Table of Contents

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 June 30, 2020

OR

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

For the transition period from _____ to _____.

Commission File Number: 000-50484

MEI Pharma, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	**51-0407811**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

11455 El Camino Real, San Diego, CA 92130
(Address of principal executive offices) (Zip Code)

(858) 369-7100
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.00000002 par value	**MEIP**	**The NASDAQ Stock Market LLC**

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

None
(Title of Class)

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

Indicate by a 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 definition 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 checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

The aggregate market value of the voting common equity held by non-affiliates of the registrant was approximately $261.5 million as of December 31, 2019, based on the closing price of the registrant's Common Stock as reported on the NASDAQ Capital Market on such date. For purposes of this calculation, shares of the registrant's common stock held by directors and executive officers have been excluded. This number is provided only for purposes of this Annual Report on Form 10-K and does not represent an admission that any particular person or entity is an affiliate of the registrant.

As of September 3, 2020, there were 112,522,001 shares of the registrant's common stock, par value $0.00000002 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Part III of this Annual Report on Form 10-K is incorporated by reference from the registrant's definitive proxy statement for the annual meeting of stockholders to be held in December 2020, which will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended June 30, 2020.

Table of Contents

MEI PHARMA, INC.
TABLE OF CONTENTS

Forward-Looking Statements

This Annual Report on Form 10-K, or Annual Report, includes forward-looking statements, which involve a number of risks and uncertainties. These forward-looking statements can generally be identified as such because the context of the statement will include words such as "may," "will," "intend," "plan," "believe," "anticipate," "expect," "estimate," "predict," "potential," "continue," "likely," or "opportunity," the negative of these words or other similar words. Similarly, statements that describe our future plans, strategies, intentions, expectations, objectives, goals or prospects and other statements that are not historical facts are also forward-looking statements. Discussions containing these forward-looking statements may be found, among other places, in "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report. For such statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. Readers of this Annual Report are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the time this Annual Report was filed with the Securities and Exchange Commission, or SEC. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, without limitation, those discussed in "Risk Factors" and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report. Other sections of this report and our other filings with the SEC may include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. There is substantial uncertainty regarding the impact of the COVID-19 outbreak (as defined below) on our business, industry, global economic conditions and government policy. New risk factors emerge from time to time and it is not possible for us to predict all risk factors, 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. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we undertake no obligation to update publicly or revise our forward-looking statements to reflect events or circumstances that arise after the filing of this Annual Report or documents incorporated by reference herein that include forward-looking statements.

Unless the context requires otherwise, references in this Annual Report to "MEI Pharma," "we," "us" and "our" refer to MEI Pharma, Inc.

MEI Pharma, Inc. and our corporate logo are registered service marks of MEI Pharma. Any other brand names or trademarks appearing in this Annual Report are the property of their respective holders.

PART I

Item 1. Business

Overview

We are a late-stage pharmaceutical company focused on leveraging our extensive development and oncology expertise to identify and advance new therapies intended to meaningfully improve the treatment of cancer. Our portfolio of drug candidates contains four clinical-stage assets, including zandelisib (formerly known as ("f/k/a") ME-401), currently in an ongoing Phase 2 clinical trial that, subject to the results upon completion of the trial, we intend to submit to the U.S. Food and Drug Administration ("FDA") to support accelerated approval of a marketing application. Our common stock is listed on the NASDAQ Capital Market under the symbol "MEIP."

Our approach to building our pipeline is to license promising cancer agents and build value in programs through development, commercialization and strategic partnerships, as appropriate.

In January 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus (the "COVID-19 outbreak") and the risks to the international community. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic based on the rapid increase in exposure globally. As a result of the ongoing and rapidly evolving COVID-19 pandemic, various public health orders and guidance measures have been implemented across much of the United States, and across the globe, including in the locations of our office, clinical trial sites, key vendors and partners. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines have been negatively affected by COVID-19. The extent to which the ongoing pandemic continues to impact our business, including our preclinical studies, chemistry, manufacturing and controls ("CMC") studies and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to minimize its economic impact.

In light of the COVID-19 outbreak, the FDA issued a number of new guidance documents. Specifically, as a result of the potential effect of the COVID-19 outbreak on many clinical trial programs in the US and globally, the FDA issued guidance concerning potential impacts on clinical trial programs, changes that may be necessary to such programs if they proceed, considerations regarding trial suspensions and discontinuations, the potential need to consult with or make submissions to relevant ethics committees, Institutional Review Boards ("IRBs"), and the FDA, the use of alternative drug delivery methods, and

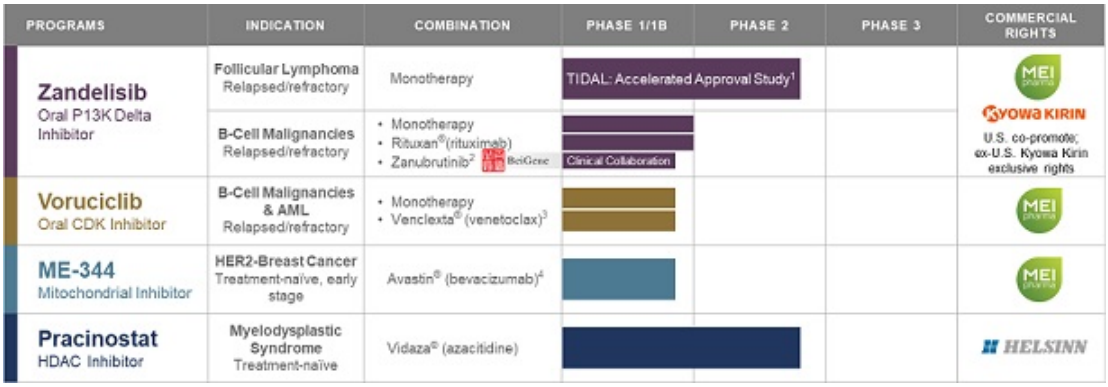
considerations with respect the outbreak's impacts on endpoints, data collection, study procedures, and analysis. In addition, the European Medicines Agency ("EMA") as well as various country regulatory authorities have issued similar guidance. We have adapted the FDA and EMA guidance for study procedures, data collection, and oversight resulting from the pandemic.

On March 27, 2020, President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security ("CARES") Act." The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. Regulatory guidance has indicated that public companies are ineligible to participate in certain of the loan programs provided by the CARES Act. We continue to examine the impact that the CARES Act may have on our business. Currently, we do not expect that the CARES Act will have a material impact on our financial condition, results of operations, or liquidity.

Clinical Development Programs

Our approach to building our pipeline is to license promising cancer agents and build value in programs through development, commercialization and strategic partnerships, as appropriate. Our existing drug candidate pipeline includes:

- Zandelisib (f/k/a ME-401), an oral phosphatidylinositol 3-kinase ("PI3K") delta inhibitor;
- Voruciclib, an oral cyclin-dependent kinase ("CDK") inhibitor;
- ME-344, a mitochondrial inhibitor targeting the oxidative phosphorylation ("OXPHOS") complex; and
- Pracinostat, an oral histone deacetylase ("HDAC") inhibitor.



1. Phase 2 study intended to support an accelerated approval marketing application with FDA.
2. Study arm initiated under clinical collaboration with BeiGene, Ltd.
3. Initiation of clinical studies is subject to opening of a new Investigational New Drug application with FDA.
4. Investigator-initiated trial; completed.

Zandelisib (f/k/a ME-401): PI3Kd Inhibitor in a Phase 2 Trial Intended to Support an Accelerated Approval in Relapsed or Refractory Follicular Lymphoma

Zandelisib is an oral, once-daily, selective PI3Kd inhibitor in clinical development for the treatment of B-cell malignancies. In April 2020, we entered a global license, development and commercialization agreement to further develop and commercialize zandelisib with Kyowa Kirin Co., Ltd. ("KKC"). MEI and KKC will co-develop and co-promote zandelisib in the U.S., with MEI recording all revenue from U.S. sales. KKC has exclusive commercialization rights outside of the U.S. We are conducting multiple ongoing studies evaluating zandelisib including TIDAL (Trials of PI3K DeltA in Non-Hodgkin's Lymphoma), a Phase 2 clinical trial evaluating zandelisib as a monotherapy for the treatment of adults with relapsed or refractory ("r/r") follicular lymphoma ("FL") after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Subject to the results, upon completion of TIDAL, we are planning a submission with the FDA to support an accelerated approval of a marketing application under 21 CFR Part 314.500, Subpart H. We are also conducting a multi-arm, open-label, Phase 1b dose escalation and expansion trial evaluating zandelisib as a monotherapy and in combination with other therapies in patients with relapsed or refractory B-cell malignancies. Other initiated studies include a Phase 1 study, conducted by KKC, evaluating zandelisib as a monotherapy in patients in Japan with indolent B-cell malignancy, pursuant to a 2018 license, development and commercialization agreement with respect to development and commercialization in Japan that was superseded by the April 2020 global agreement.

While PI3Kd inhibitors as a group are a clinically validated class for the treatment of B-cell malignancies, the FDA approved orally administered products, idelalisib (marketed as Zydelig®) and duvelisib (marketed as COPIKTRA®), and the intravenously administered PI3Kd/α inhibitor copanlisib (marketed as Aliqopa®), are challenged by dose-limiting toxicities. We believe this

provides an opportunity for the development of a next-generation candidate with pharmaceutical properties that may better maximize the therapeutic potential of PI3Kd inhibition by limiting toxicities, which hinder clinical utility.

The molecular structure and pharmacodynamic characteristics of zandelisib are distinct from the FDA approved PI3Kd inhibitors. Zandelisib is characterized by prolonged target binding, preferential cellular accumulation, high volume of distribution throughout the body tissues, and an approximately 28-hour half-life suitable for once daily oral administration. These properties of zandelisib allow exploration of flexible dosing regimens such as an intermittent dosing schedule, which has demonstrated the potential to maintain clinical benefit while minimizing immune-related toxicities common to other PI3Kd agents, either as a monotherapy or in combination with other therapies.

KKC License, Development and Commercialization Agreement

In April 2020, we entered a License, Development and Commercialization Agreement with KKC (the "KKC Commercialization Agreement"). We granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S., and an exclusive (subject to certain retained rights to perform obligations under the agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the United States (the "Ex-U.S"). KKC grants to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. The KKC Commercialization Agreement substantially retains and consolidates the terms of the 2018 license agreement with KKC to develop and commercialize zandelisib in Japan.

KKC will be responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, will be solely responsible for all costs related thereto. We and KKC will co-develop and co-promote zandelisib in the U.S., with us recording all revenue from U.S. sales. We and KKC will share U.S. profits and costs (including development costs) on a 50-50 basis. We will also provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S. pursuant to supply agreements to be entered into on customary terms, with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable.

Under the terms of the KKC Commercialization Agreement, KKC paid us an initial payment of $100 million in May 2020. Of the $100 million paid by KKC, $20.4 million was remitted to the Japanese taxing authorities as a result of the U.S. Internal Revenue Service being closed due to the COVID pandemic, and therefore being unable to provide necessary documentation to support an exemption from the required foreign withholding. We expect to receive the amount paid to the Japanese taxing authorities in fiscal year 2021. We may also earn up to approximately $582.5 million in potential development, regulatory and commercialization milestone payments, plus royalties on net sales of zandelisib in the Ex-U.S., which are tiered beginning in the teens.

Zandelisib Scientific Overview: at the Crossroads of B-cell Signaling Pathways

The PI3K/AKT/mTOR pathway is an important signaling pathway for many cellular functions such as cell survival, cell cycle progression and cellular growth. PI3Ks are a family of enzymes within this pathway that have been shown to play a critical role in the proliferation and survival of certain cancer cells.

There are several isoforms of PI3K that are expressed in different types of cells. The PI3Kd isoform is at the crossroads of B-cell receptor signaling pathways that are major drivers of survival and proliferation of many B-cell malignancies. Because the d isoform is often overexpressed in cancer cells of the B-lymphocyte lineage, such as B-cell leukemias and lymphomas, it is understood to be important for survival of these cells. Zandelisib displays high selectivity for the PI3K delta isoform and functions to inhibit its activity.

Clinical Program

We are conducting multiple ongoing studies evaluating zandelisib including TIDAL, a global Phase 2 trial evaluating patients with relapsed or refractory follicular lymphoma intended to support an accelerated approval of a marketing application with the FDA, and a multi-arm, open-label, Phase 1b dose escalation and expansion trial as a monotherapy and in combination with other therapies in patients with FL and other B-cell malignancies. Additionally, in 2019, KKC initiated a Phase 1 study evaluating zandelisib as a monotherapy in patients in Japan with indolent B-cell malignancy.

Phase 1b Multi-arm Trial

In May 2020, we reported updated data from the ongoing Phase 1b clinical trial evaluating zandelisib as a monotherapy and in combination with rituximab in patients with relapsed or refractory B-cell malignancies as featured in a poster discussion at the American Society of Clinical Oncology 2020 Virtual Scientific Program.

Data were reported from a total of 57 patients treated with zandelisib, including 36 patients with r/r FL, 10 patients with r/r chronic lymphocytic leukemia ("CLL"), and 11 patients with other B-cell malignancies. Zandelisib was administered once daily at 60 mg for two 28-day cycles and then on an intermittent schedule ("IS") of once daily dosing for the first seven days of each subsequent 28-day cycle. A previous cohort of 39 patients in the trial was treated with zandelisib at 60 to 180 mg administered continuously once daily ("CS") or were switched to the IS in later cycles.

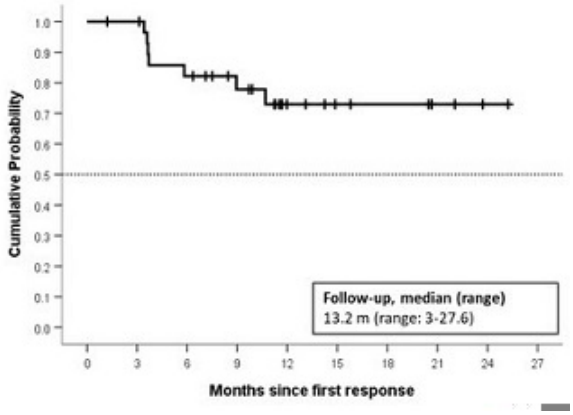
The overall response rate in the 36 patients with r/r FL was 83%, with 22% achieving a complete response. The overall response rate was 76% in 17 patients administered zandelisib as a monotherapy and 89% in 19 patients administered zandelisib in combination with rituximab. The overall response rate in nine evaluable patients with CLL was 89%.

Overall Response Rates ("ORR")

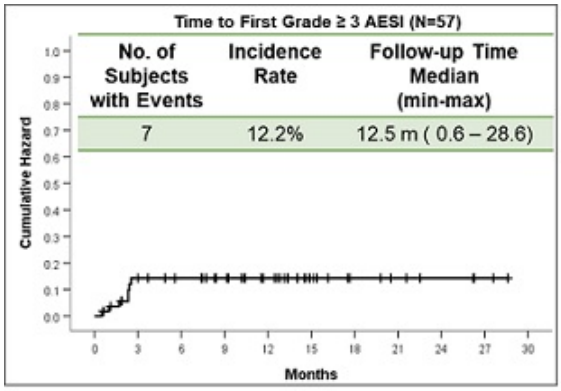
Diagnosis	Evaluable Subjects N	ORR N (%)
FL	36	30 (83%)
By treatment group		
zandelisib monotherapy	17	13 (76%)
zandelisib + rituximab	19	17 (89%)
By prior lines of therapy		
1 prior	16	13 (81%)
³ 2 prior	20	17 (85%)
CLL SLL		
By treatment group	9	8 (89%)
zandelisib monotherapy	3	3 (100%)
zandelisib + rituximab	6	5 (83%)

Median duration of response in patients with FL has not yet been reached and median follow-up was 13.2 months (range: 3.0-27.6). Responses appeared durable across patient subsets analyzed (prior lines of therapy (1 vs ³ 2), treatment group (i.e. monotherapy or in combination with rituximab) or tumor bulk (< 5 cm vs ³5 cm)).

Duration of Response: Follicular Lymphoma Patients (N=30)



Zandelisib was generally well-tolerated. The rate of drug related grade 3 Adverse Events of Special Interest ("AESI") was: diarrhea 3.5% (2/57); colitis 3.5% (2/57); rash 1.8% (1/57); alanine aminotransferase ("ALT")/ aspartate aminotransferase ("AST") elevation 1.8% (1/57); non-infectious pneumonitis 1.8% (1/57). No grade ³3 AESI was reported after Cycle 3, when patients are treated with the IS, and the discontinuation rate due to adverse events was 7% (4/57). There were no isolated grade 3 elevations in ALT and AST: such elevations were transient and in each case were associated with grade 3 diarrhea or rash.



The Phase 1b trial is additionally evaluating zandelisib (60 mg) in combination with zanubrutinib (marketed as Brukinsa®), an inhibitor of Bruton's tyrosine kinase ("BTK") developed by BeiGene, Ltd. ("BeiGene"). Pursuant to a collaboration initiated with BeiGene in October 2018, we began evaluating the safety and efficacy of zandelisib in combination with zanubrutinib for the treatment of patients with various relapsed or refractory B-cell malignancies. The cost of the combination trial is being equally shared. Each company is supplying its own investigational agent. We retain all commercial rights to zandelisib (subject to the KKC Commercialization Agreement) and BeiGene retains all commercial rights to zanubrutinib.

