable, or administrative action that may be brought, instituted, or taken by Employee, or on Employee's behalf, against the Company or the Releasees, and shall forever be a complete bar to the commencement or prosecution of any claim, demand, lawsuit, charge, or other legal proceeding of any kind against the Company and the Releasees.

13. This Agreement and all covenants and releases set forth herein shall be binding upon and shall inure to the benefit of the respective Parties hereto, their legal successors, heirs, assigns, partners, representatives, parent companies, subsidiary companies, agents, attorneys, officers, employees, directors and shareholders.

14. The Parties hereto acknowledge each has read this Agreement, that each fully understands its rights, privileges and duties under the Agreement, that each has had an opportunity to consult with an attorney of its choice and that each enters this Agreement freely and voluntarily.

15. This Agreement may not be released, discharged, abandoned, changed or modified in any manner, except by an instrument in writing signed by Employee and an officer of the Company. The failure of any Party to enforce at any time any of the provisions of this Agreement shall in no way be construed as a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part thereof or the right of any Party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach.

16. This Agreement and the provisions contained herein shall not be construed or interpreted for or against any party hereto because that party drafted or caused that party's legal representative to draft any of its provisions.

17. In the event of litigation arising out of or relating to this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

18. Employee acknowledges Employee may hereafter discover facts different from, or in addition to, those Employee now knows or believes to be true with respect to the claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, wages, obligations, debts, expenses, damages, judgments, orders and liabilities herein released, and agrees the release herein shall be and remain in effect in all respects as a complete and general release as to all matters released herein, notwithstanding any such different or additional facts.

19. The undersigned each acknowledge and represent that no promise or representation not contained in this Agreement has been made to them and acknowledge and represent that this Agreement and the Severance Agreement contains the entire understanding between the Pmties

and contains all terms and conditions pertaining to the compromise and settlement of the subjects referenced herein. The undersigned further acknowledge that the terms of this Agreement are contractual and not a mere recital.

20. Employee expressly acknowledges, understands and agrees that this Agreement includes a waiver and release of all claims which Employee has or may have under the Age Discrimination in Employment Act of 1967, as amended, 29 U.S.C. §621, et seq. **("ADEA'').** The terms and conditions of Paragraphs 20 through 22 apply to and are part of the waiver and release of ADEA claims under this Agreement. Company hereby advises Employee in writing to discuss this Agreement with an attorney before signing it. Employee acknowledges the Company has provided Employee at least forty-five days within which to review and consider this Agreement before signing it. If Employee elects not to use all forty-five days, then Employee knowingly and voluntarily waives any claim that Employee was not in fact given that period of time or did not use the entire forty-five days to consult an attorney and/or consider this Agreement.

21. Within three calendar days of signing and dating this Agreement, Employee shall deliver the signed original of this Agreement to of the Company. However, the Parties acknowledge and agree that Employee may revoke this Agreement for up to seven calendar days following Employee's execution of this Agreement and that it shall not become effective or enforceable until the revocation period has expired. The Parties further acknowledge and agree that such revocation must be in writing addressed to and received by of the Company not later than midnight on the seventh day following execution of this Agreement by Employee. If Employee revokes this Agreement under this Paragraph, this Agreement shall not be effective or enforceable and Employee will not receive the benefits described above, including those described in Paragraph 5.

22. If Employee does not revoke this Agreement in the timeframe specified in Paragraph 21 above, the Agreement shall be effective at 12:00:01 a.m. on the eighth day after it is signed by Employee (the **"Effective Date").**

23. This Agreement is intended to be exempt from the requirements of section 409A of the Internal Revenue Code of 1986 as amended **("Section 409A")** and will be interpreted accordingly. While it is intended that all payments and benefits provided under this Agreement to Employee or on behalf of Employee will be exempt from Section 409A, the Company makes no representation or covenant to ensure that such payments and benefits are exempt from or compliant with Section 409A. The Company will have no liability to Employee or any other party if a payment or benefit under this Agreement is challenged by any taxing authority or is ultimately determined not to be exempt from or compliant with Section 409A.

24. This Agreement may be executed in any number of counterparts, each of which so executed shall be deemed to be an original and such counterparts shall together constitute one and the same Agreement.

25. This Agreement shall be construed in accordance with, and be deemed governed by, the Employee Retirement Income Security Act of 1974, as amended, and, to the extent applicable, the laws of the State of Delaware, without reference to the conflict of law provisions thereof.

26. The Company executes this Agreement for itself and on behalf of all other respective Releasees.

I have read the foregoing Separation Agreement and General Release of All Claims, consisting of [J pages, and I accept and agree to the provisions contained therein and hereby execute it voluntarily and with full understanding of its consequences.

PLEASE READ CAREFULLY. TIDS AGREEMENT CONTAINS A GENERAL RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

Dated:__

Bonne Adams

Pharmaceuticals, Inc.

Dated:_ _

Name: Title:

TRACON

[Signature Page to Separation Agreement and General Release of All Claims]

Exhibit 10.18

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Execution Version

Dated as of December 22, 2022

Investment Agreement

CONTENTS

SECTION PAGE

INVESTMENT AGREEMENT, dated as of December 22, 2022 ("***Agreement***"), between TRACON Pharmaceuticals, Inc., an entity organized or formed under the laws of the jurisdiction identified in Annex I (the "***Counterparty***"), on the one hand, and each of Batiste Investments LLC, a limited liability company and Maplewood Park Investments LP, a limited partnership, in each case formed under the laws of the jurisdiction identified on Annex I ("***Investor No. 1***" and "***Investor No. 2***", respectively, and each of them, severally but not jointly an "***Investor***", and collectively, the "***Investors***"), on the other hand.

WHEREAS, the Counterparty before interacting with the Investors has pursued the Claim (as defined herein) and has requested that the Investors provide external capital based on the value of the Claim;

WHEREAS, the Investors have committed to provide such capital in accordance with the terms and conditions of this Agreement and, in consideration for providing such capital, the Investors shall be entitled to a share of Proceeds (as defined herein) that arise if the Claim is successful; and

WHEREAS, the Investors are passive providers of capital and do not own or control the Claim; consequently, while the Investors will receive information about the Claim and consult with the Counterparty thereon, the Counterparty remains in full control of the assertion and resolution of the Claim;

NOW, THEREFORE, in consideration of the mutual agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. DEFINITIONS

Capitalized terms used herein have the meanings assigned to them in in Exhibit A or elsewhere in this Agreement.

2. INVESTMENT OBLIGATIONS AND INVESTORS' ENTITLEMENT

2.1 Capital Amounts

The Investors shall provide capital to the Counterparty as set forth below.

(a) Capital Amounts: Up to *the lesser* of (x) thirty million dollars (US$30,000,000) or (y) [***] percent ([***]%) of the Award (such amount, the "***Maximum Commitment Amount***"), to be deployed as follows:

(i) three million five hundred thousand dollars (US$3,500,000) shall be provided to the payment account of the Counterparty set forth on Annex II within [***] Business Days of the Closing Date (the "***Closing Capital Amount***");

(ii) provided the Threshold Recovery Condition has been satisfied, twenty-five percent (25%) of the Maximum Commitment Amount shall be provided to the payment account of the Counterparty within fifteen (15) Business Days of the issuance of an Award by the ICC tribunal considering the Claim (the "***Post-Award Capital Amount***");

(iii) provided the Threshold Recovery Condition has been satisfied, up to [***] dollars (US$[***]) shall be provided for reasonable legal fees and costs associated with an Award confirmation process (the "***Confirmation Capital Amounts***") and/or Award enforcement effort (the ***"Enforcement Capital Amounts***", and together with the Confirmation Capital Amount, the "***Confirmation & Enforcement Capital Amounts***"), subject to the following conditions:

(A) Covington & Burling LLP ("***Covington***") and Foley Hoag LLP ("***Foley***") shall serve as the Counterparty's initial counsel in connection with confirming the Award in the United States of America and Kobre & Kim LLP ("***K&K***") shall serve as the Counterparty's initial counsel in connection with all other litigation to enforce and monetize the Award, with any subsequent change to confirmation process counsel or enforcement counsel to be mutually agreed between Counterparty and Investors;

(B) the Counterparty and the Investors have mutually approved in writing the respective estimated budgets for such confirmation and enforcement proceedings;

(C) Confirmation & Enforcement Capital Amounts shall be provided by the Investors on behalf of the Counterparty directly to the payment account of the relevant counsel (using the wire information provided by such counsel to the Investors in writing) within [***] Business Days following receipt by the Investors of satisfactory invoices, but not more frequently than [***]; and

(D) prior to the Enforcement Trigger Date, not more than [***] dollars (US$[***]) of Confirmation & Enforcement Capital Amounts shall be available to the Counterparty absent the Investors' consent;

(iv) provided the Threshold Recovery Condition has been satisfied, an amount equal to the (x) Maximum Commitment Amount minus (y)(i) the Closing Capital Amount, (ii) the Post-Award Capital Amount, and (iii) US$[***] shall be provided to the payment account of the Counterparty in six (6) equal tranches beginning [***] after the date on which the Post-Award Capital Amount is due in accordance with Section 2.1(a)(ii) and every [***] thereafter until *the earlier* of (x) the [***]-year anniversary of the date on which the Post-Award Capital Amount is due in accordance with Section 2.1(a)(ii) or (y) such time as an Occurrence occurs (the "***Subsequent Capital***

Amounts"), subject to the following provisos:

(A) the Counterparty may terminate the commitment of Investors to provide any given tranche of Subsequent Capital Amounts by written notice to the Investors provided not less than [***] days prior to the date upon which such Subsequent Capital Amount tranche is to be funded, whereupon such tranche of Subsequent Capital Amounts shall be removed from the Maximum Commitment Amount and not included among Subsequent Capital Amounts; and

(B) for the avoidance of doubt, if [***].

(b) Allocation of Funding. Capital Amounts shall be provided in accordance with the following allocation:

(i) Investor No. 1: [***]%

(ii) Investor No. 2: [***]%

(c) Transaction Costs. The Investors shall retain [***] percent ([***]%) of the Closing Capital Amount to cover their closing and other costs (the "***Transaction Costs***").

(d) Commercial Viability. Notwithstanding the foregoing, if any court of competent jurisdiction issues a ruling that, in the sole discretion of the Investors, has the effect of rendering the Claim not commercially viable, then the Investors may terminate their obligations with respect to any unfunded portion of the Capital Amounts and no Investors' Entitlement shall be payable with respect to such unfunded Capital Amounts.

2.2 Investors' Entitlement

In consideration of their agreement to provide the Capital Amounts, the Investors shall be entitled to receive the Investors' Entitlement set forth below.

(a) Investors' Entitlement: The Investors' Entitlement shall be the following to be paid first dollar after payment only of all Applicable Attorney Fees:

(A) an amount equal to [***] plus

(B) a return calculated on each tranche of Capital Amounts actually paid to or on behalf of the Counterparty by the Investors hereunder, equal to a multiple of such Capital Amount, as follows:

(I) for the Closing Capital Amount, [***]x such Capital Amount;

(II) for all Capital Amounts other than the Closing Capital Amount, if an Occurrence does not occur, then:

(aa) if the Investors' Entitlement with respect to such Capital Amount is paid in full within [***] months of the Multiple Start Date applicable to such Capital Amount, [***]x such Capital Amount; or

(bb) if the Investors' Entitlement with respect to such Capital Amount is paid in full on or after the [***]-month anniversary but before the [***]-month anniversary of the Multiple Start Date applicable to such Capital Amount, [***]x such Capital Amount; or

(cc) if the Investors' Entitlement with respect to such Capital Amount is paid in full on or after the [***]-month anniversary but before the [***]-month anniversary of the Multiple Start Date applicable to such Capital Amount, [***]x such Capital Amount; or

(dd) if the Investors' Entitlement with respect to such Capital Amount has not been paid in full before the [***]-month anniversary of the Multiple Start Date applicable to such Capital Amount, [***]x such Capital Amount; or

(III) for all Capital Amounts other than the Closing Capital Amount, if and only if an Occurrence occurs, then:

(aa) if the Investors' Entitlement with respect to such Capital Amount is paid in full before the [***]-month anniversary of the Multiple Start Date applicable to such Capital Amount, [***]x such Capital Amount; or

(bb) if the Investors' Entitlement with respect to such Capital Amount has not been paid in full before the [***]-month anniversary of the Multiple Start Date applicable to such Capital Amount, [***]x such Capital Amount;

plus

(C) as to each tranche of Capital Amounts actually paid to or on behalf of the Counterparty by the Investors hereunder, a [***]% rate of

return, accruing daily and compounding annually, on the sum of such Capital Amount and its applicable return set forth in Section 2.2(a)(B), with such accrual beginning [***] months from the Multiple Start Date applicable to such Capital Amount and ending on the date that the Investors' Entitlement with respect to such Capital Amount is paid in full.

(b) Applications of Payments. The components of the Investors' Entitlement shall be payable on a first-in, first-out basis such that payment of Proceeds shall be applied to the earliest deployed and unreturned Capital Amount first, next the second earliest deployed and unreturned Capital Amount, and so on. As to each Capital Amount, payment of Proceeds shall be applied as follows: (i) ***first***, towards payment of the returns on the applicable Capital Amount as specified in clause (C) of Section 2.2(a); (ii) ***second***, towards payment of the returns on the applicable Capital Amount, as specified in clause (B) of Section 2.2(a); and (iii) ***third***, towards the repayment of the Invested Amount with respect to such Capital Amount as specified in clause (A) of Section 2.2(a). For the avoidance of doubt, in the event of a partial repayment of a Capital Amount, the outstanding portion of such Capital Amount shall continue to accrue its return by reference to its Multiple Start Date.

(c) No Prepayment. The Investors' Entitlement may not be prepaid in whole or in part by the Counterparty without the Investors' written consent.

(d) Allocation of Entitlement. Each Investor shall be entitled to a pro rata portion of the Investors' Entitlement based on the Capital Amounts provided by it. In the event that there is an additional Investor added to this Agreement, such Investor shall be entitled to a portion of the Investors' Entitlement as specified by the Investors at the time of such new Investor's addition to this Agreement.

3. PAYMENT OBLIGATIONS OF THE COUNTERPARTY

3.1 Payments

(a) Non-Recourse Agreement. For purposes of all references in this Agreement to payment of Proceeds for all or any portion of the Investors' Entitlement, including all references to Proceeds in this Section 3.1(a), Proceeds shall mean, and be calculated as, Proceeds minus the amount of Proceeds used to pay all Applicable Attorney Fees. The Capital Amounts are provided to the Counterparty on a non-recourse basis, and the Investors' Entitlement is derived and paid from (and capped at the total amount of) Proceeds. Notwithstanding anything to the contrary in this Agreement, if there are no Proceeds, then the Counterparty shall not have an obligation to pay any portion of the Investors' Entitlement (including any repayment of the Invested Amount) and the Investors' Entitlement with respect to all Capital Amounts shall be [***] dollars (US$[***]); if Proceeds are less than the Investors' Entitlement, then the Counterparty shall not have an obligation to pay the portion of the Investors' Entitlement that exceeds Proceeds and the Investors'

Entitlement in aggregate with respect to all Capital Amounts shall equal the amount of Proceeds; provided, however, that if the Counterparty accepts a settlement offer made by the Adverse Party that resolves the Claim in an amount which does not permit the Investors to recover the Investors' Entitlement (as calculated at the time of the Counterparty accepting the settlement offer) absent Investors' prior written consent, then the Counterparty shall pay the Investors the difference between the full Investors' Entitlement (as calculated at the time of the Counterparty accepting the settlement offer) and the amount of the settlement.

(b) Payment and Delivery of Proceeds.

(i) Prior to the payment of any Proceeds to the Counterparty, the Counterparty shall direct the payor to remit such Proceeds not to the Counterparty but rather to the payment account of the Payment Agent set forth on Annex II, with proper endorsements if by check or other instrument.

(ii) If Proceeds consist of property that is not freely transferable immediately available funds, then the Counterparty shall diligently take such actions as are necessary to (x) monetize such property in a commercially reasonable manner that has been approved by the Investors in their sole discretion (not to be unreasonably withheld, conditioned or delayed) and (y) cause the prompt payment of the Investors' Entitlement from the cash realized from such monetization. Notwithstanding the foregoing, in the event Proceeds consist of property that is not freely transferable immediately available funds and can only be received or monetized by the Counterparty over a period of time which is greater than [***] months from the date such Proceeds arise, then the parties shall negotiate in good faith to establish commercially reasonable monetization and payment parameters and if the parties cannot agree, shall initiate an Expert Determination.

(iii) If, notwithstanding the foregoing, any Proceeds are instead received by the Counterparty or a third party other than the Payment Agent on the Counterparty's behalf at any time when any portion of the Investors' Entitlement remains unpaid, the Counterparty shall, or shall direct such third party to, (x) hold such Proceeds in trust for the benefit of the Investors; (y) segregate such Proceeds from all other funds and property; and (z) forthwith remit such Proceeds to the Payment Agent in accordance with clauses (i) and (ii) of this Section 3.1(b).

(c) Due Date for Payment; Payment Mechanics. Except as otherwise set forth in Section 3.1(b)(ii), the Counterparty (directly or through the Payment Agent) shall pay Proceeds to the Investors in respect of the Investors' Entitlement within [***] Business Days of the Counterparty's (or the Payment Agent's) receipt of such Proceeds. Payment of Proceeds received by the Counterparty or the Payment Agent that are cash shall be made in U.S. Dollars by wire transfer of freely transferable and immediately available funds to the payment accounts of the Investors specified

in writing. The rights of the Investors to receive the Investors' Entitlement pursuant to this Agreement will terminate upon receipt thereof by the Investors.