Phase 2 Trial Intended to Support an Accelerated Approval Marketing Application

We are recruiting patients in TIDAL, a global Phase 2 trial evaluating the efficacy, safety, and tolerability of zandelisib in patients with FL after failure of at least two prior systemic therapies including chemotherapy and anti-CD20 antibody. This study is intended to support an FDA accelerated approval New Drug Application ("NDA"). The study is evaluating zandelisib administered once daily at 60 mg for two 28-day cycles and then on an intermittent schedule of once daily dosing for the first seven days of each subsequent 28-day cycle (i.e. IS). Approximately 120 patients will be enrolled and treated with the IS regimen; the primary efficacy endpoint will be the rate of objective responses to therapy and other endpoints will include duration of response and tolerability of zandelisib.

Impact of COVID-19 on the Phase 2 TIDAL Study

While the extent to which the COVID-19 pandemic will impact the completion of the TIDAL study is subject to future developments, which are highly uncertain and cannot be predicted with confidence, currently the integrity of the study remains intact and patient enrollment continues, although at a reduced rate. At this time, TIDAL enrollment is projected to be completed in the first calendar quarter of 2021. We will continue efforts to be proactive in managing the impact from the pandemic, including various actions to communicate with sites and investigators, and making accommodations to patients consistent with FDA guidance and guidance from other regulatory authorities, as we may deem appropriate.

Voruciclib: CDK Inhibitor with CDK9 Inhibition in Phase 1 Studies

Voruciclib is an orally administered CDK inhibitor differentiated by its potent in vitro inhibition of CDK9 in addition to CDK6, 4 and 1. Voruciclib is being evaluated in a Phase 1b trial evaluating dose and schedule in patients with acute myeloid leukemia ("AML") and B-cell malignancies.

Voruciclib Scientific Overview: Cell Cycle Signaling

The CDK family of proteins are important cell cycle regulators. CDK9 is a transcriptional regulator of the myeloid leukemia cell differentiation protein ("MCL1"), a member of the family of anti-apoptotic proteins which, when elevated, may prevent the cell from undergoing cell death. Inhibition of CDK9 blocks the production of MCL1, which is an established resistance mechanism to the B-cell lymphoma ("BCL2") inhibitor venetoclax (marketed as Venclexta®).

In pre-clinical studies voruciclib shows dose-dependent suppression of MCL1; in December 2017 a study of voruciclib published in the journal *Nature Scientific Reports* reported that the combination of voruciclib plus the BCL-2 inhibitor venetoclax was capable of inhibiting two master regulators of cell survival, MCL-1 and BCL-2, and achieved synergistic antitumor effect in an aggressive subset of DLBCL pre-clinical models. (Scientific Reports. (2017) 7:18007. DOI:10.1038/s41598-017-18368-w).

Additionally, a peer reviewed manuscript published in 2020 by Luedtke et al, concluded that the inhibition of CDK9 by voruciclib synergistically enhances cell death induced by the Bcl-2 selective inhibitor venetoclax in preclinical models of acute myeloid leukemia. (Sig Transduct Target Ther 5, 17 (2020). https://doi.org/10.1038/s41392-020-0112-3.

CDK9 is also a transcriptional regulator of MYC proto-oncogene protein ("MYC"), a transcription factor regulating cell proliferation and growth which contributes to many human cancers and is frequently associated with poor prognosis and

unfavorable patient survival. Targeting MYC directly has historically been difficult, but CDK9 is a transcriptional regulator of MYC and is a promising approach to target this oncogene.

Clinical Program

We are evaluating patients with hematological malignancies in a Phase 1b clinical trial evaluating the dose and schedule of voruciclib. The trial is initially intended to evaluate the dose and schedule of voruciclib as a monotherapy in patients with relapsed and/or refractory B-cell malignancies or AML after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. Once initial safe dose levels and schedules have been established, we plan in parallel, subject to FDA agreement, to evaluate the dose and schedule of voruciclib in combination with a BCL2 inhibitor such as venetoclax to assess synergies and the opportunity for combination treatments, initially in patients with AML and subsequently across multiple indications.

Voruciclib was previously evaluated in more than 70 patients with solid tumors in multiple Phase 1 studies with a tolerability profile consistent with other drugs in its class. In pre-clinical studies, voruciclib shows dose-dependent suppression of MCL1 at concentrations achievable with doses that appear to be generally well tolerated in earlier Phase 1 studies. Pre-clinical studies additionally show inhibition of MYC protein expression.

ME-344: Mitochondrial Inhibitor with Combinatorial Potential

ME-344 is our novel and tumor selective, isoflavone-derived mitochondrial inhibitor drug candidate. It directly targets the OXPHOS complex 1, a pathway involved in ATP production in the mitochondria. ME-344 was studied in an investigator-initiated, multi-center, randomized clinical trial in combination with the vascular endothelial growth factor ("VEGF") inhibitor bevacizumab (marketed as Avastin ®) in a total of 42 patients with human epidermal growth factor receptor 2 ("HER2") negative breast cancer.

ME-344 Scientific Overview: Cancer Metabolism

Tumor cells often display a high metabolic rate to support cell division and growth. This heightened metabolism requires a continual supply of energy in the form of adenosine triphosphate ("ATP"). The two major sources of ATP are the specialized cellular organelles termed mitochondria and through the metabolism of carbohydrates, proteins and lipids.

ME-344 was identified through a screen of more than 400 new chemical structures originally created based on the central design of naturally occurring plant isoflavones. We believe that some of these synthetic compounds, including our drug candidate ME-344, interact with specific mitochondrial enzyme targets, resulting in the inhibition of ATP generation. When these compounds interact with their target, a rapid reduction in ATP occurs, which leads to a cascade of biochemical events within the cell and ultimately to cell death.

Clinical Program

ME-344 demonstrated evidence of single agent activity against refractory solid tumors in a Phase 1 trial, and in pre-clinical studies tumor cells treated with ME-344 resulted in a rapid loss of ATP and cancer cell death. In addition to single agent activity, ME-344 may also have significant potential in combination with anti-angiogenic therapeutics. In pre-clinical studies, it was shown that one outcome of anti-angiogenics was to reduce the rate of glycolysis in tumors as a mechanism to slow tumor growth. However, tumor metabolism was able to shift to mitochondrial metabolism for energy production to support continued tumor proliferation. In such cases of tumor plasticity in the presence of treatment with anti-angiogenics, targeting the alternative metabolic source with ME-344 may open an important therapeutic opportunity.

Support for this combinatorial use of ME-344 was first published in the June 2016 edition of *Cell Reports*; pre-clinical data from a collaboration with the Spanish National Cancer Research Centre in Madrid demonstrated mitochondria-specific effects of ME-344 in cancer cells, including substantially enhanced anti-tumor activity when combined with agents that inhibit the activity of VEGF. These data demonstrating the potential anti-cancer effects of combining ME-344 with a VEGF inhibitor due to an inhibition of both mitochondrial and glycolytic metabolism provided a basis for commencement of an investigator-initiated trial of ME-344 in combination with bevacizumab in HER2 negative breast cancer patients.

Results published in the November 2019 issue of Clinical Cancer Research from a multicenter, investigator-initiated, randomized, open-label, clinical trial that evaluated the combination of ME-344 and bevacizumab in 42 women with early HER2-negative breast cancer further support for the combinatorial use of ME-344 with anti-angiogenic therapeutics.

The primary objective of the trial was to show proof of ME-344 biologic activity as measured by Ki67 reductions in the presence of the nuclear protein Ki67 (expression of which is strongly associated with tumor cell proliferation and growth) from days 0 to 28 compared to the control group who received bevacizumab alone. Secondary objectives included determining whether ME-344 biologic activity correlates with vascular normalization. The data demonstrate significant biologic activity in the ME-344 treatment group:

- In ME-344 treated patients, mean absolute Ki67 decreases were 13.3 compared to an increase of 1.1 in the bevacizumab monotherapy group (P=0.01).
- In ME-344 treated patients, mean relative Ki67 decreases were 23% compared to an increase of 186% in the bevacizumab monotherapy group (P < 0.01).
- The mean relative Ki67 reduction in patients experiencing vascular normalization in the ME-344 treated patients was 33%, compared to an increase of 11.8% in normalized patients from the bevacizumab monotherapy group (P=0.09).

Approximately one-third of patients in each arm had vascular normalization.

Treatment was generally well tolerated; three grade 3 adverse events of high blood pressure were reported, two in the ME-344 arm and one in the bevacizumab monotherapy arm.

Results from our earlier, first-in-human, single-agent Phase 1 clinical trial of ME-344 in patients with refractory solid tumors were published in the April 1, 2015 issue of *Cancer*. The results indicated that eight of 21 evaluable patients (38%) treated with ME-344 achieved stable disease or better, including five who experienced progression-free survival that was at least twice the duration of their last prior treatment before entry into the trial. In addition, one of these patients, a heavily pre-treated patient with small cell lung cancer, achieved a confirmed partial response and remained on study for two years. ME-344 was generally well tolerated at doses equal to or less than 10 mg/kg delivered on a weekly schedule for extended durations. Treatment-related adverse events included nausea, dizziness and fatigue. Dose-limiting toxicities were observed at both the 15 mg/kg and 20 mg/kg dose levels, consisting primarily of grade 3 peripheral neuropathy.

Pracinostat: HDAC Inhibitor Candidate in a Phase 2 Clinical Trial

Pracinostat is an oral HDAC inhibitor being evaluated in a Phase 2 trial in patients with high or very high-risk myelodysplastic syndrome ("MDS") who are previously untreated with hypomethylating agents (the "POC study").

In August 2016, we entered into an exclusive worldwide license, development, manufacturing and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical corporation ("Helsinn") for pracinostat (the "Helsinn License Agreement") as a treatment for patients with MDS or AML. Under the agreement, Helsinn is primarily responsible for funding global development and commercialization costs for pracinostat. We are responsible for conducting the POC study, the cost of which is being shared equally with Helsinn. Any future development and commercialization costs after the completion of the Phase 2 trial will be the responsibility of Helsinn.

Pracinostat Scientific Overview; Epigenetics

HDACs play a key role in epigenetic regulation of gene expression by regulating chromatin structure. Acetylation of positively charged lysine residues present in histone proteins by the histone acetyltransferase ("HATs") reduces the affinity between histones and negatively charged DNA, resulting in the opening of the chromatin structure. This makes it easier for the transcriptional machinery to access the DNA, enhancing RNA transcription. Conversely, deacetylation by the HDACs closes the chromatin structure leading to a repression of gene transcription. In normal cells, HDACs and HATs together control histone acetylation levels to maintain a balance. In diseases such as cancer, this regulation can be disturbed. HDAC inhibitors cause accumulation of acetylated histones, enhance transcription and result in changes to a variety of cellular responses including differentiation, proliferation, migration, survival and response to metabolic and hypoxic stress. In general, tumor cells are more susceptible than normal cells to the anti-proliferative and pro-apoptotic effects of HDAC inhibitors.

There are currently three HDAC inhibitors, one oral and two injectable, approved by the FDA for the treatment of T-cell lymphoma and a fourth orally administered HDAC inhibitor approved for multiple myeloma. Other HDAC inhibitors are being evaluated in clinical trials as monotherapies and in combination for the treatment of various hematologic diseases and solid tumors.

Pracinostat is an orally available, potent HDAC inhibitor that we believe has potentially improved physicochemical, pharmaceutical and pharmacokinetic properties when compared to other compounds of this class, including increased bioavailability and increased half-life.

Clinical Program

Pracinostat is being investigated in a Phase 2 dose optimization trial evaluating patients with high and very high-risk MDS who are previously untreated with hypomethylating agents. This patient group represents the highest unmet need in MDS, with median survival estimates of 1.6 years and 0.8 years, respectively (Greenberg et al, *Blood 2012*). The ongoing Phase 2 open-label trial is evaluating a 45 mg dose of pracinostat in combination with the standard dose of azacitidine. The trial is designed to evaluate tolerability of the combination, with the intent of maintaining patient enrollment longer than in an earlier Phase 2 trial evaluating a 60 mg dose. A prolonged treatment may result in a systemic exposure to pracinostat and azacitidine sufficient to achieve the desired treatment effect; data from the earlier Phase 2 trial suggested that insufficient exposure to treatment may have limited the treatment effect of the combination.

A pre-planned interim analysis of the ongoing Phase 2 MDS trial demonstrated a 10% discontinuation rate among the first 20 evaluable patients treated, meeting the predefined threshold in the first 3 treatment cycles. The 10% rate is consistent with the discontinuation rate for azacitidine given as a monotherapy in earlier studies with pracinostat. Having met this threshold, the trial expanded open-label enrollment to a total of 60 patients in the study. An interim analysis presented at the 2018 ASH meeting demonstrated a discontinuation rate due to adverse events in the first three cycles of 4%, substantially lower than the rate of 26% reported in our prior Phase 2 trial.

The ongoing Phase 2 trial completed enrollment and patients have been followed for at least one year to evaluate safety and efficacy. The primary endpoints of the trial are 1) safety and tolerability and 2) overall response rate, defined as complete remission ("CR"), partial remission ("PR") and marrow CR. Secondary endpoints include CR rate, overall hematologic improvement ("HI") response rate, clinical benefit rate (defined as rate of CR + PR + HI + Marrow CR), rate of cytogenetic complete response/remission,

duration of response, rate of leukemic transformation, event-free survival, progression-free survival and overall survival.

Data from the ongoing Phase 2 study (n=64) presented as part of the American Society of Clinical Oncology 2020 Virtual Scientific Program in June 2020 demonstrated an estimated median overall survival ("OS") rate of 23.5 months with a one-year OS rate of 77%. The median follow-up was 17.6 months (range, 15.7–18.8) and the overall response rate ("ORR") was 33% (21/64), all of which are complete responses ("CR"). The clinical benefit rate (CR, mCR plus hematologic improvement ("HI"), mCR with no HI, or HI with no mCR) was 77% (49/64). Twenty seven percent of patients (17/64) proceeded to a stem cell transplant while on study. Eleven percent of patients discontinued treatment because of adverse events. The most common grade ³3 treatment emergent adverse events were hematologic, and included decreased neutrophil count (50%), anemia (39%), febrile neutropenia (34%), decreased platelet count (33%), thrombocytopenia (27%), and decreased white blood cell count (20%).

A Phase 3 study evaluating pracinostat in combination with azacitidine in patients with AML who are unfit to receive standard intensive chemotherapy was discontinued by Helsinn, the study sponsor, in July 2020 after an interim futility analysis undertaken by the study Independent Data Monitoring Committee demonstrated it was unlikely to meet the primary endpoint of overall survival compared to the control group. Following the discontinuation of the Phase 3 AML study, Helsinn communicated to us their plan to continue therapy and observation of the patients currently in the Phase 2 MDS study and that further development of pracinostat, including for the treatment of MDS, is under review.

Competition

The marketplace for our drug candidates is highly competitive. A number of other companies have products or drug candidates in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which our drug candidates are being developed. Some of these potential competing drug candidates are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing products that receive regulatory approval, such products may not compete successfully with products produced by our competitors or with products that may subsequently receive regulatory approval.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing oncology drugs have significantly greater capital resources, larger research and development staffs and facilities, and greater experience in drug development, regulation, manufacturing, marketing and commercialization than we do. They compete with us in recruiting sites and eligible patients to participate in clinical studies and in attracting development and/or commercialization partners. They also license technologies that are competitive with our technologies. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies or our drug candidates obsolete or non-competitive.

Intellectual Property

We own, by assignment or exclusive license, worldwide rights to each of our current drug candidates. Our intellectual property portfolio includes approximately 37 issued U.S. patents, 293 issued foreign patents, 21 pending U.S. patent applications, and 115 pending foreign applications.

We have acquired, by assignment, worldwide rights to zandelisib and other related compounds from Pathway Therapeutics, Inc. The U.S. Patent and Trademark Office ("USPTO") has issued five patents covering the composition of matter and pharmaceutical compositions of zandelisib which are projected to expire in January 2031 and December 2032, not including any patent term extension. There are currently seven U.S. and 53 foreign applications for zandelisib and related compounds pending.

We have acquired exclusive worldwide rights to develop, manufacture and commercialize voruciclib from Presage Biosciences, Inc. ("Presage"). The USPTO has issued three patents covering the composition of matter and pharmaceutical compositions of voruciclib which are projected to expire between April 29, 2024 and September 2028, not including any patent term extension. In total there are currently 13 allowed or issued U.S. patents, 70 allowed or issued foreign patents, 6 pending U.S. applications and 20 pending foreign applications for voruciclib and related compounds.

We have acquired, by assignment, patents and patent applications from Novogen, our former majority shareholder, which relate to a large family of isoflavonoid compounds, including ME-344. The USPTO has issued 11 patents covering ME-344, including its composition of matter, pharmaceutical compositions and methods of use to treat cancer. The composition of matter and pharmaceutical composition claims covering ME-344 are expected to expire in March 2027 and November 2031, not including patent term extension.