3.2 Waiver of Right of Set-Off

Subject to Section 13 of this Agreement, each amount that the Counterparty is obligated to pay under this Agreement shall be paid without set-off, deduction or counterclaim.

4. COVENANTS

4.1 Covenants of Each Party

Each party agrees that, so long as such party has or may have any obligation under any Transaction Document to the other party:

(a) it shall maintain its corporate existence, except to the extent that the failure to do so would not have a Material Adverse Effect;

(b) it shall use all reasonable efforts to obtain and maintain in effect all consents, approvals, actions, authorizations, exceptions, notices, filings and registrations of or with any Governmental Authority that are required with respect to any Transaction Document; and

(c) it shall comply with all applicable laws and orders of any Governmental Authority to which it may be subject if failure so to comply could reasonably be expected to have a Material Adverse Effect.

4.2 Covenants of the Investors

Each Investor agrees that:

(a) it is not, by virtue of entering into the Transaction Documents or otherwise, a party to any Claim;

(b) without limiting the obligations of the Counterparty or the rights of the Investors under this Agreement, it is not entitled to control or direct the conduct of any Claim, or to require settlement thereof;

4.3 Covenants of the Counterparty

The Counterparty agrees that:

(a) with respect to the Claim:

(i) it shall use commercially reasonable efforts to: (A) pursue all of the Counterparty's legal and equitable rights arising in connection with the Claim; and (B) bring about the reasonable monetization of the Claim through

a Claim Resolution (including, if so advised by the Nominated Lawyers, by mediating with the Adverse Party as a means of resolving the Claim prior to going to trial); and (C) collect and enforce any Claim Resolution.

(ii) it shall at its own expense (taking into account the Capital Amounts) and in a timely manner: (A) retain, remunerate and cooperate with the Nominated Lawyers to prosecute the Claim; (B) discharge all fees, expenses and other payment obligations necessarily or reasonably recommended or incurred in connection with the Claim; (C) use commercially reasonable efforts to collect and enforce any settlement, final judgment or award; (D) if applicable, discharge any obligation to pay adverse costs or post security for an adverse costs order or award (the costs and expenses of doing all of the foregoing described in clauses (A) – (D), "***Claim Costs***"); and (E) actively manage the incurrence of Claim Costs with the goal of achieving a Claim Resolution, and the collection and enforcement thereof, efficiently and cost-effectively;

(iii) it shall keep the Investors fully and promptly apprised of each material development in the Claim and direct the Nominated Lawyers to do the same; and it shall respond fully and promptly to any reasonable request from the Investors or a Representative of an Investor (which Representative, if requested by the Counterparty, shall be designated by the Investors in writing and, with respect to any information that the Counterparty reasonably considers material non-public information, subject to confidentiality and non-use obligations reasonably satisfactory to the Counterparty) for information regarding the Claim;

(iv) it shall not knowingly prejudice the Claim; and

(v) other than Permitted Liens, it shall not Transfer any portion of the Claim or any Proceeds of the Claim; other than Permitted Liens, it shall not permit to exist any Adverse Interest with respect to any portion of the Claim or any Proceeds thereof; and it shall not set off or agree to set off any amounts against the Claim or any Proceeds of the Claim;

(b) it shall at its sole cost maintain an effective, enforceable Payment Instruction Letter with the Payment Agent;

(c) it shall not permit any amendments to the economic terms or scope of representation set forth in any Engagement Agreement without the Investors' prior written consent; and

(d) if the Nominated Lawyers cease to act as its legal counsel for any reason or if it needs to retain new legal counsel outside the scope of the Engagement Agreement(s) with the Nominated Lawyers, then it shall appoint successor attorneys or new attorneys who have a similar level of quality and reputation in the relevant field of practice as the Nominated Lawyers, subject to the Investors' prior

written approval (not to be unreasonably withheld) of the choice of counsel and the economic terms of the appointment. Upon the engagement of any new counsel, all references to "Nominated Lawyers" will be deemed to refer to and include such successor or additional counsel. The Counterparty will promptly deliver to the Investors a copy of the Engagement Agreement(s) with any successor or new attorney and Annex II shall be deemed updated to reflect such new Engagement Agreements without the necessity of a formal amendment to this Agreement. If pre-existing Nominated Lawyers were acting as Payment Agent prior to their replacement, then the Counterparty will (i) require as a condition of the replacement counsel's engagement that such counsel agree to a Payment Instruction Letter and (ii) deliver a duly executed copy of such Payment Instruction Letter to the Investors immediately upon engaging such replacement counsel. The parties acknowledge and agree that, notwithstanding anything in this Agreement to the contrary, the Counterparty may terminate the engagement of any Nominated Lawyer at any time without the Investors' consent.

4.4 Notice and Information Rights

(a) The Counterparty shall promptly (and in any event within [***] Business Day) notify the Investors of:

(i) any settlement offer made by an Adverse Party, in which case the Counterparty shall in good faith give the Investors an opportunity to discuss such settlement offer prior to accepting or rejecting it;

(ii) any Claim Resolution or any receipt of any Proceeds (including the amount of such Proceeds and the Claim to which such Proceeds relate), or of any event that is expected to generate a Claim Resolution or the receipt of any Proceeds; and

(iii) any Potential Remedy Event or Remedy Event or any event which could reasonably be expected to result in a Potential Remedy Event or Remedy Event.

(b) Within the [***] Business Days following the end of each calendar month, the Counterparty shall itself, or cause the applicable Nominated Lawyers to, provide the Investors with a written or oral Monthly Report.

(c) The Counterparty shall respond fully and promptly to any reasonable request by the Investors or a Representative of an Investor (which Representative, if requested by the Counterparty, shall be designated by the Investors in writing and, with respect to any information that the Counterparty reasonably considers material non-public information, subject to confidentiality and non-use obligations reasonably satisfactory to the Counterparty) for information regarding the financial condition, operations, business or prospects of the Counterparty.

5. REPRESENTATIONS AND WARRANTIES

5.1 Representations and Warranties of Each Party

On each Representation Date, each party represents to the other party that:

(a) it (i) is duly organized or formed and validly existing under the laws of the jurisdiction of its organization or formation and, if relevant under such laws, in good standing, (ii) is qualified to do business in each jurisdiction in which the nature of its business so requires, except where the failure to be so qualified could not reasonably be expected to result in a Material Adverse Effect, and (iii) has not filed any certificates of dissolution or liquidation, or any certificates of domestication, transfer or continuance in any jurisdiction;

(b) it has the power to execute and deliver each Transaction Document to which it is a party and to perform its obligations under each Transaction Document to which it is a party; and it has taken all necessary action to authorize such execution, delivery and performance;

(c) such execution, delivery and performance do not violate or conflict with any law applicable to it, any provision of its constitutional documents, any order or judgment of any court or other Governmental Authority applicable to it or any of its assets or any contractual restriction binding on or affecting it or any of its assets;

(d) all consents, approvals, actions, authorizations, exceptions, notices, filings and registrations that are required to have been obtained by it with respect to the Transaction Documents to which it is a party have been obtained and are in full force and effect, and all conditions of any such consents, approvals, actions, authorizations, exceptions, notices, filings and registrations have been complied with;

(e) the Transaction Documents to which it is a party constitute its legal, valid and binding obligations of such party, enforceable in accordance with their respective terms (subject to applicable bankruptcy, reorganization or similar laws and to general equitable principles); and

(f) (i) it is acting for its own account and has made its own independent decision based on advice from its advisers in entering into the Transaction Documents to which it is a party; (ii) no communication received from any other party shall be deemed an assurance as to the expected results of the transactions contemplated hereby; (iii) explanations related to the terms and conditions of the Transaction Documents and the transactions contemplated hereby shall not be considered legal advice or a recommendation; and (iv) it has assessed (on its own behalf or through independent professional legal advice), understands and accepts the terms, conditions and risks of the Transaction Documents.

5.2 Representations and Warranties of the Counterparty

On each Representation Date, the Counterparty represents and warrants to the Investors that:

(a) no Remedy Event or Potential Remedy Event has occurred and is continuing; no Remedy Event or Potential Remedy Event would occur as a result of its entering into or performing its obligations under the Transaction Documents;

(b) except as set forth on Schedule 5.2(b), no litigation or other proceedings before any court or other Governmental Authority, official, tribunal or arbitrator that could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect, have been commenced by or against the Counterparty or, to the Counterparty's knowledge, are threatened against, the Counterparty;

(c) it is not Insolvent; it is able to pay its debts when due and has no insolvency proceedings threatened or outstanding against it;

(d) as of the date of this Agreement, it has entered into Engagement Agreement(s) with the Nominated Lawyers; true and complete copies of the Engagement Agreement(s) have been provided to the Investors and are set forth on Annex II;

(e) with respect to the Claim:

(i) (A) it is the sole legal and beneficial owner of, has good title to, and possesses sole control of, the Claim, free and clear of any Adverse Interest other than Permitted Liens; (B) it has not Transferred any portion of the Claim or any Proceeds thereof (other than in connection with Permitted Liens); (C) it has full power and authority and has obtained all necessary corporate and other authorizations to bring the Claim; (D) the security interest granted to the Investors under the Security Agreement is a legal, validly created, perfected, first priority security interest, subject to no other Adverse Interest other than Permitted Liens; and (E) it has not set off or agreed to set off and there exist no rights against the Counterparty that could permit any set-off of or counterclaim of any amounts against the Claim;

(ii)(A) as of the date of this Agreement, it has not received any payments in connection with the Claim, and (B) any payments in connection with the Claim received after the date of this Agreement have been disclosed to the Investors in accordance herewith;

(iii)it has and reasonably expects to continue to have sufficient assets (taking into account the Capital Amounts) available to discharge Claim Costs;

(iv)it has not taken or omitted to take any steps or executed or omitted to execute any documents which could reasonably be expected, either individually or in

the aggregate, to have a Material Adverse Effect; and it has disclosed to the Investors any facts or circumstances of which it is aware that could reasonably be expected, either individually or in the aggregate, to have a Material Adverse Effect; and

(v) it has disclosed to the Investors all information in its knowledge, possession or control that is or is likely to be material to the Investors' assessment of the Claim (including the enforcement and collection of any related settlement, award or judgment); all information provided to the Investors in due diligence or otherwise has been provided in its true and complete form and is, to the knowledge of the Counterparty, accurate; the Counterparty believes that the Claim is meritorious; and the Counterparty has not been advised by the Nominated Lawyers or any other legal counsel or litigation funder that the Claim is unlikely to succeed;

(f) it has not agreed to pay any compensation to any agent or broker in connection with the transactions contemplated by this Agreement; and

(g) it is not materially overdue in the filing of any Tax return nor overdue in the payment of any material amount of Tax.

6. CONFIDENTIALITY

Provisions relating to confidentiality are attached hereto as Exhibit E and incorporated herein.

7. LEGAL PRIVILEGE

Provisions relating to legal privilege are attached hereto as Exhibit F and incorporated herein.

8. EXCULPATION; REINSTATEMENT

(a) Other than its obligations to provide the Capital Amounts to the Counterparty, no Investor shall have any obligation to fund any penalties, costs orders, damages, fees, expenses or other sums (including any in respect of counterclaims) in relation to any Claim, and all such sums shall be the sole responsibility of the Counterparty.

(b) The liability of each Investor under the Transaction Documents (and the transactions contemplated by the Transaction Documents) shall in no event exceed [***], except in the event of any fraud or reckless activity amounting to fraud perpetrated by such Investor. This limitation of liability is absolute and extends to each Investor and its Representatives.

(c) To the extent any payment received by the Investors from or on behalf of the Counterparty, or obligation incurred by the Counterparty, is subsequently invalidated, declared to be fraudulent or preferential, set aside or required to be

repaid in whole or in part by the Investors or paid over to a trustee, receiver or any other entity, whether under any bankruptcy law, insolvency, fraudulent transfer law or otherwise (any such payment or obligation being hereinafter referred to as a "***Challenged Item***"), then the obligations of the Counterparty with respect to such Challenged Item shall (i) be fully reinstated and revived, as the case may be, notwithstanding such payment or incurrence, and (ii) to the extent of each such Challenged Item, remain effective and continue in full force and effect as if said Challenged Item had not occurred or been made. The Counterparty shall indemnify the Investors on demand for all reasonable third-party costs and expenses incurred by the Investors in connection with defending, repaying and/or reviving a Challenged Item.

9. REMEDY EVENTS

The occurrence of any of the following events constitutes a "***Remedy Event***":

9.1 Failure to Pay or Deliver

The Counterparty fails to make any payment owing to an Investor when and where due.

9.2 Failure to Discharge Claim Costs

The Counterparty fails to comply with any of its obligations to discharge Claim Costs under Section 4.3(a)(ii) and fails to remedy such failure within [***] Business Days.

9.3 Breach or Repudiation

Other than the obligations referenced in Sections 9.1 and 9.2, which are respectively governed by such sections, the Counterparty fails to comply with any of its obligations in any Transaction Document if (a) such failure, if remediable, is not (subject to the next sentence) remedied within [***] Business Days and (b) (i) such failure could reasonably be expected to have a Material Adverse Effect; (ii) such failure could reasonably be expected to cause any Security Agreement to cease to be in full force and effect; or (iii) the Counterparty or any of its Representatives acting as an agent of the Counterparty disaffirms, disclaims, repudiates or rejects or challenges the validity of any Transaction Document in whole or in part. If the failure to cure a Remedy Event described in this Section 9.3 within fewer than [***] Business Days would be reasonably likely to result in an adverse effect on the Claim due to exigencies of the litigation or arbitration process, then, upon notice to the Counterparty, the Investors may shorten the cure period to the extent necessary to avoid or minimize such likelihood.

9.4 Misrepresentation

A representation by the Counterparty in this Agreement or any other Transaction Document proves to have been incorrect or misleading in any material respect when made or deemed to have been made.

9.5 Bankruptcy

Any of the following occurs: (a) the voluntary or involuntary commencement of a case or proceeding by or against the Counterparty under any applicable bankruptcy, insolvency or similar law affecting creditors' rights, or any other procedure under any law of any jurisdiction having a similar or analogous nature or effect, and such case, proceeding or procedure, if involuntarily commenced, is not dismissed or otherwise terminated within [***] days of its commencement; or an administrator, provisional liquidator, conservator, receiver, trustee, custodian or similar official having powers over the Counterparty or all or a substantial part of its property is appointed; (b) the Counterparty is unable or fails generally, or admits in writing of its inability, to pay its debts as they become due; (c) the Counterparty's dissolution (other than pursuant to a consolidation, amalgamation or merger); or (d) the adoption of any resolution or other authorization, or the taking of any action in furtherance of, or indicating its consent or intent to consent to, approval of, or acquiescence in, any of the foregoing by its board of directors (or similar governing body) or any committee thereof or by its equityholders entitled to vote on and authorize the same.

9.6 Reorganization Without Assumption

The Counterparty consolidates or amalgamates with, or merges with or into, or transfers all or substantially all its assets to, or reorganizes, reincorporates, reconstitutes or divides into or as, another entity (or other entities) and, as a direct or indirect result of such consolidation, amalgamation, merger, transfer, reorganization, reincorporation, reconstitution or division, (a) no single resulting, surviving or transferee entity (a "***Counterparty Successor***") has assumed (or remain liable for) all the obligations of the Counterparty under this Agreement and/or the other Transaction Documents; or (b) any benefit of any Security Agreement fails to extend to the Investors; or (c) all rights to the Claim and Proceeds are no longer held by such a Counterparty Successor.

10. REMEDIES

10.1 Available Remedies Generally

If at any time a Remedy Event has occurred, in addition to all other legal and equitable remedies, the Investors shall be entitled to exercise one or more of the following remedies in each case without thereby relieving the Counterparty of any of its obligations hereunder:

(a) the Investors may terminate their commitment to provide Capital Amounts hereunder;

(b) if the Remedy Event is continuing, the Investors may exercise their rights and remedies under the Security Agreement;

(c) if the Remedy Event is continuing, the Investors may take actions that they deem necessary or advisable on behalf of the Counterparty in order to prosecute the Claim to which the Remedy Event relates and to bring about the monetization thereof and

to collect and enforce any settlement, final judgment or award; in connection therewith, the Counterparty hereby (i) irrevocably appoints Investor No. 1 as the Counterparty's attorney-in-fact, with full authority in the place and stead of the Counterparty and in the name of the Counterparty or otherwise, from time to time following the date such Remedy Event has occurred and is continuing, in Investor No. 1's discretion, to take any such actions to the extent consistent with the Counterparty's interests in the Claim, including to settle or compromise the Claim or to appoint new Nominated Lawyers, and (ii) agrees to, and to cause its Affiliates and to use commercially reasonably efforts to cause its and their Representatives to, cooperate fully with the Investors and counsel in all matters pertaining to the Claim from time to time following the date such Remedy Event has occurred and is continuing; and

(d) if the Remedy Event is continuing, the Investors may pursue all other legal and equitable remedies available to the Investors under applicable law in connection with the enforcement of their rights under the Transaction Documents.

10.2 Additional Remedy for Failure to Pay

If a Remedy Event under Section 9.1 has occurred and is continuing, the Counterparty shall on demand pay interest to the Investors at the Default Rate on the overdue amount.