We have acquired, by assignment, patents and patent applications from S*Bio Pte Ltd ("S*Bio") relating to a family of heterocyclic compounds, which include pracinostat, that inhibit histone deacetylases. The USPTO has issued eight patents covering a number of these heterocyclic-based compounds, including pracinostat, and their composition of matter, pharmaceutical compositions, and methods of use to treat proliferative diseases. The composition of matter claims covering pracinostat are projected to expire in May 2028, not including patent term extension. In the Helsinn License Agreement, we granted to Helsinn an exclusive (subject to certain retained rights to perform obligations under the agreement), sublicensable, payment-bearing, license under and to certain

patents and know-how controlled by us to develop, manufacture and commercialize pracinostat and any pharmaceutical product containing pracinostat for all human and animal indications.

Our success depends in large part on our ability to protect our proprietary technologies, compounds and information, and to operate without infringing the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright, and trademark laws, as well as confidentiality, licensing and other agreements, to establish and protect our proprietary rights. We seek patent protection for our key inventions, including drug candidates we identify, routes for chemical synthesis and pharmaceutical formulations. There is no assurance that any of our pending patent applications will issue, or that any of our patents will be enforceable or will cover a drug or other commercially significant product or method. In addition, we regularly review our patent portfolio to identify patents and patent applications that we deem to have relatively low value to our ongoing business operations for potential abandonment. There is also no assurance that we will correctly identify which of our patents and patent applications should be maintained and which should be abandoned. The term of most of our other current patents commenced, and most of our future patents, if any, will commence, on the date of issuance and terminate 20 years from the earliest effective filing date of the patent application. Because any marketing and regulatory approval for a drug often occurs several years after the related patent application is filed, the resulting market exclusivity afforded by any patent on our drug candidates and technologies will likely be substantially less than 20 years.

As most patent applications in the U.S. are maintained as confidential until published by the USPTO at 18 months from filing for all cases filed after November 29, 2000, or at issue, for cases filed prior to November 29, 2000, we cannot be certain that we or Presage were the first to make the inventions covered by the patents and applications referred to above. Additionally, publication of discoveries in the scientific or patent literature often lags behind the actual discoveries. Moreover, pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of twenty years from the date of such filing except for provisional applications, irrespective of the period of time it may take for such patent to ultimately issue. This may shorten the period of patent protection afforded to therapeutic uses of zandelisib, voruciclib, ME-344 or pracinostat as patent applications in the biopharmaceutical sector often take considerable time to issue. However, in some countries the patent term may be extended.

In order to protect the confidentiality of our technology, including trade secrets and know-how and other proprietary technical and business information, we require all of our consultants, advisors and collaborators to enter into agreements that prohibit the use or disclosure of information that is deemed confidential. These agreements also oblige our consultants, advisors and collaborators to assign to us, or negotiate a license to developments, discoveries and inventions made by such persons in connection with their work relating to our products. We cannot be sure that confidentiality will be maintained by those from whom we have acquired technology or disclosure prevented by these agreements. We also cannot be sure that our proprietary information or intellectual property will be protected by these agreements or that others will not independently develop substantially equivalent proprietary information or intellectual property.

The pharmaceutical industry is highly competitive, and patents may have been applied for by, and issued to, other parties relating to products competitive with zandelisib, voruciclib, ME-344 or pracinostat. Use of these compounds and any other drug candidates may give rise to claims that they infringe the patents or proprietary rights of other parties, existing now and in the future. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties. We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded.

Research and Development

The objective of our research and development program is the generation of data sufficient to achieve regulatory approval of our drug candidates in one or more dosage forms in major markets such as the U.S., to meet medical needs and develop a clinical and commercial profile with attractive attributes, and/or to allow us to enter into a development and/or commercial relationship with another party. The data are generated by our pre-clinical studies and clinical trial programs.

The key aspects of our research and development program are to provide more complete characterization of the following:

- the relevant molecular targets of action of our drug candidates;
- the relative therapeutic benefits and indications for use of our drug candidates as a monotherapy or as part of combinational therapy with other agents; and
- the most appropriate therapeutic indications and dosage forms for zandelisib, voruciclib, ME-344 and pracinostat.

Government Regulation

U.S. Regulatory Requirements

The FDA, and comparable regulatory agencies in other countries, regulate and impose substantial requirements upon the research, development, pre-clinical and clinical testing, labeling, manufacture, quality control, storage, approval, advertising, promotion, marketing, distribution, import, and export of pharmaceutical products including biologics, as well as significant reporting and record-keeping obligations. State governments may also impose obligations in these and other areas.

In the U.S., pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA") and other laws, including in the case of biologics, the Public Health Service Act. We believe, but cannot be certain, that our products will be regulated as drugs by the FDA. The process required by the FDA before drugs may be marketed in the U.S. generally involves the following:

- pre-clinical laboratory evaluations, including formulation and stability testing, and animal tests performed under the FDA's Good Laboratory Practices regulations to assess pharmacological activity and toxicity potential;
- submission and approval of an Investigational New Drug ("IND") application, including results of pre-clinical tests, manufacturing information, and protocols for clinical tests, which must become effective before clinical trials may begin in the U.S.;
- obtaining approval of IRBs to administer the products to human subjects in clinical trials;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for the product's intended use;
- development of manufacturing processes which conform to FDA's current Good Manufacturing Practices ("cGMP"), as confirmed by FDA inspection;
- submission of results for pre-clinical, toxicology, and clinical studies, and chemistry, manufacture and control information on the product to the FDA in an NDA; and
- FDA review and approval of an NDA, prior to any commercial sale or shipment of a product.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on a timely basis, if at all.

The results of the pre-clinical studies, together with initial specified manufacturing information, the proposed clinical trial protocol, and information about the participating investigators are submitted to the FDA as part of an IND, which must become effective before we may begin human clinical trials in the U.S. Clinical trials must be conducted in accordance with federal regulations and Good Clinical Practice ("GCP") requirements, and with investigational products that follow cGMP. GCPs include, among other requirements, the requirements related to monitoring, drug accountability, data integrity, and that all research subjects provide their informed consent in writing for their participation in any clinical trial. Additionally, an independent IRB must review and approve each study protocol and oversee conduct of the trial. An IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. If the FDA imposes a clinical hold, the IND sponsor must resolve the FDA's concerns before clinical trials can begin. Pre-clinical tests and studies can take several years to complete, and there is no guarantee that an IND we submit based on such tests and studies will become effective within any specific time period, if at all.

Sponsors must make certain reports and submissions to FDA and the IRB, including annual reports, and reports of investigator financial interests, serious adverse events and other significant safety information, study amendments, and new study protocols. Information about certain clinical trials, including a description of the study and study results, must also be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on the clinicaltrials.gov website. Sponsors of investigational products for serious diseases must also have a publicly available policy on requests for expanded access.

Investigational drugs and active ingredients imported into the United States are also subject to regulation by the FDA. Further, the export of investigational products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

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

- *Phase 1:* The drug is initially introduced into healthy human subjects or patients and tested for safety and dosage tolerance. Absorption, metabolism, distribution, and excretion testing is generally performed at this stage.
- *Phase 2:* The drug is studied in controlled, exploratory therapeutic trials in a limited number of subjects with the disease or medical condition for which the new drug is intended to be used in order to identify possible adverse effects and safety risks, to determine the preliminary or potential efficacy of the product for specific targeted diseases or medical conditions, and to determine dosage tolerance and the optimal effective dose.
- *Phase 3:* When Phase 2 studies demonstrate that a specific dosage range of the drug may be effective and the drug has an acceptable safety profile for further investigation, controlled, large-scale therapeutic Phase 3 trials are undertaken at multiple study sites to demonstrate clinical efficacy and to further test for safety in an expanded patient population. Typically, two Phase 3 trials are required by the FDA for product approval. Under some limited circumstances, however, the FDA may approve an NDA based upon a single Phase 3 clinical study plus confirmatory evidence or a single large multicenter trial without confirmatory evidence.

Concurrent with clinical trials, companies usually complete additional non-clinical and toxicology studies and must also develop additional information about the CMC of the product candidate.

We cannot be certain that we will successfully complete clinical testing of our products within any specific time period, if at all. Furthermore, the FDA, the IRB or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable safety risk or noncompliance with applicable regulatory requirements.

Results of pre-clinical and toxicology studies, and clinical trials, as well as detailed information about the manufacturing process, quality control methods, and product composition, among other things, are submitted to the FDA as part of an NDA seeking approval to market and commercially distribute the product on the basis of a determination that the product is safe and effective for its intended use. Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the goals agreed to by the FDA under the Prescription Drug User Fee Act, ("PDUFA"), the agency aims to review 90% of all applications for new molecular entities within ten months of the 60-day filing date. The PDUFA date is only a goal, thus, the FDA does not always meet its PDUFA dates. The PDUFA date may also be extended if the FDA requests or the sponsor provides substantial additional information regarding the submission.

The FDA may refer certain applications to an advisory committee, which is a panel of experts that make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and may inspect the Sponsor, clinical study vendors, and clinical sites at which the product candidate was studied and will not approve the product unless cGMP and GCP compliance is satisfactory. If applicable regulatory criteria are not satisfied, the FDA may issue a complete response letter, ("CRL"), to the Sponsor requiring additional non-clinical or clinical studies or additional CMC information. If a CRL is issued, the applicant may either: resubmit the marketing application, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing.

Once FDA determines that the approval requirements are met, it will issue an approval letter that authorizes commercial marketing of the product with specific prescribing information for specific indications. As a condition of approval, the FDA also may require post-marketing commitments and requirements and/or surveillance to monitor the product's safety or efficacy. The FDA also may require a risk evaluation and mitigation strategy, or REMS, as a condition of product approval or following approval to ensure that the benefits of the product candidate outweigh the risks. Moreover, even if the FDA approves a product, it may limit the approved indications or populations for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a black box warning, impose other conditions, such as post-approval studies, or may not approve label statements that are necessary for successful commercialization and marketing.

Even after an NDA is approved, the FDA may impose additional obligations or restrictions (such as labeling changes, or clinical post-marketing requirements), or even suspend or withdraw a product approval or require additional testing or label revisions on the basis of data that arise after the product reaches the market, or if compliance with regulatory standards is not maintained. We cannot be certain that any NDA we submit will be approved by the FDA for full or accelerated approval on a timely basis, if at all. Also, any such approval may limit the indicated uses for which the product may be marketed. Any refusal to approve, delay in approval, suspension or withdrawal of approval, or restrictions on indicated uses could have a material adverse impact on our business prospects.

Each NDA must be accompanied by a substantial user fee pursuant to the requirements of the PDUFA and its amendments. Fee waivers or reductions are available in certain circumstances. Following product approval, drug products are also subject to annual program fees. The FDA adjusts the PDUFA user fees on an annual basis. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no small business waivers for program fees. Product candidates that are designated as orphan products are not subject to application user fees unless the application includes an indication other than the orphan indication and may be exempt from program fees if certain criteria are met. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that may be incurred in the future and must be paid at the time of application submissions to the FDA.

Satisfaction of FDA requirements typically takes many years. The actual time required varies substantially, based upon the type, complexity, and novelty of the pharmaceutical product, among other things. Government regulation imposes costly and time-consuming requirements and restrictions throughout the product life cycle and may delay product marketing for a considerable period of time, limit product marketing, or prevent marketing altogether. Success in pre-clinical or early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from pre-clinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit, or prevent marketing approval. Even if a product receives marketing approval, the approval is limited to specific clinical indications. Further, even after marketing approval is obtained, the discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

After product approval, there are continuing significant regulatory requirements imposed by the FDA, including record-keeping requirements, obligations to report adverse side effects in patients using the products, and restrictions on advertising and promotional activities. Quality control and manufacturing procedures must continue to conform to cGMPs, and the FDA periodically inspects facilities to assess cGMP compliance. Additionally, post-approval changes in ingredient composition, manufacturing processes or facilities, product labeling, or other areas may require submission of an NDA Supplement to the FDA for review and approval. New indications will require additional clinical studies and submission of an NDA Supplement.

Failure to comply with FDA regulatory requirements may result in an enforcement action by the FDA, including clinical

holds, refusal to approve marketing applications or supplements, Warning Letters, product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, impositions of injunctions prohibiting product manufacture or distribution, and civil and criminal penalties, among other actions. Maintaining compliance is costly and time-consuming. We cannot be certain that we, or our present or future suppliers or third-party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of noncompliance could have a material adverse impact on our business prospects.

The FDA's policies may change, and additional governmental regulations may be enacted that could delay, limit, or prevent regulatory approval of our products or affect our ability to manufacture, market, or distribute our products after approval. Moreover, increased attention to the containment of healthcare costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payers. European Union member states and U.S. government and other third-party payers increasingly are attempting to contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. Our failure to obtain coverage, an adequate level of reimbursement, or acceptable prices for our future products could diminish any revenues we may be able to generate. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Our activities also may be subject to state laws and regulations that affect our ability to develop and sell our products. We are also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, clinical, laboratory, and manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future, and the failure to comply may have a material adverse impact on our business prospects.

The FDCA includes provisions designed to facilitate the development and expedite the review of drugs and biological products intended for treatment of serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions. These provisions set forth a procedure for designation of a drug as a "fast track product". The fast track designation applies to the combination of the product and specific indication for which it is being studied. A product designated as fast track is ordinarily eligible for additional programs for expediting development and review, such as increased FDA interactions and rolling submission and review of the application.

Products that are intended to treat serious or life-threatening conditions and that provide a meaningful therapeutic benefit over existing treatments may also be eligible for accelerated approval. Drug approval under the accelerated approval regulations may be based on evidence of clinical effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. A post-marketing clinical study will be required to verify clinical benefit, and other restrictions to assure safe use may be imposed. Failure to conduct required post-approval studies, or confirm a clinical benefit, will allow the FDA to withdraw the drug or biologic from the market on an expedited basis.

A third potential designation that may be available is breakthrough therapy designation. A breakthrough therapy is a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Products designated as breakthrough therapies are eligible for intensive FDA guidance, a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review, rolling submission and review of the application, and the facilitation of cross-disciplinary review.

Finally, if a product is intended to treat a serious condition and, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of the condition, the product may be eligible for priority review meaning that FDA's goal for the review of an NDA is shortened to six months (after a two month period during which FDA decides whether the application is ready for filing) rather than the standard review of ten months from application acceptance. Currently, we have fast track designation for one of our clinical programs (zandelisib for patients with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies). If we should seek additional designations for any of our programs, we cannot be assured that it will be granted by the FDA. There is also no guarantee that we will be able to maintain any designation that we have received or may receive.

Following FDA approval of an NDA, sponsors are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. These patents are published in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can be cited by potential competitors as a reference listed drug in support of a 505(b)(2) NDA or an Abbreviated New Drug Application, ("ANDA"). A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use as a previously approved product. ANDAs applicants generally must only scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the

innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Generally, FDA may not approve an ANDA or 505(b)(2) NDA unless the reference listed drug's Orange Book listed patents have expired and/or if the applicant certifies that it is not seeking approval for a patented method of use. FDA may approve these applications, however, if the 505(b)(2) NDA or ANDA sponsor certifies that the Orange Book listed patents for the reference listed drug are invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This later certification is called a paragraph IV certification. If the ANDA or 505(b)(2) NDA applicant has made a paragraph IV certification, following notice to the NDA and patent holders, the NDA and patent holders may then initiate a patent infringement lawsuit. If a lawsuit is brought, FDA may not make an approval effective until the earlier of 30 months from the patent or application owner's receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent is favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court.

Recently, Congress, the U.S. federal government administration, and U.S. federal administrative agencies have taken certain measures to increase drug competition and thus decrease drug prices, including by facilitating 505(b)(2) NDAs and ANDAs, and by introducing additional products into the U.S. market. By example, in 2019 FDA introduced a proposed rule and draft guidance to facilitate drug importation. Congress also passed a bill requiring sponsors of NDA products to provide sufficient quantities of drug product on commercially reasonable ma based terms to entities developing generic and 505(b)(2) products. This bill also included provisions on shared and individual REMS for generic drug products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may obtain marketing exclusivity for a specified period of time following FDA approval of certain drug applications. By example, new drugs containing new chemical entities that have not been previously approved by the FDA may obtain five years of exclusivity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a paragraph IV certification. This exclusivity is not absolute. For instance, it will not delay the submission or approval of a full NDA; though, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Following NDA approval, a patent owner may obtain an extension of a single unexpired patent that has not previously been extended for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval, with a five year maximum patent extension. The total patent life of the product with the extension cannot exceed fourteen years from the product's approval date. The period of patent extension may also be reduced for any time that the applicant did not act with due diligence. We cannot be certain that we will be able to take advantage of either the patent term extension or marketing exclusivity provisions of these laws or that, if received, they will adequately protect any approved products from competition.

The Best Pharmaceuticals for Children Act ("BPCA"), signed into law on January 4, 2002, was reauthorized and amended by the FDA Amendments Act of 2007 ("FDAAA"). The reauthorization of BPCA adds an additional six months of marketing exclusivity and patent protection to unexpired exclusivities and unexpired patents listed with FDA for NDA applicants that conduct acceptable pediatric studies of new and currently marketed drug products for which pediatric information would be beneficial, as identified by the FDA in a Pediatric Written Request. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted.