10.3 Additional Remedy for Failure to Discharge Claim Costs

If a Remedy Event under Section 9.2 has occurred and is continuing, the Investors shall be entitled to provide to or on behalf of the Counterparty additional Capital Amounts beyond those set forth in Section 2, to the extent necessary to discharge all Claim Costs. In consideration thereof, the Investors' Entitlement with respect to such additional Capital Amounts shall be an amount equivalent to [***].

10.4 Remedies Cumulative

Except as provided otherwise in this Agreement, the rights, powers, remedies and privileges provided in Section 10 of this Agreement are cumulative; may be exercised singularly, concurrently or successively at the Investors' option; and may be exercised or enforced without constituting a bar to the exercise or enforcement of any other such rights, powers, remedies and privileges.

11. ENFORCEMENT OF CLAIM RESOLUTION

If (x) K&K or a replacement of K&K approved by the Investors pursuant to Section 4.3(d) ceases to act as the Counterparty's counsel to enforce and monetize the Award, or (y) by the date that is [***] days after the date of a Claim Resolution (the "***Standstill Period***"), any portion of a judgment, award or settlement payment owing to the Counterparty as a result thereof remains unsatisfied, the Investors shall, at their option and upon notice to the Counterparty, be entitled to engage judgment enforcement professionals of their own

choosing (including those affiliated with the Investors) to pursue collection or enforcement of the same; provided that, notwithstanding the expiration of the Standstill Period, in no event shall the Investors pursue collection or enforcement of the Claim Resolution if the Counterparty shall have commenced, and shall be diligently pursuing, collection or enforcement. In the event the Investors elect to do so, (a) they shall pay their designated judgment enforcement professionals their reasonable and customary fees and expenses, (b) any costs incurred by the Investors in such regard shall constitute Capital Amounts, and (c) in consideration of such additional Capital Amounts, the Investors' Entitlement with respect to such additional Capital Amounts shall be an amount equivalent to such additional Capital Amounts plus [***].

12. Limitations on Transfer, Successors and Assigns; Third Party Beneficiaries

Provisions relating to limitations on transfer, successors and assigns and third-party beneficiaries are attached hereto as Exhibit G and incorporated herein.

13. Tax Withholding and Other Tax Matters

Provisions relating to tax withholding and certain other tax matters are attached hereto as Exhibit H and incorporated herein.

14. Anti-Corruption; Data Protection

Provisions relating to Anti-Corruption Rules and Data Protection are attached hereto as Exhibit C and incorporated herein.

15. Notices

All notices under the Transaction Documents shall be in writing and may be given in any manner described below to the address or number provided for the recipient in Annex I and shall be deemed effective (i) if delivered in person or by courier, on the date it is received; (ii) if sent by certified or registered mail or the equivalent (return receipt requested), on the date it is received; or (iii) if sent by email, on the date sent in the absence of any immediate automated response indicating the message was not received or would not be timely read, and if such an immediate automated response is received by the sender, on the date the sender receives an acknowledgement from the recipient, unless the date of receipt is not a Business Day or the communication is received after the close of business on a Business Day, in which case such communication shall be deemed given and effective on the first following day that is a Business Day. Notices to the Counterparty shall be copied to the Nominated Lawyers. Either party may change the address or email details at which notices or other communications are to be given to it by notice to the other in accordance with this Section 15.

16. AMENDMENTS

No amendment, modification or waiver of this Agreement shall be effective unless in writing and executed by the Counterparty and the Investors.

17. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between the parties relating to the subject matter hereof and is the final and complete expression of their intent. Other than the CDA, the parties represent and warrant that no prior or contemporaneous negotiations, promises, agreements, covenants or representations of any kind or nature, whether made orally or in writing, have been made or relied upon by them, whether in negotiations leading to this Agreement or relating to the subject matter hereof, which are not expressly contained herein, or which have not become merged and finally integrated herein; it being the intention of the parties that in the event of any subsequent litigation, controversy or dispute concerning the terms and provisions of this Agreement, no party shall be permitted to introduce oral or extrinsic evidence not included herein and not reflected in writing.

18. COUNTERPARTS

This Agreement and the other Transaction Documents (and each amendment, modification and waiver in respect thereof) may be executed and delivered in counterparts (including by facsimile or digital transmission), each of which shall be deemed an original.

19. NO WAIVER

A failure or delay in exercising any right, power or privilege in any Transaction Document shall not be presumed to operate as a waiver, and a single or partial exercise of any right, power or privilege shall not be presumed to preclude any subsequent or further exercise, of that right, power or privilege or the exercise of any other right, power or privilege.

20. SEVERABILITY

If any term of any Transaction Document, or the application thereof to any party or any circumstance, is held to be unenforceable, invalid or illegal (in whole or in part) for any reason, the remaining terms, modified by the deletion of the unenforceable, invalid or illegal portion, shall continue in full force and effect, and such unenforceability, invalidity, or illegality shall not otherwise affect that of the remaining terms, so long as the Transaction Documents as so modified continues to express, without material change, the original intentions of the parties and the deletion of such portion of the relevant Transaction Document shall not substantially impair the expectations or reciprocal obligations of the parties or the practical realization of the benefits that would otherwise be conferred upon the parties. The parties shall endeavour in good faith negotiations to replace any prohibited or unenforceable provision with a valid provision the economic effect of which comes as close as possible to that of the prohibited or unenforceable provision.

21. EXPENSES

(a) Except as otherwise expressly provided in any Transaction Document, each party shall bear its own expenses in connection with the negotiation, execution, delivery and performance of the Transaction Documents.

(b) The Counterparty shall indemnify and hold harmless the Investors for all reasonable out-of-pocket expenses, including legal fees and disbursements (but not including taxes), incurred by the Investors in enforcing and protecting their rights under any Transaction Document.

22. RELATIONSHIP OF PARTIES

(a) Nothing in any Transaction Document is intended to create (i) a fiduciary, lawyer-client, lender-borrower, agency or other non-contractual relationship between the Counterparty and any Investor; (ii) any partnership, joint venture or any other type of affiliation between the Counterparty and any Investor; or (iii) a joint interest in any Claim for any purpose, including for U.S. federal, state and local income Tax purposes. The Investors are not partners, nor are they engaged in any partnership or joint venture with one another.

23. GOVERNING LAW

Except as set forth otherwise in Section 24, this Agreement and all matters arising out of or relating in any way whatsoever to this Agreement (whether in contract, tort or otherwise) shall be construed in accordance with and shall be governed by the law of the State of [***] (without reference to any conflict of law principles or choice of law doctrine that would have the effect of causing this Agreement to be construed in accordance with or governed by the law of any other jurisdiction).

24. DISPUTE RESOLUTION

Provisions relating to Dispute Resolution are attached hereto as Exhibit D and incorporated herein.

25. ADMINISTRATIVE AND COLLATERAL AGENT

(a) Investor No. 2 hereby appoints Investor No. 1 as administrative and collateral agent for the Investors hereunder. As such, Investor No. 1 is hereby authorized to act on behalf of Investor No. 2 for the purpose of (i) giving and receiving notices, waivers, consents, approvals and instructions; (ii) acquiring, holding and enforcing any and all liens on collateral granted by the Counterparty to secure the Investors' rights hereunder; (iii) enforcing any other rights of the Investors under any Transaction Document, including filing and proving a claim for the aggregate amount of the Counterparty's obligations to the Investors hereunder in the event of any bankruptcy or insolvency proceeding relating to the Counterparty; and (iv) taking

such other actions as Investor No. 1 deems appropriate to administer the Transaction Documents; in each case together with such powers and discretion as are reasonably incidental thereto.

(b) The use of the term "agent" or any similar or equivalent term in connection with the foregoing appointment is not intended to imply any fiduciary or other duties arising under legal principles governing agency relationships. Investor No. 1 shall not have any duties or obligations in its capacity as administrative and collateral agent except those expressly set forth herein, and its appointment and all rights and duties of it as an agent hereunder shall be ministerial and administrative in nature. Notwithstanding the appointment of Investor No. 1 as administrative and collateral agent, Investor No. 1 shall have the same rights and powers in its capacity as an Investor hereunder as Investor No. 2, and Investor No. 1 may exercise all such rights and powers as though it were not administrative or collateral agent. The provisions of this Section 25 are for the benefit of the Investors; no other party shall have any rights as a third party beneficiary of any provision of this Section 25, provided that the Counterparty shall be entitled to rely on any notices, waivers, consents, approvals or instructions provided to it by Investor No. 1, or any action to be taken as described in clauses (ii) through (iv) in Section 25(a), as being on behalf of all the Investors.

(c) Investor No. 1 may perform its duties and exercise its rights and powers as administrative and collateral agent hereunder by or through any one or more sub-agents or servicing entities appointed by it. The exculpatory provisions in the following clause (d) shall apply to any such sub-agent or servicing entity.

(d) Investor No. 1 shall not be liable to any other Investor for any action taken or not taken by it (i) with the consent or at the request of Investor No. 2, (ii) as Investor No. 1 believed in good faith was necessary under the circumstances or (iii) in the absence of its own gross negligence or willful misconduct. In its capacity as administrative and collateral agent, Investor No. 1 shall be entitled to rely upon any notice, request, certificate, consent, statement, instrument, document or other writing believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person.

26. Rules of Construction

Unless the context otherwise clearly requires: (a) the definitions of terms herein shall apply equally to the singular and plural forms of the terms defined; (b) whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms; (c) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; (d) the word "shall" shall be construed to have the same meaning and effect as the word "will"; (e) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented, restated or otherwise modified (subject to any restrictions on such amendments, supplements or

modifications set forth herein); (f) any reference herein to any Person shall be construed to include such Person's successors and assigns; (g) the phrase "to its knowledge" and phrases of similar import shall be construed to mean the best knowledge, after due inquiry, of the Counterparty's Chief Executive Officer and Chief Financial Officer; (h) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (i) all references herein to Sections, Annexes, Exhibits and Schedules, as applicable, shall be construed to refer to Sections of, and Annexes, Exhibits and Schedules to, this Agreement, and the same are incorporated herein as part of this Agreement; and (j) the headings used in this Agreement are for convenience of reference only and are not to affect the construction of or to be taken into consideration in interpreting this Agreement.

27. LIMITED INDEMNITY

Provisions relating to a limited indemnity are attached hereto as Exhibit I and incorporated herein.

[Remainder of this page intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed and delivered this Investment Agreement as of the date first written above.

Investor No. 1:

BATISTE INVESTMENTS LLC

By: /s/ [***]_____
Name: [***]
Title: Authorized Signatory

Investor No. 2:

MAPLEWOOD PARK INVESTMENTS LP

By:[***]
Its General Partner

By: /s/ [***]_____
Name: [***]
Title: Director

IN WITNESS WHEREOF, the parties have executed and delivered this Investment Agreement as of the date first written above.

Counterparty:

TRACON PHARMACEUTICALS, INC.

By: /s/ Scott B. Brown
Name: Scott B. Brown
Title: Chief Financial Officer

EXHIBIT A

Defined Terms

"***Adverse Interest***" means, with respect to any Claim or any Proceeds, (i) any mortgage, deed of trust, lien, pledge, hypothecation, encumbrance, charge, security interest, purchase option, call or similar right of a third party in, on or affecting such asset, and (ii) any other claim that a claimant has an interest in such asset or that it is a violation of the rights of the claimant for another Person to hold, Transfer or deal with such asset. For purposes of clarity, the items set forth on Schedule 5.2(b) shall not be deemed an Adverse Interest for purposes of the Transaction Documents.

"***Adverse Party***" means, with respect to any Claim, individually and collectively, the Person(s) named as defendants or counterclaim defendants in the Claim, as set forth on Annex II, and any other Person added or joined to the Claim from time to time as a defendant or indemnitor or against whom proceedings are asserted or threatened even if such Person is not named or served, and in each case their respective Affiliates and successors.

"***Affiliate***" means, with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with the Person specified.

"***Agreed Purpose***" has the meaning set forth on Exhibit C.

"***Anti-Corruption Rules***" has the meaning set forth on Exhibit C.

"***Applicable Attorney Fees***" means the aggregate of the Covington Entitlement and the Foley Entitlement.

"***Award***" means the total amount awarded by the ICC tribunal considering the Claim to the Counterparty in respect of the Claim.

"***Business Day***" means a day on which commercial banks and foreign exchange markets settle payments and are open for general business (including dealings in foreign exchange and foreign currency deposits) in New York.

"***Capital Amounts***" means each of the Closing Capital Amount, the Post-Award Capital Amount, the Confirmation & Enforcement Capital Amounts and the Subsequent Capital Amounts.

"***CDA***" means that certain Confidentiality, Common Interest and Non-Disclosure Agreement, dated as of August 1, 2022 by and between the Counterparty and an Affiliate of the Investors.

"***Claim***" means the claim described on Annex II.

"***Claim Costs***" has the meaning set forth in Section 4.3(a).

"***Claim Resolution***" means either full and final settlement of the Claim or the entry of a final, non-appealable and enforceable award or judgment, in either case resolving with prejudice all aspects and elements of the Claim. In circumstances where a final, non-appealable and enforceable award or judgment does not automatically come into being upon the rendering of a dispositive decision, a Claim Resolution shall be deemed to have occurred on the date that is [***] days following such dispositive decision in the absence of any subsequent challenge thereto.

"***Closing Capital Amount***" has the meaning set forth in Section 2.1(a)(i).

"***Closing Date***" means the date of the execution and delivery of this Agreement, December 22, 2022.

"***Confirmation Capital Amounts***" has the meaning set forth in Section 2.1(a)(iii).

"***Confirmation & Enforcement Capital Amounts***" has the meaning set forth in Section 2.1(a)(iii).

"***Conservatory Measures***" has the meaning set forth in Exhibit D.

"***Control***" means the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of a Person, whether through the ability to exercise voting power, by contract or otherwise; "***Controlling***" and "***Controlled***" have meanings correlative thereto.

"***Counterparty***" has the meaning set forth in the introductory paragraph of this Agreement.

"***Counterparty Successor***" has the meaning set forth in Section 9.6.

"***Covington***" has the meaning set forth in Section 2.1(a)(iii)(A).

"***Covington Entitlement***" means Covington's contingency fee with respect to the Claim, to be paid [***].

"***CPD***" has the meaning set forth on Exhibit C.

"***Data Protection Laws***" has the meaning set forth on Exhibit C.

"***Default Rate***" means a rate per calendar month of [***]%, compounded [***], or the maximum rate permitted by law, whichever is lower.

"***Enforcement Capital Amounts***" has the meaning set forth in Section 2.1(a)(iii).

"***Enforcement Trigger Date***" means the earlier of (x) the date which is [***] months after the date of confirmation of the Award if the Adverse Party fails to pay the full amount of

such Award voluntarily by such date or (y) the date upon which the Adverse Party expressly repudiates its obligation to pay the full amount of such Award (unless another date is mutually agreed by the parties).

"***Engagement Agreement***" means any engagement, retainer or similar agreement between the Counterparty and its counsel governing or purporting to govern the terms of the representation of the Counterparty with respect to the Claim.

"***Expert Determination***" means a determination made by an expert appointed by the [***].

"***Foley***" means Foley Hoag LLP.

"***Foley Entitlement***" means Foley's contingency fee with respect to the Claim, to be paid [***].

"***Governmental Authority***" means the government of the United States of America, any other nation or any political subdivision thereof, whether state or local, and any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government.

"***Indemnified Parties***" has the meaning set forth in Exhibit I.

"***Indemnifying Party***" has the meaning set forth in Exhibit I.

"***Invested Amount***" means (i) the sum of all amounts actually paid to or on behalf of the Counterparty by the Investors hereunder plus (ii) the Transaction Costs.

"***Insolvent***" means any of the following: (i) the sum of the Counterparty's debts exceeds the present fair market value of its assets (not including any fraudulently transferred property); (ii) after the transactions contemplated by this Agreement, the Counterparty is left with unreasonably small capital for the operation of its business; or (iii) the Counterparty intends or expects to incur debts beyond its ability to pay.

"***Investors***", "***Investor No. 1***" and "***Investor No. 2***" have the meanings set forth in the introductory paragraph of this Agreement.

"***Investors' Entitlement***" means the amounts set forth as such in Section 2.2.

"***Kobre & Kim LLP***" has the meaning set forth in Section 2.1(a)(iii)(A).

"[***]" has the meaning set forth in Exhibit D.

"***Losses***" has the meaning set forth in Exhibit I.

"***Material Adverse Effect***" means, with respect to any event or circumstance and any party, one or more of (i) the material impairment of its ability to perform any of its obligations

under this Agreement or any other Transaction Document, (ii) the material impairment of the rights or remedies available under this Agreement or any other Transaction Document to the other party and (iii) solely in the case of the Counterparty, an adverse effect on any Claim or the value or collectability thereof.

"***Maximum Commitment Amount***" has the meaning set forth in Section 2.1(a).

"***Monthly Report***" means a report containing the information described on Exhibit B.

"***Multiple Start Date***" means (x) in respect of each tranche of Capital Amounts (other than Enforcement Capital Amounts deployed to the relevant counsel on or after the Enforcement Trigger Date), the date of the funding of such tranche of Capital Amounts; and (y) in respect of each tranche of Enforcement Capital Amounts deployed to the relevant counsel on or after the Enforcement Trigger Date, the Enforcement Trigger Date.