The Pediatric Research Equity Act ("PREA"), signed into law on December 3, 2003, also was reauthorized and amended by the FDAAA. The reauthorization of PREA requires that most applications for drugs and biologics include a pediatric assessment (unless waived or deferred) to ensure the drugs' and biologics' safety and effectiveness in children. Such pediatric assessment must contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective. The pediatric assessments can only be deferred provided there is a timeline for the completion of such studies. The FDA may waive (partially or fully) the pediatric assessment requirement for several reasons, including if the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed. Orphan products are also exempt from the PREA requirements. The Food and Drug Administration Safety and Innovation Act signed into law on July 9, 2012, permanently renewed and strengthened BPCA and PREA.

Under the FDA Reauthorization Act of 2017, beginning in 2020, sponsors submitting applications for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer must submit an agreed-to Pediatric Study Plan, with the application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, using appropriate formulations, to inform potential pediatric labeling. While orphan products are not exempt from this requirement, the FDA may grant full or partial waivers, or deferrals, for submission of data.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or

condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the U.S. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan drug designation if there is a product already approved by the FDA that is considered by the FDA to be the same as the already approved product and is intended for the same indication. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation does, however, entitle a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and certain user-fee waivers. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances. If there is already a product approved by FDA that is the same product for the same indication, the orphan designated product will only receive orphan drug exclusivity if the prior hypothesis of clinical superiority is demonstrated.

Foreign Regulatory Requirements

Outside the U.S., our ability to market our products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities and compliance with applicable post-approval regulatory requirements. Although the specific requirements and restrictions vary from country to country, as a general matter, foreign regulatory systems include risks similar to those associated with FDA regulation, described above.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or a decentralized procedure ("DCP"). Under the centralized procedure, a single application to the EMA leads to an approval granted by the European Commission which permits the marketing of the product throughout the EU. The centralized procedure is mandatory for certain classes of medicinal products, but optional for others. For example, all medicinal products developed by certain biotechnological means, and those developed for cancer and other specified diseases and disorders, must be authorized via the centralized procedure. The centralized procedure will apply to any of our products that are developed by means of a biotechnology process or are intended for treatment of cancer. The DCP is used for products that are not required to be authorized by the centralized procedure. Under the DCP (where there is no pre-existing marketing authorization granted by one member state) or mutual recognition procedure ("MRP"), an application for a marketing authorization is submitted to the competent authority of one member state of the EU (the reference member state). The holders of a national marketing authorization may submit further applications to the competent authorities of any or all the remaining member states (the concerned member states). The DCP enables applicants to submit an identical application to the competent authorities of all member states where approval is sought at the same time as the first application, while under the MRP, products are authorized initially in one member state, and other member states where approval is sought are then requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. Under the decentralized and mutual recognition procedures, the reference member state assessment takes 210 days (MRP) or 120 days (DCP) and the concerned member states process should take no longer than 90 days. However, if one member state makes an objection, which under the legislation can only be based on a possible risk to human health, the application will be automatically referred to the Committee for Medicinal Products for Human Use ("CHMP") of the EMA. If a referral for arbitration is made, the procedure is suspended. However, member states that have already approved the application may, at the request of the applicant, authorize the product in question without waiting for the result of the arbitration. Such authorizations will be without prejudice to the outcome of the arbitration. For all other concerned member states, the opinion of the CHMP, which is binding, could support or reject the objection or alternatively could reach a compromise position acceptable to all EU countries concerned. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

As with FDA approval, we may not be able to secure regulatory approvals in the EU in a timely manner, if at all. Additionally, as in the U.S., post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in the EU, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

The conduct of clinical trials in the European Union is governed by the European Clinical Trials Directive, which was implemented in May 2004. This Directive governs how regulatory bodies in member states control clinical trials. No clinical trial may be started without a clinical trial authorization granted by the national competent authority and favorable ethics approval. New legislation to revise and replace the European Clinical Trials Directive has been passed but is not yet implemented (currently estimated for 2020).

Accordingly, there is a marked degree of change and uncertainty both in the regulation of clinical trials and in respect of marketing authorizations which we face for our products in the EU.

Manufacturing

We do not have the facilities or capabilities to commercially manufacture any of our drug candidates. We are and expect to continue to be dependent on contract manufacturers for supplying our existing and future candidates for clinical trials and commercial scale manufacturing of our candidates in accordance with regulatory requirements, including cGMP. Contract manufacturers may utilize their own technology, technology developed by us, or technology acquired or licensed from third parties. FDA approval of the manufacturing procedures and the site will be required prior to commercial distribution.

Employees

As of June 30, 2020, we had 51 employees, 14 of whom hold a Ph.D. or M.D. degree. Other personnel resources are used from time to time as consultants or third-party service organizations on an as-needed basis. All members of our senior management team have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced personnel, but there can be no assurance that we will be able to attract and retain the individuals needed. None of our employees are represented by a collective bargaining agreement, nor have we experienced work stoppages. We believe that our relations with our employees are good.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with or furnished to the Securities and Exchange Commission pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website at www.meipharma.com as soon as reasonably practicable after they are electronically filed with, or furnished to, the Securities and Exchange Commission.

Item 1A. Risk Factors

Investment in our securities involves a high degree of risk. You should consider carefully the risks described below, together with other information in this Annual Report and other public filings, before making investment decisions regarding our securities. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. Moreover, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition.

Risks Related to Our Business and Industry

We will need substantial additional funds to progress the clinical trial program for our drug candidates, and to develop new compounds. The actual amount of funds we will need will be determined by a number of factors, some of which are beyond our control.

We will need substantial additional funds to progress the clinical trial program for our drug candidates and to develop any additional compounds. The factors that will determine the actual amount of funds that we will need to progress the clinical trial programs may include, but are not limited to, the following:

- the therapeutic indications for use being developed;
- the clinical trial endpoint required to achieve regulatory approval;
- the number of clinical trials required to achieve regulatory approval;
- the number of sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients who participate in the trials and the rate that they are recruited;
- the number of treatment cycles patients complete while they are enrolled in the trials;
- costs and potential difficulties encountered in manufacturing sufficient drug product for the trials; and
- the efficacy and safety profile of the product.

We have been opportunistic in our efforts to obtain cash, and we expect to continue to evaluate various funding alternatives from time to time. If we obtain additional funding, it may adversely affect the market price of our common stock and may be dilutive to existing stockholders. If we are unable to obtain additional funds on favorable terms or at all, we may be required to cease or reduce our operations. We may sell additional shares of common stock, and securities exercisable for or convertible into shares of our common stock, to satisfy our capital and operating needs; however, such transactions will be subject to market conditions and there can be no assurance any such transactions will be completed.

We are a clinical research and development stage company and are likely to incur operating losses for the foreseeable future.

You should consider our prospects in light of the risks and difficulties frequently encountered by clinical research stage and developmental companies. We have incurred net losses of $277.2 million from our inception through June 30, 2020, including a net loss of $23.1 million for the year ended June 30, 2020 (excluding $22.9 million of non-cash expense resulting from a change in fair value of our warrant liability), a net loss of $44.5 million for the year ended June 30, 2019 (excluding $27.6 million of non-cash income resulting from a change in the fair value of our warrant liability), and a net loss of $30.4 million for the year ended June 30, 2018 (excluding a $9.7 million non-cash expense resulting from a change in the fair value of our warrant liability). We anticipate that we will incur operating losses and negative operating cash flow for the foreseeable future. We have not yet commercialized any drug candidates and cannot be sure that we will ever be able to do so, or that we may ever become profitable.

The outbreak of the novel coronavirus disease, COVID-19, or other pandemic, epidemic or outbreak of an infectious disease may materially and adversely impact our business, including our preclinical studies and clinical trials.

In December 2019, the novel coronavirus disease, COVID-19, was identified in Wuhan, China. This virus has been declared a pandemic and has spread to multiple global regions. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the COVID-19 outbreak, "shelter in place" orders and other public health guidance measures have been implemented across much of the United States, Europe and Asia, including in the locations of our offices, clinical trial sites, key vendors and partners. Although some of such orders have been lifted in certain geographic locations, other areas, including California, where our headquarters is located, have experienced an increase in the number of positive cases of COVID-19 and have re-implemented restrictive public health measures. These restrictions, as well as government restrictions on travel and a lack of public confidence in the safety of air travel and the use of public transportation have reduced and may continue to reduce the willingness of patients to participate in our clinical trials and the ability of regulatory officials to perform visits of our clinical trial locations. A "second wave" of the COVID-19 pandemic could lead to even further restrictions and reduced travel. As a result, our clinical development program timelines have been and may continue to be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. Further, due to "shelter in place" orders and other public health guidance measures, we have implemented a work-from-home policy for all staff members excluding those necessary to maintain minimum basic operations. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business.

As a result of the COVID-19 outbreak, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials, including the potential need to suspend enrollment;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions, due to social distancing measures or state law requirements, or being forced to quarantine;
- diversion of healthcare resources away from the conduct of clinical trials or the closure of clinical trial sites, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- the need to modify, suspend, or terminate clinical trials;
- the need to implement alternative study procedures, including alternative methods for drug candidate delivery and administration, alternative study sites, remote study procedures, and alternative methods to obtain subject informed consent;
- potential noncompliance or deviations from the protocol or regulatory requirements due to necessary safety or public health measures;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines and may limit our ability to interact with agency representatives;
- delays or disruptions in preclinical experiments and investigational new drug application-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations and vendors;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations and other clinical study materials due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on our ability to recruit and hire key personnel due to our inability to meet with candidates because of travel restrictions and "shelter in place" orders;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- interruption or delays to our sourced discovery and clinical activities.

The COVID-19 pandemic and the governmental response continues to rapidly evolve. In light of the COVID-19 outbreak, the FDA has issued a number of new guidance documents. Specifically, as a result of the potential effect of the COVID-19 outbreak on many clinical trial programs in the U.S. and globally, the U.S. FDA issued guidance concerning potential impacts on clinical trial programs, changes that may be necessary to such programs if they proceed, considerations regarding trial suspensions and discontinuations, the potential need to consult with or make submissions to relevant ethics committees, IRBs, and the FDA, the use of alternative drug delivery methods, and considerations with respect the outbreak's impacts on endpoints, data collection, study procedures, and analysis. FDA also issued guidance on additional steps that are required to maintain GMPs during the pandemic. Additionally, in March 2020, the U.S. Congress passed the CARES Act, which includes a number of provisions that are applicable to the pharmaceutical industry.

The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms.

If KKC, Helsinn or other parties with whom we collaborate on the development and commercialization of our drug candidates do not satisfy their obligations, do not otherwise pursue development or commercialization of our drug candidates or if they terminate their agreements with us, we may not be able to develop or commercialize our drug candidates.

In April 2020, we entered into an agreement with KKC to collaborate on the development, manufacturing, and commercialization of zandelisib globally. The agreement substantially retains and consolidates the terms of the 2018 agreement with KKC to develop and commercialize in Japan. In August 2016, we entered into an exclusive license, development and commercialization agreement with Helsinn to collaborate on the global development, manufacturing and commercialization of pracinostat. In July 2020, we announced the discontinuation of the Phase 3 study conducted by Helsinn with respect to the use of pracinostat for the treatment of AML, but patients currently remain enrolled in other pracinostat studies for MDS. We may enter into additional agreements to collaborate with other third parties on the development, manufacturing or commercialization of our drug candidates in the future. In connection with these agreements, we may grant certain rights regarding the use of our patents and technology. The counterparties may be responsible for development, manufacturing or commercialization of our drug candidates and the costs related thereto.

Our counterparties might not fulfill all of their obligations to us. In addition, the agreements with our counterparties provide the counterparties with substantial control of the development and commercialization of our drug candidates and discretion whether to devote resources to the full pursuit thereof. or otherwise fail to fully pursue the development and commercialization of our drug candidates Even without breaching their obligations to us, our counterparties may not devote adequate resources or otherwise pursue the development and commercialization of our drug candidates, whether as a result of their assessment of the likelihood of success of such efforts, for financial reasons or otherwise. In particular, we cannot predict the extent to which Helsinn will continue to pursue the ongoing Phase 2 study of pracinostat for the treatment of MDS. Our ability to receive revenue from our drug candidates may be dependent upon their efforts. If they fail to devote adequate resources or otherwise do not successfully develop, commercialize or manufacture our drug candidates, we may not receive the future milestone payments or royalties provided for in the agreement. In addition, under certain circumstances, including our failure to satisfy our obligations under the agreement, the counterparty may have the right to terminate the agreement.

We could also become involved in disputes with our counterparties, which could lead to delays in or termination of the agreement and time-consuming and expensive litigation or arbitration.

If our counterparties are unwilling or unable to fulfill their obligations or otherwise fail to fully pursue the development and commercialization of our drug candidates or if the agreement is terminated, we may lack sufficient resources to develop and commercialize our drug candidates on our own and may be unable to reach agreement with a suitable alternative collaborator. The failure to develop and commercialize our drug candidates would have a material adverse effect on our business, operating results, prospects and financial condition.

We are subject to significant obligations to Presage in connection with our license of voruciclib, and we may become subject to significant obligations in connection with future licenses we obtain, which could adversely affect the overall profitability of any products we may seek to commercialize, and such licenses of drug candidates, the development and commercialization for which we are solely responsible, may never become profitable.

In September 2017, we entered into a license agreement with Presage ("the Presage License Agreement"). Under the terms of the agreement, Presage granted us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid Presage $2.9 million and are obligated for additional potential payments of up to $181 million upon the achievement of certain development, regulatory and commercial milestones. We will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed pursuant to such agreement. We are also subject to continuing payment obligations to S*Bio in connection with our acquisition of patents and patent applications relating to pracinostat in August 2012. We may enter into similar agreements in the future that require us to make significant payments upon obtainment of development, regulatory or commercial milestones. We may be obligated to make milestone or royalty payments when we do not have the cash on hand to make these payments or have available cash for our other development efforts. These milestone and royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize. In addition, if we fail to comply with our obligations under the license agreement, the counterparty may have the right to terminate the agreement. In such a case, we would lose our rights to the intellectual property covered by the license agreement and we would not be able to develop, manufacture or commercialize our drug candidates.

The profitability of our license agreement with Presage depends on the successful development, regulatory approval and commercialization of voruciclib. We are solely responsible for the development and commercialization of voruciclib, including the related costs. Drug development is a long, expensive and uncertain process and delay or failure can occur at any stage of our clinical trials. We cannot be certain that we will ever receive regulatory approval for voruciclib or that it will be successfully commercialized, even if approved.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Pre-clinical studies and Phase 1 and Phase 2 clinical trials are an expensive and uncertain process that may take years to complete. Pre-clinical studies and Phase 1 and Phase 2 clinical trials are usually not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. Favorable results in early studies or trials may not be repeated in later studies or trials, including ongoing pre-clinical studies, large-scale Phase 3 clinical trials, or other studies intended as registration trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Interim and top-line results, as well as any results from post-hoc data analyses, may also not be predictive of the final results of a clinical study and/or may not support product approval.

In July 2020, we announced the discontinuation of the Phase 3 study conducted by Helsinn with respect to the use of pracinostat for the treatment of AML because of the failure to meet the primary endpoint of the study, despite prior successful results in our earlier Phase 1 and Phase 2 clinical trials. The results of the Phase 3 pracinostat study for the treatment of AML may also impact the interpretation of the results from our pracinostat study for MDS. Moreover, comparisons of results across different studies should be viewed with caution as such comparisons are limited by a number of factors, including differences in study designs and populations. Such comparisons also will not provide a sufficient basis for any comparative claims following product approval. Unfavorable results from ongoing pre-clinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Pre-clinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

Final approval by regulatory authorities of our drug candidates for commercial use may be delayed, limited or prevented, any of which would adversely affect our ability to generate operating revenues.

We will not generate any operating revenue until we, a licensee, or a potential collaborator successfully commercialize one of our drug candidates. Currently, we have drug candidates at different stages of development, and each will need to successfully complete certain clinical studies and obtain regulatory approval before potential commercialization. We may experience unforeseen events during product development that may substantially delay or prevent product approval. For example, the FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to clinical trial patients. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to clinical trial patients, a lack of favorable results, or changing business priorities.

The pre-clinical and clinical development, manufacturing, labeling, packaging, storage, recordkeeping, export, marketing and distribution, and other possible activities relating to our drug candidates are subject to extensive regulation by the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements may, either before or after product approval, subject us to administrative or judicially imposed sanctions that may negatively impact the approval of one or more of our drug candidates or otherwise negatively impact our business.

Neither collaborators, licensees nor we are permitted to market a drug candidate in the United States until the particular drug candidate is approved for marketing by the FDA. Specific pre-clinical data, chemistry, manufacturing and controls data, a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND application, and clinical trials may commence only after the IND application becomes effective. To market a new drug in the United States, we must submit to the FDA and obtain FDA approval of an NDA. An NDA must be supported by extensive clinical and pre-clinical data, as well as extensive information regarding chemistry, manufacturing and controls to demonstrate the safety and effectiveness of the drug candidate.

Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. Regulatory approval of an NDA is not guaranteed. The number and types of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to target and the regulations applicable to any particular drug candidate. Despite the time and expense exerted in pre-clinical and clinical studies, failure can occur at any stage, and we could encounter problems that delay our product candidate development or that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The FDA can delay, limit or deny approval of a drug candidate for many reasons, and product candidate development programs may be delayed or may not be successful for many reasons including but not limited to, the following:

- the FDA or IRBs may not authorize us to commence, amend, or continue clinical studies;
- we may be required to amend our clinical studies in such a way that it compromises the study data or makes the ongoing conduct of the study is impracticable;
- there may be deviations from the clinical study protocol that may result in the need to drop patients from the study, increase the study enrollment size or duration, or that may compromise the reliability of the study and the resulting data;
- we may not be able to enroll a sufficient number of qualified patients for clinical trials in a timely manner or at all, patients may drop out of our clinical trials or be lost to follow-up at a higher rate than we anticipate, patients may not follow the clinical trial procedures, or the number of patients required for clinical trials may be larger than we anticipate;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- a drug candidate may not be deemed adequately safe or effective for an intended use;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development;
- to the extent that we are developing drug candidates for use in combination with other products, clinical trials may be more complex, resulting data may be more difficult to interpret, we may not be able to demonstrate that clinical trial results are attributable to our drug candidate, or developments with respect to the other product or standard of care may impact our ability to obtain product approval for our drug candidate or to successfully market our drug candidate;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA may require that we conduct additional pre-clinical or clinical studies, change our manufacturing process, or gather additional manufacturing information above what we currently have planned for;
- the FDA's interpretation and our interpretation of data from pre-clinical studies and clinical trials may differ significantly;
- the FDA may not agree with our intended indications, the design of our clinical or pre-clinical studies, or there may be a flaw in the design that does not become apparent until the studies are well advanced;
- we may not be able to establish agreements with contractors or collaborators, including clinical trial sites and CROs, or they or we may fail to comply with applicable FDA, protocol, and other regulatory requirements, including those identified in other risk factors;
- the FDA may not approve the manufacturing processes or facilities;
- the FDA may change its approval policies or adopt new laws or regulations and our development program may not meet newly imposed requirements. By example, recently FDA issued guidance on the development of drug products for the treatment cancer, including a draft guidance specifically concerning AML and hematological malignancies;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the filing of a marketing application; or
- the FDA may not accept an NDA or other submission due to, among other reasons, the content or formatting of the submission.

Our pre-clinical and clinical data, other information and procedures relating to a drug candidate may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory authority, or regulatory interpretation of these data and procedures may be unfavorable. Our efforts to take advantage of expedited regulatory pathways for serious or life-threatening illnesses, such as accelerated approval, to secure marketing authorization more quickly may not be successful. Securing accelerated approval requires demonstrating a meaningful therapeutic benefit over available existing treatments. Accelerated approvals are based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. If approved, FDA will require post-marketing studies to verify clinical benefit. Failure to conduct required post-approval studies, or confirm a clinical benefit, will allow the FDA to withdraw the drug from the market on an expedited basis. We plan to seek FDA marketing approval of zandelisib via the accelerated approval pathway, based on the results of our ongoing phase 2 clinical trial. FDA, however, may not agree that the accelerated approval pathway is appropriate, may disagree with our chosen surrogate

endpoints, or may find that the accelerated approval criteria are not met. Should FDA disagree with our approach, we would be required to conduct additional clinical studies prior to submitting an NDA and prior to FDA granting marketing approval. Should we receive accelerated approval for zandelisib, the FDA-approved label will indicate that the clinical benefit of the product has not been established and that continued approval is contingent upon verification of a clinical benefit in confirmatory trials.

Our business and reputation may be harmed by any failure or significant delay in receiving regulatory approval for the sale of any drugs resulting from our drug candidates. As a result, we cannot predict when or whether regulatory approval will be obtained for any drug we develop. Additionally, other factors may serve to delay, limit or prevent the final approval by regulatory authorities of our drug candidates for commercial use, including, but not limited to:

- Zandelisib, voruciclib, ME-344 and pracinostat are in various stages of development, and we or our licensees will need to conduct significant clinical testing and development work to demonstrate the quality, safety, and efficacy of these drug candidates before applications for marketing can be filed with the FDA, or with the regulatory authorities of other countries;
- development and testing of product formulation, including identification of suitable excipients, or chemical additives intended to facilitate delivery of our drug candidates;
- it may take us many years to complete the testing of our drug candidates, and failure can occur at any stage of this process; and
- negative or inconclusive results, statistically or clinically insignificant results, or adverse medical events during a clinical trial could cause us to delay or terminate our development efforts.

Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do. This may prevent us from receiving marketing approvals and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. If we experience delays in obtaining approval, if we fail to obtain approval of a product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate will be materially impaired. Accordingly, the successful development of any of our drug candidates is uncertain and, accordingly, we may never commercialize any of these drug candidates or generate significant revenue.

The FDA may determine that our drug candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our drug candidates could cause us, IRBs, and other reviewing entities or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Undesirable side effects may also result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products. These could prevent us from commercializing and generating revenues from the sale of our drug candidates.

Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects that prevented further development of the compound. In addition, adverse events which had initially been considered unrelated to the study treatment may later be found to be caused by the study treatment. Moreover, incorrect or improper use of our drug candidates could cause unexpected side effects or adverse events. If any of our drug candidates is associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that drug candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects.

If we experience delays or difficulties in the enrolment of patients in clinical trials, our completion of clinical trials and receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue conducting clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Competitors may also have ongoing clinical trials for drug candidates that are intended to treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates. Patient enrollment is affected by other factors including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the existence of current treatments for the indications for which we are conducting clinical trials;

- the eligibility criteria for and design of the clinical trial in question, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- the perceived risks and benefits of the drug candidate, including the potential advantages or disadvantages of the drug candidate being studied in relation to other available therapies;
- competition in recruiting and enrolling patients in clinical trials;
- efforts to facilitate timely enrolment in clinical trials;
- patient referral practices of physicians;
- effectiveness of publicity created by clinical trial sites regarding the trial;
- patients' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the drug candidate;
- an inability to obtain or maintain patient informed consents;
- the risk that enrolled patients will drop out before completion or not return for post-treatment follow-up;
- the ability to monitor patients adequately during and after treatment;
- the ability to compensate patients for their time and effort; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. In particular, there may be low or slow enrollment, and the studies may enroll subjects that do not meet the inclusion criteria, requiring the erroneously enrolled subjects to be excluded and the trial population to be increased. Moreover, patients in our clinical trials may be at risk for dropping out of our studies if they are not experiencing relief of their disease. A significant number of withdrawn patients would compromise the quality of our data.

Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, or the inability to complete development of our drug candidates, which would cause the value of our company to decline, limit our ability to obtain additional financing, and materially impair our ability to generate revenues.

Changes in drug candidate manufacturing or formulation may result in additional costs or delay.

As drug candidates are developed through preclinical studies to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, manufacturing sites, and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification, or FDA approval. Any of the foregoing could limit our future revenues and growth.

Changes in funding for the FDA and other government agencies or future government shutdowns could cause delays in the submission and regulatory review of marketing applications, which could negatively impact our business or prospects.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept submission, applications, and the payment of user fees, and statutory, regulatory, and policy changes. 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, including as a result of the COVID-19 pandemic, may also slow the time necessary for new drugs 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, had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs or if agency operations are otherwise impacted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business or prospects.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.

We intend to have our drug candidates marketed outside the United States. In order to market our products in many non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. To date, we have not filed for marketing approval for any of our drug candidates and may not receive the approvals necessary to commercialize our drug candidates in any market.

The approval procedure varies among countries and may include all of the risks associated with obtaining FDA approval. Further, the time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval, and additional pre-clinical studies, clinical trials, other testing and data review may be required. We may not obtain foreign regulatory approvals on a timely basis, if at all. Additionally, approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could limit commercialization of our products, reduce our ability to generate profits and harm our business.

Any designation granted by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval. We may also not be able to obtain or maintain any such designation.

We currently hold an FDA Fast Track Designation for zandelisib for the treatment of adult patients with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies. Previously, in August 2016, the FDA granted Breakthrough Therapy Designation to pracinostat for the treatment of AML. However, in July 2020, we announced the discontinuation of the Phase 3 clinical trial of pracinostat, conducted by Helsinn, for the treatment of AML. As described in the Government Regulation section of this Annual Report, there are a number of FDA programs that are intended to speed the development of drugs that are intended to treat serious diseases and conditions when there is an unmet need, including Fast Track and Break Through Therapy Designation. Receipt of such designations is within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for a designation, the FDA may disagree. If we receive any designation, the potential reduced timelines associated with designation may introduce significant chemistry, manufacturing and controls challenges for product development as manufacturing development may need to take place at a faster pace than would otherwise be required because the FDA will expect that properly qualified and manufactured product be available at the time of product approval. In any event, the receipt of a designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even after granting a Breakthrough Therapy Designation, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind such designations.

Any orphan drug designations we receive may not confer marketing exclusivity or other benefits.

In the United States, under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition. Such diseases and conditions are those that affect fewer than 200,000 individuals in the United States, or if they affect more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug available in the United States for these types of diseases or conditions will be recovered from sales of the drug. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by that agency. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, but it can lead to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. The EMA also has a program for orphan drugs.

There is no guarantee that a drug candidate will receive orphan drug designation. There is also no guarantee that we would be able to maintain any designations that we receive. For instance, orphan drug designation in the U.S. or EU may be revoked for a number of reasons. If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the drug is entitled to orphan drug marketing exclusivity for a period of seven years. Orphan drug marketing exclusivity generally prevents the FDA from approving another application, including a full NDA, to market the same drug or biological product for the same indication for seven years, except in limited circumstances, including if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. For purposes of small molecule drugs, the FDA defines “same drug” as a drug that contains the same active moiety and is intended for the same use as the drug in question. We may not be able to obtain future orphan drug designations that we may apply for or maintain any orphan drug designations that we may receive. A designated orphan drug also may not receive orphan drug marketing exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation or if it is deemed to be the same drug as a previously approved drug and cannot demonstrate clinical superiority. Similarly, in the EMA, orphan drugs can receive an exclusivity period of ten years, but can be reduced to six years if the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. By example, we received FDA and EMA orphan drug designation for pracinostat for the treatment of AML. However, in July 2020, we announced the discontinuation of the Phase 3 clinical trial of pracinostat, conducted by Helsinn, for the treatment of AML.

Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity also may not protect a product from competition. For instance, the FDA may approve a drug that is the same drug with orphan exclusivity for a different indication or a different drug for the same indication as the orphan product. Even after an orphan product is approved, the FDA can also subsequently approve a product containing the same principal molecular

features for the same condition if the FDA concludes that the latter product is clinically superior. The FDA may further grant orphan designation to multiple sponsors for the same compound or active molecule and for the same indication. If another sponsor receives FDA approval for such product before we do, we would be prevented from launching our product in the United States for the orphan indication for a period of at least seven years unless we can demonstrate clinical superiority.

Even if we or our licensees receive regulatory approval to commercialize our drug candidates, our ability to generate revenues from any resulting products will be subject to a variety of risks, many of which are out of our control.

Even if our drug candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, healthcare payers or the medical community. We believe that the degree of market acceptance and our ability to generate revenues from such products will depend on a number of factors, including, but not limited to, the following:

- timing of market introduction of our drugs and competitive drugs;
- actual and perceived efficacy and safety of our drug candidates;
- prevalence and severity of any side effects;
- potential or perceived advantages or disadvantages over alternative treatments;
- potential post-marketing commitments imposed by regulatory authorities, such as patient registries;
- strength of sales, marketing and distribution support;
- price of our future products, both in absolute terms and relative to alternative treatments;
- the effect of current and future healthcare laws on our drug candidates; and
- availability of coverage and reimbursement from government and other third-party payers.

If any of our drugs are approved and fail to achieve market acceptance, we may not be able to generate significant revenue to achieve or sustain profitability.

If any products we develop become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, our ability to successfully commercialize our products will be impaired.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payers to manage, contain or reduce the costs of health care through various means, such as capping prices, limiting price increases, reducing reimbursement, and requiring rebates. We are also unsure of the impact that the potential repeal of health care reform legislation or other changes in healthcare policy resulting from executive orders or court decisions may have on our business or what actions federal, state, foreign and private payers may take or reforms that may be implemented in the future. Therefore, it is difficult to predict the effect of any potential reform on our business. Our ability to commercialize our drug candidates successfully will depend, in part, on the extent to which reimbursement for the cost of such drug candidates and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective treatment or for which medical care typically is not sought. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payers for use of our products, our products may fail to achieve market acceptance without a substantial reduction in price or at all and our results of operations will be harmed.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills by Congress and the states 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 addition, the United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the United States government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration has released a “Blueprint”, or plan, to reduce the cost of drugs. The current administration’s Blueprint contains certain measures that the U.S. Department of Health and Human Services is already working to implement. The upcoming presidential and congressional elections may lead to changes in the composition of the presidential administration and Congress, resulting in additional policy changes. Individual states in the United States have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical 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.

Our drug candidates are subject to ongoing government regulation both before and after regulatory approval.

Both before and after regulatory approval, our drug candidates are subject to strict and ongoing regulation. Compliance with such regulations may consume substantial financial and management resources and expose us and our collaborators to the potential for other adverse circumstances. For example, a regulatory authority can place restrictions on the sale or marketing of a drug in order to manage the risks identified during initial clinical trials or after the drug is on the market. A regulatory authority can condition the approval for a drug on costly post-marketing follow-up studies. Based on these studies, if a regulatory authority does not believe that the drug demonstrates a clinical benefit to patients or an acceptable safety profile, it could limit the indications for which a drug may be sold or revoke the drug's marketing approval. In addition, identification of certain side effects either during clinical trials or after a drug is on the market may result in reformulation of a drug, additional pre-clinical and clinical trials, labeling changes, termination of ongoing clinical trials or withdrawal of approval. Any of these events could delay or prevent us from generating revenue from the commercialization of these drugs and cause us to incur significant additional costs.

Compliance with the applicable regulatory requirements may result in significant expenses and we and our third-party contractors and collaborators may be subject to unannounced FDA and other regulatory authority inspections. Any failure to comply with the applicable regulatory requirements or problems with our drug candidates may result in regulatory enforcement or other actions, including:

- restrictions on manufacturing or distribution, or marketing of any approved products;
- restrictions on the labeling, including restrictions on the indication or approved patient population, and required additional warnings, such as black box warnings, contraindications, and precautions;
- modifications to promotional pieces or issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or a comparable foreign authority may require that we establish or modify a similar strategy;
- changes to the way the product is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Non-compliance with any foreign jurisdictions' requirements, including requirements regarding the protection of personal information, can also lead to significant penalties and sanctions.

Any of these events could prevent us from achieving or maintaining regulatory product approval and market acceptance of the particular drug candidate, if approved, or could substantially increase the costs and expenses of developing and commercializing such product, which in turn could delay or prevent us from generating significant revenues from its sale.

Other changes may also impact the approvability or marketability of our drug candidates, including changes in law, government regulation, or changes in medical practice or standard of care. If we are slow or unable to adapt to changes in existing requirements, standards of care, 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 be subject to regulatory enforcement action. Should any of the above actions take place, they could adversely affect our ability to achieve or sustain profitability.

We may not be able to establish the contractual arrangements necessary to develop, market and distribute our drug candidates.

A key part of our strategy is to establish contractual relationships with third parties to package, market and distribute our drug candidates. There is no assurance that we will be able to negotiate commercially acceptable licensing or other agreements for the future exploitation of our drug candidates, including continued clinical development, manufacture or marketing. If we are unable to successfully contract for these services, or if arrangements for these services are terminated, we may have to delay our commercialization program which will adversely affect our ability to generate operating revenues.

Our commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than our drug candidates.

The development of drug candidates is highly competitive. A number of other companies have products or drug candidates that have either been approved or are in various stages of pre-clinical or clinical development that are intended for the same therapeutic indications for which our drug candidates are being developed. Some of these potential competing drug candidates are further advanced in development than our drug candidates and may be commercialized sooner. Even if we are successful in developing effective drugs, our compounds may not compete successfully with products produced by our competitors.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies active in different but related fields represent substantial competition for us. Many of our competitors developing oncology drugs have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us and our service providers, to recruit qualified personnel, and with us to attract partners for joint ventures and to license technologies that are competitive with us. As a result, our competitors may be able to more easily develop technologies and products that would render our technologies or our drug candidates obsolete or non-competitive.

We rely on third parties to conduct our clinical trials and pre-clinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a timely manner or at all.

In the course of our pre-clinical testing and clinical trials, we rely on third parties, including laboratories, investigators, clinical contract research organizations (“CROs”), manufacturers, and distributors to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our pre-clinical studies, which are required to be conducted consistent with regulations on Good Laboratory Practice. CROs and study sites are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our pre-clinical and clinical trials, we are responsible for ensuring that each of our trials is conducted in accordance with its investigational plan and protocol and that the integrity of the studies and resulting data is protected. While we have agreements governing the activities of such third parties, we have limited influence and control over their actual performance and activities. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as GCPs, for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not devote sufficient time or resources to our studies, may not comply with all regulatory and contractual requirements, or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with our protocols or the applicable regulatory requirements, our trials may not meet regulatory requirements or may need to be repeated, we may not receive marketing approvals, or we or such third parties may face regulatory enforcement.