"***Nominated Lawyers***" means, with respect to any Claim, the Person or Persons identified as such on Annex II and/or any successor or new legal counsel appointed as described herein.

"***Occurrence***" means any of the following events: (i) the Claim is [***], or (ii) the Claim is [***] on, or (iii) an insolvency event occurs with respect to the Adverse Party; or (iv) after a court confirms the Award and/or any action undertaken by the Adverse Party to set aside the Award has been denied and all appeals are exhausted, [***].

"***Payment Agent***" means Covington.

"***Payment Instruction Letter***" means an agreement with the Payment Agent, in substantially the form attached as Exhibit 1 to the Security Agreement, pursuant to which the Payment Agent agrees to accept all Proceeds and remit the Investors' Entitlement directly to the Investors, which Payment Instruction Letter shall be in a form and substance satisfactory to the Investors in all respects.

"***Permitted Lien***" means any of the following: (i) a lien pursuant to the Security Agreement, and (ii) a lien in favor of the Nominated Lawyers securing amounts payable to them under their Engagement Agreement(s) and (iii) a lien pursuant to the Runway Facility provided such lien is subject to a Subordination Agreement.

"***Person***" means any natural person, corporation, limited liability company, trust, joint venture, association, company, partnership or other entity or Governmental Authority.

"***Post-Award Capital Amount***" has the meaning set forth in Section 2.1(a)(ii).

"***Potential Remedy Event***" means any event which, with the giving of notice or the lapse of time or both, would constitute a "Remedy Event".

"***Proceeds***" means, collectively: (i) [***]; (ii) [***]; (iii) [***]. All of the foregoing constitute Proceeds regardless of form, including cash, personal property, real property,

legal or equitable rights, a reduction of or set-off against an amount owed by the Counterparty, and any other thing of value conveyed, directly or indirectly, to the Counterparty, whether delivered in a lump sum or in installments. In the event that the Claim is resolved directly or indirectly as a result of or contemporaneously with [***], all proceeds of [***] shall constitute Proceeds relating to the Claim hereunder [***].

"***Recipient***" has the meaning set forth in Exhibit E.

"***Remedy Event***" has the meaning set forth in Section 9.

"***Representation Date***" means (i) the date hereof, (ii) each date on which the Investors are obligated to or do make any payment of Capital Amounts and (iii) in the case of the Counterparty, each date on which a Monthly Report is due to be delivered.

"***Representatives***" means, with respect to any person or entity, as applicable, its Affiliates and its and their directors, officers, managers, members, partners, principals, employees, shareholders and participants (or potential shareholders and participants), agents, permitted assignees, insurers, lawyers, accountants, consultants, advisors, auditors and independent contractors.

"***Rules***" has the meaning set forth in Exhibit D.

"***Runway Facility***" means the credit facility provided by Runway Growth Finance Corp. ("***Runway***") under that certain Loan and Security Agreement, dated as of September 2, 2022, between the Counterparty and Runway, as in effect on the Closing Date and as amended.

"***Security Agreement***" means the security agreement entered into on or around the date hereof between the Investors and the Counterparty pursuant to which the Counterparty grants to the Investors a security interest in certain collateral to secure the obligations of the Counterparty hereunder.

"***Subordination Agreement***" means a subordination agreement among the Investors and another lienholder pursuant to which the other lienholder (i) subordinates its lien on all collateral granted to the Investors pursuant to the Security Agreement to the lien of the Investors, and (ii) subordinates its right to receive any payments derived from Proceeds or from any collateral granted to the Investors pursuant to any Security Agreement to the prior payment in full of all obligations owing by the Counterparty to the Investors under any Transaction Document, which subordination agreement shall be in form and substance satisfactory to the Investors in all respects.

"***Subsequent Capital Amounts***" has the meaning set forth in Section 2.1(a)(iv).

"***Tax***" means any tax, duty, contribution, impost, withholding, levy or other charge or withholding of a similar nature (including use, sales and value added taxes), whether domestic or foreign, and any fine, penalty, surcharge or interest in connection therewith.

"***Threshold Recovery Condition***" means the issuance of an Award of at least US$[***].

"***Transaction Costs***" has the meaning set forth in Section 2.1(c).

"***Transaction Documents***" means, collectively, this Agreement, the Security Agreement, and any other agreements, documents, instruments or certificates entered into by the parties in connection with this Agreement.

"***Transfer***" means to, directly or indirectly, sell, transfer, assign, pledge, encumber, hypothecate, or similarly dispose of, either voluntarily or involuntarily, by operation of law or otherwise, or to enter into any agreement, arrangement or understanding with respect to the sale, transfer, assignment, pledge, encumbrance, hypothecation, or similar disposition of, any Claim, any Proceeds, any interest in or obligations under a Transaction Document, or any portion of any of the foregoing, or any economic or other interest, including a participation, in any of the foregoing, as applicable.

"***Tribunal***" has the meaning set forth in Exhibit D.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

This First Amendment to Loan and Security Agreement (this "**Amendment**") is entered into as of December 22, 2022, by and among **TRACON PHARMACEUTICALS, INC.**, a Delaware corporation ("**Borrower Representative**"), and each other Person party to the Loan Agreement (as defined below) as a borrower from time to time (individually and collectively, jointly and severally, "**Borrower**"), the lenders from time to time party to the Loan Agreement (collectively, "**Lenders**", and each, a "**Lender**"), and **RUNWAY GROWTH FINANCE CORP.**, as administrative agent and collateral agent for Lenders (in such capacity, "**Agent**").

RECITALS

Borrower, Agent and the Lenders are parties to that certain Loan and Security Agreement dated as of September 2, 2022 (as amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). The parties desire to amend the Loan Agreement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree as follows:

1. Section 2.2(a)(i) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"(i) Subject to the terms and conditions of this Agreement, on the Closing Date the Lenders, severally and not jointly, made term loans, in a single disbursement, to Borrower in an aggregate amount of Ten Million Dollars ($10,000,000) according to each Lender's Term A Loan Commitment as set forth on Schedule 1 hereto (such term loans are hereinafter referred to singly as a "**Term A Loan**", and collectively as the "**Term A Loans**"). After the Repayment Event, subject to Borrower's achievement of the New Equity Milestone and other terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the New Term A Draw Period, to allow Borrower to re-borrow the Term A Loans, in a single disbursement, in an aggregate amount of Ten Million Dollars ($10,000,000) according to each Lender's Term A Loan Commitment as set forth on Schedule 1 hereto. Other than as permitted explicitly in the foregoing sentence, once repaid no Term A Loan may be re-borrowed."

2. Section 2.2(b) of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"(b) Repayment. On January 3, 2023, Borrower shall repay all principal and accrued and unpaid interest in respect of the Term A Loans (the "**Repayment Event**"). Thereafter, if the Term A Loans are re-borrowed in accordance with Section 2.2(a)(i) or any other Term Loans are advanced, commencing on the Amortization Date, and continuing thereafter on each Payment Date, Borrowers shall make consecutive monthly payments of equal principal, which would fully amortize the principal amount by the Maturity Date, plus accrued and unpaid interest. Any and all unpaid Obligations, including principal and accrued and unpaid interest in respect of the Term Loans, the Final Payment, other fees and other sums, if any, shall be due and payable in full on the Maturity Date. The Term Loans may only be prepaid in accordance with Sections 2.2(c) or (d). For the sake of clarity, the Final Payment due on the Maturity Date shall apply to the Term A Loans, measured with such Term A Loans equal to an aggregate amount of Ten Million Dollars ($10,000,000), whether or not such Term A Loans are re-borrowed in accordance with Section 2.2(a)(i)."

3. Section 2.2(d)(ii) and (iii) of the Loan Agreement hereby are amended and restated in its entirety to read as follows:

"(ii) except for the Repayment Event prepayment, the Prepayment Fee; plus

(iii) except for the Repayment Event prepayment, the Final Payment; plus"

4. Section 8.9 of the Loan Agreement hereby is amended and restated in its entirety to read as follows:

"**8.9 Subordinated Debt**. Except as permitted thereunder (i) the Investor Subordination Agreement**,** or (ii) any Subordination Agreement governing any Subordinated Debt, shall for any reason be revoked or invalidated or otherwise cease to be in full force and effect, any party thereto shall be in breach thereof or contest in any manner the validity or enforceability thereof or deny that it has any further obligation thereunder, or the Obligations shall for any reason not have the priority contemplated by this Agreement."

5. The following defined terms in Exhibit A to the Loan Agreement hereby are added or amended and restated, as appropriate, as follows:

"**Cash Burn**" means, for any period of determination, Borrower's operating cash flow determined based on the most recently projected cash burn as provided in Borrower's board approved projections delivered in accordance with Section 6.2(c) hereof, in accordance with GAAP, and adjusted to account for principal repayments on Indebtedness and calculated on a trailing three (3) month basis, divided by three (3).