Agreements with third parties conducting or otherwise assisting with our clinical or preclinical studies might terminate for a variety of reasons, including a failure to perform by the third parties. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, if we need to enter into alternative arrangements, it could delay our product development activities and adversely affect our business. Though we carefully manage our relationships with our third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects, and results of operations.

Accordingly, as a result of our dependence on third parties, we may face delays, failures or cost increases outside of our direct control. These risks also apply to the development activities of collaborators, and we do not control their research and development, clinical trial or regulatory activities.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We also cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with drug candidates that were produced under cGMP conditions. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

We will depend on third party suppliers and contract manufacturers for the manufacturing of our drug candidates and have no direct control over the cost of manufacturing our drug candidates. Increases in the cost of manufacturing our drug candidates would increase our costs of conducting clinical trials and could adversely affect our future profitability.

We do not intend to manufacture our drug candidates ourselves, and we will rely on third parties for our drug supplies both for clinical trials and for commercial quantities in the future. We have taken the strategic decision not to manufacture active pharmaceutical ingredients ("API") for our drug candidates, as these can be more economically supplied by third parties with particular expertise in this area. We have identified contract facilities that are registered with the FDA, have a track record of large- scale API manufacture, and have already invested in capital and equipment. We have no direct control over the manufacturing of our drug candidates, or the cost thereof. If the contract manufacturers are unable to produce sufficient quantities of our drug candidates, as a result of a lack of available materials or otherwise, our ability to complete product candidate development and our future profitability would be adversely affected. If the cost of manufacturing increases, or if the cost of the materials used increases, these costs will be passed on to us, making the cost of conducting clinical trials more expensive. Increases in manufacturing costs could adversely affect our future profitability if we are unable to pass all of the increased costs along to our customers.

If these third-party manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture our drug candidates in accordance with regulatory requirements, if there are disagreements between us and such parties, or if such parties are unable to expand capacities to support commercialization of any of our drug candidates for which we obtain marketing approval, we may not be able to produce, or may be delayed in producing sufficient drug candidates to meet our supply requirements. Any delays in obtaining adequate supplies with respect to our drug candidates and components may delay the development or commercialization of our drug candidates.

Further, we, along with our contract manufacturers, are required to comply with FDA requirements for cGMPs, related to product testing, quality assurance, manufacturing and documentation. Our contract manufacturers may not be able to comply with the applicable FDA regulatory requirements, which could result in delays to our product development programs, could result in adverse regulatory actions against them or us, and could prevent us from ultimately receiving product marketing approval. They also generally must pass an FDA preapproval inspection for conformity with cGMPs before we can obtain approval to manufacture our drug candidates and will be subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other applicable government regulations and corresponding foreign standards. If we and our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP, we may experience manufacturing errors resulting in defective products that could be harmful to patients, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, clinical trial or other development program delays, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business. Not complying with FDA requirements could result in a product recall, costly and time-consuming corrective or preventative actions, or prevent commercialization of our drug candidates and delay our business development activities. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter or take other regulatory or legal enforcement action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, and potentially civil and/or criminal penalties depending on the matter.

If we need to replace any of our manufacturers or establish additional manufacturing arrangements, we may not succeed in our efforts. Our drug candidates may compete with other products and drug candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that are both capable of manufacturing for us and willing to do so. If our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product or component for commercial sale or for our clinical trials should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our drug candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. These third-party facilities may also be affected by natural disasters, such as floods or fire, or such facilities could face manufacturing issues, such as contamination or regulatory findings following a regulatory inspection of such facility. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay and

increased expense. The addition of a new or alternative manufacturer may also require FDA approvals and may have a material adverse effect on our business.

We or our third-party manufacturers may also encounter shortages in the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to produce our drug candidates in the quantities needed for our clinical trials or, if our drug candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by our competitors or others. Our or our third-party manufacturers' failure to obtain the raw materials, therapeutic substances, or active pharmaceutical ingredients necessary to manufacture sufficient quantities of our drug candidates may have a material adverse effect on our business. If for any reason we are unable to obtain adequate supplies of our drug candidates or the components used to manufacture them, it will be more difficult for us to develop our drug candidates and compete effectively.

Our business strategy may include entry into additional collaborative or license agreements. We may not be able to enter into collaborative or license agreements or may not be able to negotiate commercially acceptable terms for these agreements.

Our current business strategy may include the entry into additional collaborative or license agreements for the development and commercialization of our drug and drug candidates. The negotiation and consummation of these types of agreements typically involve simultaneous discussions with multiple potential collaborators or licensees and require significant time and resources. In addition, in attracting the attention of pharmaceutical and biotechnology company collaborators or licensees, we compete with numerous other third parties with product opportunities as well as the collaborators' or licensees' own internal product opportunities. We may not be able to consummate collaborative or license agreements, or we may not be able to negotiate commercially acceptable terms for these agreements.

If we do enter into such arrangements, we could be dependent upon the subsequent success of these other parties in performing their respective responsibilities and the cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to researching our product candidates pursuant to our collaborative agreements with them or whether our collaborators will comply with the applicable regulatory requirements. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us.

Under agreements with any collaborators or licensees we may work with in the future, we may rely significantly on them to, among other activities:

- fund research and development activities with us;
- pay us fees upon the achievement of milestones; and
- market for or with us any commercial products that result from our collaborations.

If we do not consummate collaborative or license agreements, we may use our financial resources more rapidly on our drug development efforts, continue to defer certain development activities or forego the exploitation of certain geographic territories, any of which could have a material adverse effect on our business prospects. Further, we may not be successful in overseeing any such collaborative arrangements. If we fail to establish and maintain necessary collaborative or license relationships, our business prospects could suffer.

Collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner, or at all. If any collaborations we might enter into do not result in the successful development and commercialization of drug candidates or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under the agreements, our development of our drug candidates could be delayed, and we may need additional resources to develop our drug candidates and our product platform. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of our collaborators.

We rely on acquisitions or licenses from third parties to expand our pipeline of drug candidates.

We are not presently engaged in drug discovery activities. In order to expand our pipeline of drug candidates for future development, we may need to purchase or in-license any such drug candidates. The success of this strategy depends in large part on the combination of our regulatory and development capabilities and expertise and our ability to identify, select and acquire or in-license clinically-enabled product candidates on terms that are acceptable to us. Identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical expertise, and we have limited experience in identifying and integrating any acquired product candidates into our current infrastructure. Efforts to do so may not result in the actual acquisition or in-license of a particular drug candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to identify, select and acquire or license suitable product candidates from third parties on terms acceptable to us, our business and prospects may be limited.

We face a risk of product liability claims and claims may exceed our insurance limits.

Our business exposes us to the risk of product liability claims. This risk is inherent in the manufacturing, testing and marketing of human therapeutic products. Moreover, regardless of merit or eventual outcome, liability claims can have other adverse consequences, including:

- loss of revenue from decreased demand for our products and/or drug candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our drug candidates;
- significant negative media attention;
- decrease in our stock price; or
- initiation of investigations, and enforcement actions by regulators; and product recalls, withdrawals, revocation of approvals, or labeling, marketing or promotional restrictions.

Our product liability insurance coverage is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities, or claims may exceed our insurance limits. If we cannot or do not sufficiently insure against potential product liability claims, we may be exposed to significant liabilities, which may materially and adversely affect our business development and commercialization efforts.

Our employees, independent contractors, consultants, commercial partners, principal investigators, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, manufacturers, investigators, or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, comply with federal procurement rules or contract terms, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation 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 this type of misconduct, 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 or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act, ("FCA"), case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. Further, due to the risk that a judgment in an FCA case could result in exclusion from federal health programs or debarment from government contracts, whistleblower cases often result in large settlements. 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, financial condition, and results of operations, including the imposition of significant fines or other sanctions.

Our business and operations would suffer in the event of system failures.

Our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug candidate development and, if such drug candidates are approved commercialization programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and regulatory enforcement actions, and the further development of any of our drug candidates could be delayed.

Our efforts will be seriously jeopardized if we are unable to retain and attract key employees.

Our success depends on the continued contributions of our principal management, development and scientific personnel. We face competition for such personnel, and we believe that risks and uncertainties related to our business, including the timing and risk associated with research and development, our available and anticipated cash resources, and the volatility of our stock price, may

impact our ability to hire and retain key and other personnel. The loss of services of our Chief Executive Officer or other key employees could adversely impact our operations and ability to generate or raise additional capital.

Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators.

Negative conditions in the U.S. or global economy, including financial markets, may adversely affect our business and the business of current and prospective vendors, licensees and collaborators, and others with whom we do or may conduct business. The duration and severity of these conditions is uncertain. If negative economic conditions occur, we may be unable to secure funding on terms satisfactory to us to sustain our operations or to find suitable collaborators to advance our internal programs, even if we achieve positive results from our drug development programs.

Laws, rules and regulations relating to public companies may be costly and impact our ability to attract and retain directors and executive officers.

Laws and regulations affecting public companies, including rules adopted by the Securities and Exchange Commission ("SEC") and by the National Association of Securities Dealers Automated Quotations ("NASDAQ"), may result in increased costs to us. These laws, rules and regulations could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We cannot estimate accurately the amount or timing of additional costs we may incur to respond to these laws, rules and regulations.

If we fail to establish and maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our operating results, our ability to operate our business, and our stock price, and could result in litigation or similar actions.

Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause the trading price of our common stock to fall dramatically. Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the company will be detected.

We cannot be certain that the actions we have taken to ensure we have adequate internal controls over financial reporting will be sufficient. In future periods, if the process required by Section 404 of the Sarbanes-Oxley Act reveals any material weaknesses or significant deficiencies, the correction of any such material weaknesses or significant deficiencies could require remedial measures which could be costly and time-consuming. In addition, in such a case, we may be unable to produce accurate financial statements on a timely basis. Any associated accounting restatement could create a significant strain on our internal resources and cause delays in our release of quarterly or annual financial results and the filing of related reports, increase our costs and cause management distraction. Any of the foregoing could cause investors to lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information of clinical trial participants and employees. Similarly, our third-party providers possess certain of our sensitive protected health data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated, and such systems, controls and processes may not be successful in preventing a breach. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including compliance with the Health Insurance Portability and Accountability Act of 1996 and recently enacted laws in a majority of states requiring security breach notification. The collection and use of personal health data of individuals in the European Union is also governed by strict data protection laws. In addition to existing laws, since May 25, 2018, the General Data Protection Regulation ("GDPR") has imposed new obligations with respect to European Union data and substantial fines for breaches of the data protection rules. It will increase our responsibility and potential liability in relation to personal data that we process, and we will be required to put in place additional mechanisms ensuring compliance with the new European Union data protection rules. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the European Union, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, operating results, prospects and financial condition.

We are in the process of assessing the "Schrems II" decision issued by the Court of Justice of the European Union on July 16, 2020, and its impact on our data transfer mechanisms. The Court invalidated the EU-U.S. Privacy Shield Framework as a legal basis for the transfer of personal data from the European Economic Area ("EEA") member states or the U.K. to the U.S. The Court also expressed uncertainty under which conditions data importers and exporters could use the EC's Standard Contractual Clauses option under the GDPR as a method for transferring personal data outside of the EEA. Present solutions to legitimize transfers of personal data from the EEA may be challenged or deemed insufficient. We may, in addition to other impacts, experience additional costs associated with increased compliance burdens, and we and our customers face the potential for regulators in the EEA or U.K. to apply different standards to the transfer of personal data from the EEA/ U.K. to the U.S., and to block, or require ad hoc verification of measures taken with respect to, certain data flows from the EEA or U.K. to the U.S. We also may be required to engage in new contract negotiations with third parties that aid in processing data on our behalf. We may experience reluctance or refusal by current or prospective European clinical trial sites and CROs to use our products, and we may find it necessary or desirable to make further changes to our processing of personal data of EEA or U.K. data subjects.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act ("CCPA"), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Since January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. The CCPA may significantly impact our business activities and require substantial compliance costs that adversely affect business, operating results, prospects and financial condition.

Thus, any access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations and damage our reputation, which could adversely affect our business.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

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

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

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

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Events outside of our control, including natural disasters and public health emergencies, could severely disrupt our operations and have a material adverse effect on our business, operating results, prospects or financial condition. If a natural disaster, or public health emergency such as COVID-19, power outage or other event occurred that prevented us from conducting our clinical trials, including by damaging our critical infrastructure, such as third-party facilities, or that otherwise disrupted operations and travel, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and

business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business, operating results, prospects or financial condition.

Limitations on the deductibility of net operating losses could adversely affect our business and financial condition.

We have a history of net operating losses. In December 2017, the U.S government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act limits the deduction of net operating losses to 80% of current year taxable income, however, as a result of the CARES Act, the 80% limitation was temporarily repealed until our fiscal year ending June 30, 2021. The limitations on the net operating loss deduction, as well other changes in tax policy, may subject us to additional taxation, adversely affecting our results of operations and financial condition.

Risks Relating to Our Intellectual Property

Our commercial success is dependent, in part, on obtaining and maintaining patent protection and preserving trade secrets, which cannot be guaranteed.

Patent protection and trade secret protection are important to our business and our future will depend, in part on our ability to maintain trade secret protection, obtain patents and operate without infringing the proprietary rights of others both in the United States and abroad. Litigation or other legal proceedings may be necessary to defend against claims of infringement, to enforce our patents or to protect our trade secrets. Such litigation could result in substantial costs and diversion of our management's attention.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. In August 2012, we acquired patents and patent applications related to pracinostat from S*Bio. In September 2013, we acquired patents and patent applications related to zandelisib from Pathway Therapeutics, Inc. In September 2017, we acquired patents and patent applications related to voruciclib from Presage. In 2011 we acquired both issued patents and pending patent applications related to ME-344 from Novogen in relation to our Isoflavone-based compounds, which we previously licensed from Novogen. Additionally, Novogen had previously applied for patents in a number of countries with respect to the use of their isoflavone compounds, including ME-344. The patent applications may not proceed to grant or may be amended to reduce the scope of protection of any patent granted. The applications and patents may also be opposed or challenged by third parties. Our commercial success will depend, in part, on our ability to obtain and maintain effective patent protection for our compounds and their use in treating, preventing, or curing cancer, and to successfully defend patent rights in those technologies against third-party challenges. As patent applications in the United States are maintained in secrecy until published or issued and as publication of discoveries in the scientific or patent literature often lag behind the actual discoveries, we cannot be certain that we or Presage were the first to make the inventions covered by the pending patent applications or issued patents referred to above or that we or they were the first to file patent applications for such inventions. Additionally, the breadth of claims allowed in biotechnology and pharmaceutical patents or their enforceability cannot be predicted. We cannot be sure that, should any patents issue, we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that should patents issue, they will be of commercial value to us, or that private parties, including competitors, will not successfully challenge our patents or circumvent our patent position in the United States or abroad.

Claims by other companies that we infringe on their proprietary technology may result in liability for damages or stop our development and commercialization efforts.

The pharmaceutical industry is highly competitive, and patents have been applied for by, and issued to, other parties relating to products competitive with the compounds that we have acquired. Therefore, zandelisib, voruciclib, ME-344 and pracinostat, and any other drug candidates, may give rise to claims that they infringe the patents or proprietary rights of other parties existing now and in the future.

Furthermore, to the extent that we or our consultants or research collaborators use intellectual property owned by others in work performed for us, disputes may also arise as to the rights in such intellectual property or in resulting know-how and inventions. An adverse claim could subject us to significant liabilities to such other parties and/or require disputed rights to be licensed from such other parties.

We have contracted formulation development and manufacturing process development work for our product candidates. This process has identified a number of excipients, or additives to improve drug delivery, which may be used in the formulations. Excipients, among other things, perform the function of a carrier of the active drug ingredient. Some of these identified excipients or carriers may be included in third party patents in some countries. We intend to seek a license if we decide to use a patented excipient in the marketed product or we may choose one of those excipients that does not have a license requirement.

We cannot be sure that any license required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions, or may find that the development, manufacture or sale of products requiring such licenses may be precluded.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and the employees of Helsinn, KKC and third parties upon which we rely to conduct our clinical trials were previously employed at universities or at other biotechnology or pharmaceutical companies, some of which may be competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

We may be subject to substantial costs stemming from our defense against third-party intellectual property infringement claims.

Third parties may assert that we are using their proprietary information without authorization. Third parties may also have or obtain patents and may claim that technologies licensed to or used by us infringe their patents. If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is not adverse to us. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability and require us or any third party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms or at all.

Risks Related to Securities Markets and Investment in our Stock

The trading price of the shares of our common stock has been and may continue to be highly volatile and could decline in value and we may incur significant costs from class action litigation.

The trading price of our common stock could be highly volatile in response to various factors, many of which are beyond our control, including, but not limited to, the following:

- failure to successfully develop our drug candidates;
- design, results and timing of clinical trials and pre-clinical studies;
- announcements of technological innovations by us or our competitors;
- new products introduced or announced by us or our competitors;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in operating results;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology, pharmaceutical and genomics industries;
- instability in the stock market as a result of current or future domestic and global events;
- changes in the market valuations of similar companies;
- the liquidity of any market for our securities; and
- threatened or actual delisting of our common stock from a national stock exchange.

Equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the U.S., the Europe or globally, particularly in the context of current global events, could impact upon our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or our results of operations. These broad market and industry factors may materially affect the market price of shares of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources.

Future sales of our common stock, including common stock issued upon exercise of outstanding warrants or options, may depress the market price of our common stock and cause stockholders to experience dilution.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, including upon exercise of outstanding warrants or stock options, and any subsequent sales of such shares. As of June 30, 2020, we had outstanding warrants issued in our May 2018 private placement exercisable to purchase 16,061,602 shares of common stock at an exercise price of $2.54 per share, which expire in May 2023. We also had outstanding options to purchase 11,252,976 shares of common stock. We may seek additional capital through one or more additional equity transactions in the future; however, such transactions will be subject to market conditions and there can be no assurance any such transactions will be completed. If we sell shares in the future, the prices at which we sell these future shares will vary, and these variations may be significant. Stockholders will experience significant dilution if we sell these future shares at prices significantly below the price at which such previous stockholders invested.

Because we do not intend to pay, and have not paid, any cash dividends on our shares of common stock, our stockholders will not be able to receive a return on their shares unless the value of our common stock appreciates and they sell their shares.

We have never paid or declared any cash dividends on our common stock, and we intend to retain any future earnings to finance the development and expansion of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Therefore, our stockholders will not be able to receive a return on their investment unless the value of our common stock appreciates and they sell their shares.

We will have broad discretion over the use of the net proceeds from any exercise of outstanding warrants and options.

We will have broad discretion to use the net proceeds to us upon any exercise of outstanding warrants and options, and investors in our stock will be relying on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use a substantial portion of the net proceeds from any exercise of the warrants and options for general corporate purposes and progression of our clinical trial programs, we have not allocated these net proceeds for specific purposes.

We are authorized to issue blank check preferred stock, which could adversely affect the holders of our common stock.

Our amended and restated certificate of incorporation allows us to issue blank check preferred stock with rights potentially senior to those of our common stock without any further vote or action by the holders of our common stock. The issuance of a class of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our shares, or making a change in control of the Company more difficult.

Anti-takeover provisions contained in our amended and restated certificate of incorporation and third amended and restated bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our amended and restated certificate of incorporation and third amended and restated bylaws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions include:

- a staggered board providing for three classes of directors, which limits the ability of a stockholder or group to gain control of our board;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the right of our board to elect a director to fill a vacancy created by the expansion of our board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on our board; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board or to propose matters to be acted upon at a meeting of stockholders, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Our third amended and restated bylaws require, to the fullest extent permitted by law, that derivative actions brought in our name, actions against our directors, officers, other employees or stockholders for breach of fiduciary duty and other similar actions may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, which may have the effect of discouraging lawsuits against our directors, officers, other employees or stockholders.

Our third amended and restated bylaws provide that, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for any stockholder to bring (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company's stockholders, (iii) any action asserting a claim against the Company, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any action asserting a claim against the Company, its directors, officers or employees governed by the internal affairs doctrine, and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel, provided, however, that, in each case, if the Court of Chancery does not have jurisdiction, the forum for such action shall be another state court located within the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware, in all cases subject to the court having personal jurisdiction over the indispensable parties named as defendants therein.

Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Company shall be deemed to have notice of and consented to such provisions.

Notwithstanding the foregoing, the forum selection provision of our third amended and restated bylaws will not apply to suits brought to enforce any liability or duty created by the federal securities laws or any other claim for which the federal district courts of the United States of America shall be the sole and exclusive forum.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our third amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Our executive officers and directors may sell shares of their stock, and these sales could adversely affect our stock price.

Sales of our stock by our executive officers and directors, or the perception that such sales may occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future, either as part, or outside, of trading plans under Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We have leased approximately 32,800 square feet of office space in San Diego, California. The contractual lease term begins in July 2020 and will expire in March 2028. The average annual lease payments over the term of the lease will approximate $1.5 million, plus a pro rata share of certain building expenses. Our total contractual obligation over the term of the lease is approximately $11.5 million.

Item 3. Legal Proceedings

On August 10, 2020, an individual who allegedly purchased 50 shares of our common stock filed a putative securities class action lawsuit in the United States District Court for the Southern District of California against the Company, Daniel P. Gold, and Brian G. Drazba, asserting claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder. The plaintiff seeks to sue on behalf of all purchasers of our securities from August 2, 2017 through July 1, 2020 and alleges, among other things, that we made false and misleading statements relating to pracinostat during the proposed class period. We believe that the claims are without merit, as to both the facts and the law, and intend to vigorously defend the case.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Our common stock is listed on the NASDAQ Capital Market under the symbol "MEIP".

Holders

As of September 4, 2020, there were 112,522,001 shares of our common stock outstanding and 694 holders of record of our common stock. This number was derived from our stockholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

For a discussion of outstanding warrants and other securities exercisable for or convertible into shares of our common stock, see Notes 8 and 9 under Item 8 in this Annual Report.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain all available funds and future earnings, if any, to support operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Securities authorized for issuance under equity compensation plans

The table below shows, as of June 30, 2020, information for equity compensation plans previously approved by stockholders and for compensation plans not previously approved by stockholders.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	11,252,976	$ 2.81	6,437,150
Equity compensation plans not approved by security holders	—	—	—
Total	11,252,976	$ 2.81	6,437,150

(1) Consists of 11,252,976 shares of common stock issuable upon exercise of options granted under the MEI Pharma, Inc. Amended and Restated 2008 Stock Omnibus Equity Compensation Plan ("the Plan"), under which 19,089,794 shares of common stock are authorized for issuance. The Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, employees and advisors. The weighted-average exercise price presented is the weighted-average exercise price of vested and unvested options.

Item 6. Selected Financial Data

The following Selected Financial Data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data" included below in this Annual Report. The following table presents our selected historical condensed financial data. The condensed statements of operations data for fiscal years ended June 30, 2020, 2019 and 2018 and the condensed balance sheet data as of June 30, 2020 and 2019 are derived from our audited financial statements included elsewhere in this Annual Report. The condensed statements of operations data for the fiscal years ended June 30, 2017 and 2016 and the condensed balance sheet data as of June 30, 2018, 2017 and 2016 are derived from our audited financial statements that are not included in this Annual Report.

	Years Ended June 30,				
	2020	2019	2018	2017	2016
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 28,913	$ 4,915	$ 1,622	$ 23,249	$ —
Operating expenses:					
Cost of revenue	2,671	4,263	3,383	5,000	—
Research and development	34,065	32,300	17,038	7,237	13,403
General and administrative	16,717	14,597	9,787	8,628	7,601
Total operating expenses	53,453	51,160	30,208	20,865	21,004
Income (loss) from operations	(24,540)	(46,245)	(28,586)	2,384	(21,004)
Change in fair value of warrant liability	(22,870)	27,632	(9,705)	—	—
Financing costs associated with warrants	—	—	(2,367)	—	—
Other income and expense, net	1,394	1,794	590	286	142
Net income (loss)	$ (46,016)	$ (16,819)	$ (40,068)	$ 2,670	$ (20,862)
Net income (loss):					
Basic	$ (46,016)	$ (16,819)	$ (40,068)	$ 2,670	$ (20,862)
Diluted	$ (46,016)	$ (54,613)	$ (40,068)	$ 2,670	$ (20,862)
Net income (loss) per share					
Basic	$ (0.51)	$ (0.24)	$ (0.97)	$ 0.07	$ (0.61)
Diluted	$ (0.51)	$ (0.75)	$ (0.97)	$ 0.07	$ (0.61)
Shares used to calculate net income (loss) per share					
Basic	91,080	71,139	41,431	36,813	34,400
Diluted	91,080	72,385	41,431	36,938	34,400

	As of June 30,				
	2020	2019	2018	2017	2016
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents, short-term investments, and common stock proceeds receivable	$ 182,630	$ 79,763	$ 102,743	$ 53,565	$ 45,918
Receivable for foreign tax withholding	$ 20,420	$ —	$ —	$ —	$ —
Total assets	$ 209,728	$ 82,663	$ 104,657	$ 55,704	$ 47,164
Deferred revenue, current	$ 14,777	$ 4,955	$ 788	$ 996	$ —
Deferred revenue, long-term	$ 67,723	$ 2,819	$ —	$ —	$ —
Warrant liability	$ 40,483	$ 17,613	$ 46,313	$ —	$ —
Total liabilities	$ 131,510	$ 34,733	$ 54,198	$ 4,866	$ 5,512
Accumulated deficit	$277,234	$231,218	$214,399	$174,331	$177,001
Total stockholders' equity	$ 78,218	$ 47,930	$ 50,459	$ 50,838	$ 41,652

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

The following discussion and analysis should be read in conjunction with "Item 8. Financial Statements and Supplementary Data" included below in this Annual Report. Operating results are not necessarily indicative of results that may occur in future periods.

This discussion and analysis contains forward-looking statements that involve a number of risks, uncertainties and assumptions. Actual results may differ materially from those anticipated in the forward-looking statements as a result of many factors including, but not limited to, those set forth under "Cautionary Statement About Forward-Looking Statements" and "Risk Factors" in Item 1A. included above in this Annual Report. All forward-looking statements included in this Annual Report are based on the information available to us as of the time we file this Annual Report, and except as required by law, we undertake no obligation to update publicly or revise any forward-looking statements.

Overview

We are a late-stage pharmaceutical company focused on leveraging our extensive development and oncology expertise to identify and advance new therapies intended to meaningfully improve the treatment of cancer. Our portfolio of drug candidates contains four clinical-stage candidates, including zandelisib, currently in an ongoing Phase 2 clinical trial that we intend to submit to the FDA to support accelerated approval of a marketing application. Our common stock is listed on the NASDAQ Capital Market under the symbol "MEIP."

Clinical Development Programs

Our approach to building our pipeline is to license promising cancer agents and build value in programs through development, commercialization and strategic partnerships, as appropriate. Our drug candidate pipeline includes:

- Zandelisib, an oral PI3K delta inhibitor;
- Voruciclib, an oral CDK inhibitor;
- ME-344, a mitochondrial inhibitor targeting the OXPHOS complex; and
- Pracinostat, an oral HDAC inhibitor.

Recent Developments

In April 2020, we entered a License, Development and Commercialization Agreement with KKC (the "KKC Commercialization Agreement"). We granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S., and an exclusive (subject to certain retained rights to perform obligations under the Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the United States (the "Ex-U.S."). KKC grants to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. The KKC Commercialization Agreement substantially retains and consolidates the terms of the 2018 license agreement with KKC to develop and commercialize zandelisib in Japan.

KKC will be responsible for the development and commercialization of zandelisib in the Ex-US and, subject to certain exceptions, will be solely responsible for all costs related thereto. We and KKC will co-develop and co-promote zandelisib in the U.S., with us recording all revenue from U.S. sales. We and KKC will share U.S. profits and costs (including development costs) on a 50-50 basis. We will also provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S. pursuant to supply agreements to be entered into on customary terms, with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S as soon as practicable.

Under the terms of the KKC Commercialization Agreement, KKC paid us an upfront payment of $100 million in May 2020. Of the $100 million paid by KKC, $20.4 million was remitted to the Japanese taxing authorities as a result of the U.S. Internal Revenue Service being closed due to the COVID pandemic, and therefore being unable to provide necessary documentation to support an exemption from the required foreign withholding. We may also earn up to approximately $582.5 million in potential development, regulatory and commercialization milestone payments, plus royalties on net sales of zandelisib in the Ex-U.S., which are tiered beginning in the teens.

A Phase 3 study evaluating pracinostat in combination with azacitidine in patients with AML who are unfit to receive standard intensive chemotherapy was discontinued by Helsinn in July 2020 after an interim futility analysis undertaken by the study Independent Data Monitoring Committee demonstrated it was unlikely to meet the primary endpoint of overall survival compared to the control group. Following the discontinuation of the Phase 3 AML study, Helsinn communicated to us their plan to continue therapy and observation of the patients currently in the Phase 2 MDS study and that further development of pracinostat, including for the treatment of MDS, is under review.

For a more complete discussion of our business, see the section of this Annual Report "Item 1- Business" above.

Equity Transactions

Underwritten Registered Offering

In December 2019, we completed an underwritten registered offering of 32,343,750 shares of common stock at a price per share of $1.60. We received net cash proceeds of $48.5 million associated with the offering, after costs of $3.3 million.

At-The-Market Equity Offering

In November 2017, we entered into an At-The-Market Equity Offering Sales Agreement (the "ATM Sales Agreement"), pursuant to which we may sell an aggregate of up to $30.0 million of our common stock pursuant to the shelf registration statement. During the year ended June 30, 2020, we sold 5,471,684 shares under the ATM Sales Agreement for net proceeds of $20.7 million.

Shelf Registration Statement

We have a shelf registration statement that permits us to sell, from time to time, up to $200.0 million of common stock, preferred stock and warrants. The shelf registration was filed and declared effective in May 2020, replacing our prior shelf registration statement that was filed and declared effective in May 2017, and carrying forward approximately $107.5 million of unsold securities registered under the prior shelf registration statement. Shares sold in the underwritten registered offering in December 2019 were sold under the prior shelf registration statement. Shares sold under the ATM Sales Agreement prior to and after May 2020 were issued pursuant to the prior shelf registration statement and shelf registration statement, respectively. As of June 30, 2020, there is $178.9 million aggregate value of securities available under the shelf registration statement, including up to $3.2 million remaining available under the ATM Sales Agreement.

May 2018 Private Placement

In May 2018, we sold 33,003,296 shares of our common stock, together with warrants to purchase 16,501,645 shares of common stock, in a private offering for approximately $70.2 million, after deducting offering costs.

Critical Accounting Policies and Management Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

ASC Topic 606, Revenue from Contracts with Customers ("Topic 606" or the "new revenue standard")

Beginning July 1, 2018, we recognize revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. For enforceable contracts with our customers, we first identify the distinct performance obligations – or accounting units – within the contract. Performance obligations are commitments in a contract to transfer a distinct good or service to the customer.

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, cost reimbursements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. At the inception of arrangements that include variable consideration, we use judgment to estimate the amount of variable consideration to include in the transaction price using the most likely method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not included in the transaction price until those approvals are received. At the end of each reporting period, we re-evaluate estimated variable consideration included in the transaction price and any related constraint and, as necessary, we adjust our estimate of the overall transaction price. Any adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. For the year ended June 30, 2020, we recorded a cumulative catch-up adjustment of $3.1 million related to a partially satisfied performance obligation as a result of the termination of the October 2018 license agreement with KKC to develop and commercialize zandelisib in Japan ("KKC Japan License Agreement") and execution of the KKC Commercialization Agreement (see Note 2 in our audited financial statements). The KKC Commercialization Agreement substantially retains and consolidates the terms of the 2018 license agreement with KKC to develop and commercialize zandelisib in Japan.

We develop estimates of the stand-alone selling price for each distinct performance obligation. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We develop assumptions that require judgment to determine the stand-alone selling price for license-related performance obligations, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. We estimate stand-alone selling price for

research and development performance obligations by forecasting the expected costs of satisfying a performance obligation plus an appropriate margin.

In the case of a license that is a distinct performance obligation, we recognize revenue allocated to the license from non-refundable, up-front fees at the point in time when the license is transferred to the licensee and the licensee can use and benefit from the license. For licenses that are bundled with other distinct or combined obligations, we use judgment to assess the nature of the performance obligation to determine whether the 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. If the performance obligation is satisfied over time, we evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally as costs are incurred. We generally use the cost-to-cost measure of progress because it best depicts the transfer of control to the customer which occurs as we incur costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation (an "input method" under Topic 606). We use judgment to estimate the total cost expected to complete the research and development performance obligations, which include subcontractors' costs, labor, materials, other direct costs and an allocation of indirect costs. We evaluate these cost estimates and the progress each reporting period and, as necessary, we adjust the measure of progress and related revenue recognition.

For arrangements that include sales-based or usage-based royalties, 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 sales-based royalty revenue from license agreements.

We recognized revenue associated with the following license agreements (in thousands):

	Years Ended June 30,		
	2020	2019	2018
KKC Agreements	$27,543	$2,557	$ —
Helsinn License Agreement	1,370	2,358	1,622
	$28,913	$4,915	$1,622
Timing of Revenue Recognition:			
License transferred at a point in time	$20,988	$ 879	$ —
Services performed over time	4,860	4,036	1,622
Cumulative catch-up adjustment	3,065	—	—
	$28,913	$4,915	$1,622

Based on the characteristics of the KKC Agreements (Note 2), delivery of the Ex-US license and Japan license are distinct performance obligations, and we recognized related revenue of $21.0 million and $0.9 million during the years ended June 30, 2020 and June 30, 2019, respectively, when the licenses were transferred to the licensee and the licensee could use and benefit from the licenses. We account for any partially unsatisfied performance obligations carried forward into the new agreement as the continuation of the previous contract, and we recorded a cumulative catch-up adjustment of $3.1 million to revenue during the year ended June 30, 2020 as a result of the termination of the KKC Japan License Agreement and execution of the KKC Commercialization Agreement.

The KKC Commercialization Agreement and KKC Japan License Agreement included other distinct performance obligations satisfied over time, and accordingly we recognized $6.6 million, inclusive of cumulative catch-up amounts, and $1.7 million related to our progress toward satisfying those obligations during the years ended June 30, 2020 and June 30, 2019, respectively.