"**Excluded Accounts**" means (i) any deposit accounts used exclusively for payroll, payroll taxes and other employee wage and benefit payments, and identified as such in writing to Agent, (ii) the Silicon Valley Bank collateral account [***], and (iii) the Funds Securities Account (as defined in the Investor Security Agreement) to the extent such account exclusively holds funds paid as the result of a Claim Resolution (as defined in the Investor Security Agreement).

"**First Amendment Effective Date**" means December 22, 2022.

"**Investor Documents**" means (i) that certain Investment Agreement dated as of December 22, 2022 (as the same may be amended, restated, supplemented or otherwise modified from time to time, the "Investment Agreement") pursuant to which Investor has agreed to provide financing to Borrower; and (ii) that certain Security Agreement dated as of December 22, 2022 between Borrower and Investor (as the same may be amended, restated, supplemented or otherwise modified from time to time, the "Investor Security Agreement", and collectively with the Investment Agreement and all other documents, instruments, or certificates evidencing or pertaining to all or any portion thereof.

"**Investor**" means each and collectively, jointly and severally, BATISTE INVESTMENTS LLC and MAPLEWOOD PARK INVESTMENTS LP.

"**Investor Subordination Agreement**" means that certain Subordination Agreement by and among Borrower, Investor, and Agent, dated as of December 22, 2022.

"**Maturity Date**" means March 31, 2023; provided however, if the Term A Loans are re-borrowed in accordance with Section 2.2(a)(i), on the Funding Date of such re-borrowed Term A Loans the Maturity Date shall automatically be extended to September 1, 2026.

"**New Equity Milestone**" means Borrower's receipt, on or after the First Amendment Effective Date, of at least Twenty-Five Million Dollars ($25,000,000) of net cash proceeds from the sale or issuance of a combination of (i) its equity securities to investors and on terms and conditions reasonably acceptable to Lender, (ii) Subordinated Debt to investors and on terms and conditions reasonably acceptable to Lender and (iii) Indebtedness owing to Investor under the Investor Documents so long as such Indebtedness is at all times subject to the Investor Subordination Agreement.

"**New Term A Draw Period**" is the period commencing on the date of the occurrence of the New Equity Milestone and ending on the earlier of (i) March 31, 2023 and (ii) the occurrence and continuance of an Event of Default; provided, however, that the New Term A Draw Period shall not commence if on the date of the occurrence of the New Equity Milestone an Event of Default has occurred and is continuing.

"**Repayment Event**" has the meaning set forth in Section 2.2(b).

"**Warrant**" means, collectively, each Warrant to Purchase Common Stock dated as of the as of the Closing Date and each Funding Date (except for the Funding Date, if any, where Borrower re-borrows the Term A Loans in accordance with Section 2.2(a)(i)) executed by Borrower Representative in favor of each Lender, as amended, modified, supplemented, extended or restated from time to time.

6. **Definition of Permitted Indebtedness**. The definition of "Permitted Indebtedness" in Exhibit A to the Loan Agreement is hereby amended by deleting "and" from the end of clause (i) and replacing clause (j) and adding new clause (k) as follows:

"(j) Indebtedness under the Investor Documents in an aggregate principal amount not to exceed Thirty Million Dollars ($30,000,000) so long as such Indebtedness is at all times subject to the Investor Subordination Agreement; and

(k) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness described in clause (b) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose more burdensome terms upon a Borrower or any of its Subsidiaries, as the case may be."

7. **Definition of Permitted Liens**. The definition of "Permitted Liens" in Exhibit A to the Loan Agreement is hereby amended by deleting "and" from the end of clause (k) and replacing clause (l) and adding new clause (m) as follows:

"(l) Liens in the Specific Collateral (as defined in the Investor Subordination Agreement) so long as such Liens are at all times subject to the Investor Subordination Agreement; and

(m) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in clause (b), but any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase."

8. No course of dealing on the part of Agent or the Lenders or their officers, nor any failure or delay in the exercise of any right by Agent or any Lender, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Agent's or any Lender's failure at any time to require strict performance by Borrower of any provision shall not affect any right of Agent or any Lender thereafter to demand strict compliance and performance. Any suspension or waiver of a right must be in writing signed by an officer of Agent.

9. Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Loan Agreement. The Loan Agreement, as amended hereby, shall be and remain in full force and effect in accordance with its respective terms and hereby is ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Agent or any Lender under the Loan Agreement, as in effect prior to the date hereof.

10. To induce Agent and Lenders to enter into this Amendment, Borrower hereby makes the following representations and warranties to Agent and Lenders:

a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date), and (b) no Event of Default has occurred and is continuing;

b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

c. The organizational documents of Borrower delivered to Agent on the Effective Date, and updated pursuant to subsequent deliveries by the Borrower to the Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (i) any material Requirement of Law binding on or affecting Borrower, (ii) any material agreement binding on Borrower, (iii) any applicable order, judgment or decree of any Governmental Authority binding on Borrower, or (iv) the organizational documents of Borrower;

e. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any Governmental Authority, binding on Borrower, except as already has been obtained or made; and

f. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

11. As a condition to the effectiveness of this Amendment, Agent shall have received, in form and substance satisfactory to Agent, the following:

(a) this Amendment, duly executed by Borrower;

(b) the Investor Subordination Agreement, duly executed by Investor;

(c) a Certificate of the Secretary of Borrower with respect to incumbency and resolutions authorizing the execution and delivery of this Amendment;

(d) all reasonable Lender Expenses incurred through the date of this Amendment, which may be debited from any of Borrower's accounts; and

(e) such other documents, and completion of such other matters, as Agent may reasonably deem necessary or appropriate.

12. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

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IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the date above written.

BORROWER:

TRACON PHARMACEUTICALS, INC.

By: /s/ Scott Brown
Name: Scott Brown
Title: Chief Financial Officer

AGENT AND LENDER

RUNWAY GROWTH FINANCE CORP.

By: /s/ David Spreng
Name: David Spreng
Title: Chief Executive Officer

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1)Registration Statement (Form S-8 No. 333-263591) pertaining to the Amended and Restated 2015 Equity Incentive Plan and Amended and Restated 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(2)Registration Statement (Form S-8 No. 333-258077) pertaining to the Amended and Restated 2015 Equity Incentive Plan of TRACON Pharmaceuticals, Inc.,
(3)Registration Statement (Form S-8 No. 333-253546) pertaining to the 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(4)Registration Statement (Form S-8 No. 333-236732) pertaining to the 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(5)Registration Statement (Form S-8 No. 333-229988) pertaining to the 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(6)Registration Statement (Form S-8 No. 333-223333) pertaining to the 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(7)Registration Statement (Form S-8 No. 333-216347) pertaining to the 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(8)Registration Statement (Form S-8 No. 333-209592) pertaining to the 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(9)Registration Statement (Form S-8 No. 333-201808) pertaining to the 2011 Equity Incentive Plan, 2015 Equity Incentive Plan and 2015 Employee Stock Purchase Plan of TRACON Pharmaceuticals, Inc.,
(10)Registration Statement (Form S-1 No. 333-239574) of TRACON Pharmaceuticals, Inc.,
(11)Registration Statement (Form S-1 No. 333-234651) of TRACON Pharmaceuticals, Inc.,
(12)Registration Statement (Form S-3 No. 333-263590) of TRACON Pharmaceuticals, Inc.,
(13)Registration Statement (Form S-3 No. 333-248593) of TRACON Pharmaceuticals, Inc., and
(14)Registration Statement (Form S-3 No. 333-224809) of TRACON Pharmaceuticals, Inc.

of our report dated March 8, 2023, with respect to the consolidated financial statements of TRACON Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2022.

/s/ Ernst & Young LLP

San Diego, California
March 8, 2023

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles P. Theuer, M.D., Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of TRACON Pharmaceuticals, Inc.;

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 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 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 8, 2023

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott B. Brown, CPA, certify that:

1. I have reviewed this Annual Report on Form 10-K of TRACON Pharmaceuticals, Inc.;

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 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 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 8, 2023

/s/ Scott B. Brown, CPA
Scott B. Brown, CPA
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

I, Charles P. Theuer, M.D., PhD., President and Chief Executive Officer of TRACON Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) this Annual Report on Form 10-K of the Registrant, to which this certification is attached as an exhibit (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 and results of operations of the Registrant.

Date: March 8, 2023

/s/ Charles P. Theuer, M.D., Ph.D.
Charles P. Theuer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of TRACON Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Scott B. Brown, CPA, Chief Financial Officer of TRACON Pharmaceuticals, Inc. (the "Registrant"), do hereby certify in accordance with 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) this Annual Report on Form 10-K of the Registrant, to which this certification is attached as an exhibit (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 and results of operations of the Registrant.

Date: March 8, 2023

/s/ Scott B. Brown, CPA
Scott B. Brown, CPA
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of TRACON Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.