Based on the characteristics of the Helsinn License Agreement (Note 4), control of the remaining deliverables occurs and therefore we recognize revenue based on the extent of progress towards completion of the performance obligations. Accordingly we recognized $1.4 million and $2.3 million related to our progress toward satisfying those obligations during the years ended June 30, 2020 and 2019, respectively.

As of June 30, 2020, we had $82.5 million of deferred revenue associated with our remaining performance obligations under the KKC and Helsinn license agreements. We expect to recognize approximately $14.8 million of deferred revenue in the next 12 months, and an additional $67.7 million thereafter.

Contract Balances

Receivables and contract assets are included in our balance sheet in "Prepaid expenses and other current assets", and contract liabilities are included in "Deferred revenue" and "Deferred revenue long-term". The following table presents changes in contract assets and contract liabilities during the years ended June 30, 2020 and June 30, 2019 (in thousands).:

	Years Ended June 30,	
	2020	2019
Receivables		
Receivables, beginning of year	$ —	$ 82
Net change	2,605	(82)
Receivables, end of year	$ 2,605	$ —
Contract assets		
Contract assets, beginning of year	$ 686	$ 312
Net change	(82)	374
Contract assets, end of year	$ 604	$ 686
Contract liabilities		
Contract liabilities, beginning of year	$ 7,774	$ 788
Net change	74,726	6,986
Contract liabilities, end of year	$82,500	$7,774

The timing of revenue recognition, invoicing and cash collections results in billed accounts receivable and unbilled receivables (contract assets), which are classified as "prepaid expenses and other current assets" on our Balance Sheet, and deferred revenue (contract liabilities). We invoice our customers in accordance with agreed-upon contractual terms, typically at periodic intervals or upon achievement of contractual milestones. Invoicing may occur subsequent to revenue recognition, resulting in contract assets. We may receive advance payments from our customers before revenue is recognized, resulting in contract liabilities. The contract assets and liabilities reported on the Balance Sheet relate to the KKC Commercialization Agreement, the KKC Japan License Agreement and Helsinn License Agreement.

Revenues from Collaborators

We earn revenue in connection with collaboration agreements, which are detailed in Note 2, KKC Agreements, and Note 3, BeiGene Collaboration.

At contract inception, we assess whether the collaboration arrangements are within the scope of ASC Topic 808, *Collaborative Arrangements* ("Topic 808"), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed based on the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of Topic 808 that contain multiple units of account, we first determine which units of account within the arrangement are within the scope of Topic 808 and which elements are within the scope of Topic 606. For units of account within collaboration arrangements that are accounted for pursuant to Topic 808, an appropriate recognition method is determined and applied consistently, by analogy to authoritative accounting literature. For units of account within collaboration arrangements that are accounted for pursuant to Topic 606, we recognize revenue as discussed above. Consideration received that does not meet the requirements to satisfy Topic 606 revenue recognition criteria is recorded as deferred revenue in the accompanying consolidated balance sheets, classified as either short-term or long-term deferred revenue based on our best estimate of when such amounts will be recognized.

Accounting Standard Codification ("ASC") Topic 605, Revenue Recognition ("Topic 605")

Revenue Recognition

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. We consider a variety of factors in determining the appropriate method of accounting under our license agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting.

Multiple Element Arrangements

Deliverables under an arrangement will be separate units of accounting, provided (i) a delivered item has value to the customer on a standalone basis; and (ii) the arrangement includes a general right of return relative to the delivered item, and delivery or performance of the undelivered item is considered probable and substantially in our control.

We account for revenue arrangements with multiple elements by separating and allocating consideration according to the relative selling price of each deliverable. If an element can be separated, an amount is allocated based upon the relative selling price of

each element. We determine the relative selling price of a separate deliverable using the price we charge other customers when we sell that element separately. If the element is not sold separately and third party pricing evidence is not available, we will use our best estimate of selling price.

License Fee Revenue

Non-refundable, up-front fees that are not contingent on any future performance by us and require no consequential continuing involvement on our part are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. We defer recognition of non-refundable upfront license fees if we have continuing performance obligations, without which the licensed data, technology, or product has no utility to the licensee separate and independent of our performance under the other elements of the applicable arrangement. The specific methodology for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances of the applicable agreement.

Research and Development Revenue

Research and development revenue represents ratable recognition of fees allocated to research and development activities. We defer recognition of research and development revenue until the performance of the related research and development activities has occurred. Research and development revenue for the years ended June 30, 2020 and 2019 relate to services provided by third-party vendors related to research and development activities performed under the KKC License Agreements (see Note 4 to our audited financial statements) Helsinn License Agreement (see Note 4 to our audited financial statements).

Cost of Revenue

Cost of revenue primarily includes external costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials, and internal compensation and related personnel expenses to support our research and development performance obligations associated with the Helsinn License Agreement.

Research and Development Costs

Research and development costs are expensed as incurred and include costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third-party contractors, are a significant component of research and development expenses. We expense research and development costs based on work performed. In determining the amount to expense, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase or licensing of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

Share-Based Compensation

Share-based compensation expense for employees and directors is recognized in the Statement of Operations based on estimated amounts, including the grant date fair value and the expected service period. For stock options, we estimate the grant date fair value using a Black-Scholes valuation model, which requires the use of multiple subjective inputs including estimated future volatility, expected forfeitures and the expected term of the awards. We estimate the expected future volatility based on the stock's historical price volatility. The stock's future volatility may differ from the estimated volatility at the grant date. For restricted stock unit ("RSU") equity awards, we estimate the grant date fair value using our closing stock price on the date of grant. We recognize the effect of forfeitures in compensation expense when the forfeitures occur. The estimated forfeiture rates may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. We recognize the value of the awards over the awards' requisite service or performance periods. The requisite service period is generally the time over which our share-based awards vest.

Warrant Liability

In May 2018, we issued warrants in connection with the May 2018 Private Placement. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the balance sheet. We recorded the fair value of the warrants upon issuance using the Black-Scholes valuation model, and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our statement of operations. Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock.

Income Taxes

Our income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets

will not be realized. As of June 30, 2020 and 2019, we have established a valuation allowance to fully reserve our net deferred tax assets. Changes in our ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income. As a result of the Tax Cuts and Jobs Act of 2017, beginning with our fiscal year ending June 30, 2021, the deduction of net operating losses is limited to 80% of current year taxable income.

The Financial Accounting Standards Board ("FASB") Topic on Income Taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There were no unrecognized tax benefits as of June 30, 2020 and 2019.

Results of Operations

Comparison of Years Ended June 30, 2020 and 2019

We had a loss from operations of $24.5 million for the year ended June 30, 2020 compared to a loss from operations of $46.2 million for the year ended June 30, 2019.

Revenue: We recognized revenue of $28.9 million for the year ended June 30, 2020 compared to $4.9 million for the year ended June 30, 2019. Revenue increased primarily due to our license agreement with KKC and resulted from the transfer of the Ex-U.S. license, the partial satisfaction of our research and development obligations and providing clinical trial materials. Revenue related to the license agreement with KKC was $27.5 million for the year ended June 30, 2020 compared to $2.6 million for the year ended June 30, 2019. Revenue also includes recognition of fees allocated to performance obligations in accordance with the Helsinn License Agreement. Revenue related the Helsinn License Agreement was $1.4 million for the year ended June 30, 2020 compared to $2.4 million for the year ended June 30, 2019 due to the completion of enrollment and decreased costs related to the POC study.

Cost of Revenue: We recognized cost of revenue of $2.7 million for the year ended June 30, 2020 compared to $4.3 million for the year ended June 30, 2019. The cost of revenue includes external costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials, and internal compensation and related personnel expenses associated with pracinostat. Costs of revenue relate to expenses for pracinostat incurred in connection with our development activities in accordance with the Helsinn License Agreement, including both Helsinn's share and our share of costs related to the POC study, which we are responsible for conducting. Cost of revenue decreased due to the completion of enrollment and decreased costs related to the POC study.

***Research and Development*:** The following is a summary of our research and development expenses to supplement the more detailed discussion below. The dollar values in the following table are in thousands.

	Years Ended June 30,	
Research and development expenses	**2020**	**2019**
Zandelisib	$17,356	$17,515
Voruciclib	1,946	3,120
ME-344	62	455
Pracinostat	23	17
Other	14,678	11,193
Total research and development expenses	$34,065	$32,300

Research and development expenses consist primarily of clinical trial costs (including payments to CROs), pre-clinical study costs, and costs to manufacture our drug candidates for non-clinical and clinical studies. Other research and development expenses consist primarily of salaries and personnel costs, share-based compensation, legal costs, and other costs not allocated to specific drug programs. Research and development expenses were $34.1 million for the year ended June 30, 2020 compared to $32.3 million for the year ended June 30, 2019. Costs related to zandelisib the year ended June 30, 2020 reflected a decrease of $4.5 million of drug manufacturing costs, offset by $4.4 million of increased clinical trial costs, primarily as a result of increased activity in the Phase 2 study. Costs related to voruciclib decreased for the year ended June 30, 2020 compared with the year ended June 30, 2019, due to decreased clinical trial and drug manufacturing costs. Other research and development costs increased for the year ended June 30, 2020 due to higher levels of personnel costs ($2.4 million) and share-based compensation ($0.5 million) associated with increased headcount to support our clinical activities, as well as to increased patent and consulting fees ($0.5 million).

***General and Administrative*:** General and administrative expenses increased by $2.1 million to $16.7 million for the year ended June 30, 2020 compared to $14.6 million for the year ended June 30, 2019. The increase is primarily due to $1.5 million in increased personnel costs associated with increased headcount to support our activities.

Other income or expense: We recorded a non-cash expense of $22.9 million during the year ended June 30, 2020 due to a change in the fair value of our warrant liability for warrants issued in connection with the May 2018 Private Placement. The change in the warrant liability is primarily due to changes in our stock price. Additionally, we received interest and dividend income of $1.4 million

for the year ended June 30, 2020 compared to $1.8 million for the year ended June 30, 2019. The decrease was due to lower yields during the year ended June 30, 2020 compared to the year ended June 30, 2019.

Comparison of Years Ended June 30, 2019 and 2018

We have omitted discussion of the results of operations for the fiscal year ended June 30, 2018 because it would be redundant to the discussion previously included in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended June 30, 2019, filed with the SEC on August 28, 2019.

New Accounting Pronouncements

See Note 1 to the Financial Statements included in Item 8 of this Annual Report.

Off-Balance Sheet Arrangements

We do not currently have any off-balance-sheet arrangements.

Liquidity and Capital Resources

We have accumulated losses of $277.2 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of June 30, 2020, we had $182.6 million in cash and cash equivalents, and short-term investments. Additionally, we have a receivable of $20.4 million representing the remaining amount due to us of the $100 million upfront payment paid by KKC in May 2020 associated with the KKC Commercialization Agreement. Of the $100 million paid by KKC, $20.4 million was remitted to the Japanese taxing authorities as a result of the U.S. Internal Revenue Service being closed due to the COVID pandemic, and therefore being unable to provide necessary documentation to support an exemption from the required foreign withholding. We believe that these resources will be sufficient to fund our operations into fiscal year 2022 and beyond. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. Our research and development expenses are expected to increase in the foreseeable future. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

To date, we have obtained cash and funded our operations primarily through equity financings and license agreements. In order to continue the development of our drug candidates, at some point in the future we expect to pursue one or more capital transactions, whether through the sale of equity securities, license agreements or entry into strategic partnerships. There can be no assurance that we will be able to continue to raise additional capital in the future.

Sources and Uses of Our Cash

Net cash provided by operations for the year ended June 30, 2020 was $34.3 million (net cash used in operations was $45.3 million, net of a $79.6 million license fee received from KKC, as described above). Net cash used in operating activities for the year ended June 30, 2019 was $29.4 million ($39.4 million, net of a $10.0 million license fee received from KKC, as described above). Net cash used in operating activities was $21.0 million for the year ended June 30, 2018. The increase in cash provided by operating activities year over year is due to the receipt of $79.6 million upfront payment as a result of the KKC License Agreement.

Net cash used in investing activities for the year ended June 30, 2020 was $106.3 million compared to $24.3 million provided by investing activities for the year ended June 30, 2019. The change was primarily due to higher purchases of short-term investments in 2020 as a result of the KKC License Agreement, net of maturities. Net cash used in investing activities for the year ended June 30, 2018 was $44.3 million.

Net cash provided by financing activities during the year ended June 30, 2020 was $74.8 million compared with $1.4 million provided by financing activities during the year ended June 30, 2019. Cash raised during the year ended June 30, 2020 reflected $69.2 million of net proceeds from the issuance of common stock. Cash raised during the year ended June 30, 2019 reflected $1.1 million of proceeds from the exercise of warrants. There was $70.2 million provided by financing activities related to the May 2018 Private Placement during the year ended June 30, 2018.

Contractual Obligations

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. Additionally, we have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

We have leased approximately 32,800 square feet of office space in San Diego, California. The contractual lease term is from July 2020 through March 2028. The average annual lease payments over the term of the lease will approximate $1.5 million, plus a pro rata share of certain building expenses. Our total contractual obligation over the term of the lease is approximately $11.5 million.

Presage License Agreement

In September 2017, we entered into the Presage License Agreement. Under the terms of the Presage License Agreement, Presage granted to us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid Presage $2.9 million. With respect to the first indication, an incremental $2.0 million payment, due upon dosing the first subject in the first registration trial will be owed to Presage, for total payments of $4.9 million prior to receipt of marketing approval of the first indication in the U.S., E.U. or Japan. Additional potential payments of up to $179 million will be due upon the achievement of certain development, regulatory and commercial milestones. We will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which we sublicense product rights, we will pay to Presage a tiered percent (which decreases as product development progresses) of amounts received from such sublicensees. As of June 30, 2020, we have not accrued any amounts for potential future payments.

*S*Bio Purchase Agreement*

We are party to a definitive asset purchase agreement with S*Bio, pursuant to which we acquired certain assets comprised of intellectual property and technology including rights to pracinostat. We agreed to make certain milestone payments to S*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S*Bio. Milestone payments will be made to S*Bio up to an aggregate amount of $74.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. The first milestone payment of $200,000 plus 166,527 shares of our common stock having a value of $500,000 was paid in August 2017 upon the first dosing of a patient in a Phase 3 clinical trial. Subsequent milestone payments will be due upon certain regulatory approvals and sales-based events. As of June 30, 2020, we have not accrued any amounts for potential future payments.

CyDex License Agreement

We are party to a license agreement with CyDex. Under the license agreement, CyDex granted to us an exclusive, non-transferable license to intellectual property rights relating to Captisol® for use with our two isoflavone-based drug compounds (currently ME-344). We agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties at a low, single-digit percentage rate on future sales of our approved drugs utilizing Captisol. Contemporaneously with the license agreement, CyDex entered into a commercial supply agreement with us, pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. We may terminate both the license agreement and the supply agreement for convenience at any time upon 90 days' prior written notice. As of June 30, 2020, we have not accrued any amounts for potential future payments.

COVID-19

In January 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus (the "COVID-19 outbreak") and the risks to the international community. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic based on the rapid increase in exposure globally. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines have been negatively affected by COVID-19. The extent to which the ongoing pandemic continues to impact our business, including our preclinical studies, chemistry, manufacturing, and control ("CMC") studies and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to minimize its economic impact.

In light of the COVID-19 outbreak, the FDA issued a number of new guidance documents. Specifically, as a result of the potential effect of the COVID-19 outbreak on many clinical trial programs in the U.S. and globally, the U.S. FDA issued guidance concerning potential impacts on clinical trial programs, changes that may be necessary to such programs if they proceed, considerations regarding trial suspensions and discontinuations, the potential need to consult with or make submissions to relevant ethics committees, IRBs, and the FDA, the use of alternative drug delivery methods, and considerations with respect the outbreak's impacts on endpoints, data collection, study procedures, and analysis. In addition, the European Medicines Agency ("EMA") as well as country regulatory authorities have issued similar guidance.

Item 7a. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

Our exposure to market interest rates relates primarily to the investments of cash balances and short-term investments. We have cash reserves held in U.S. dollars and we place funds on deposit with financial institutions, which are readily available. Our short-term investments consist solely of U.S. government securities with a maturity of three to twelve months.

We place our cash deposits with high credit quality financial institutions and by policy limit the amount of credit exposure to any one corporation or bank. These deposits are in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance limits. We are adverse to principal loss and we ensure the safety and preservation of our invested funds by limiting default risk, market risk and reinvestment risk. We seek to mitigate default risk by depositing funds with high credit quality financial institutions, by limiting the amount of credit exposure to any one corporation or bank, by purchasing short-term investments consisting of U.S. government securities, and by positioning our portfolio to respond appropriately to a significant reduction in a credit rating of any such financial institution.

We do not consider the effects of interest rate movements to be a material risk to our financial condition.

Item 8. Financial Statements and Supplementary Data

MEI Pharma, Inc.
Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
MEI Pharma, Inc.
San Diego, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of MEI Pharma, Inc. (the "Company") as of June 30, 2020 and 2019, the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended June 30, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2020, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Method Related to Leases and Revenue

As discussed in Note 1 to the financial statements, the Company has changed its method of accounting for leases during the year ended June 30, 2020 due to the adoption of Accounting Standards Codification Topic 842: "Leases", and changed its method of accounting for revenue during the year ended June 30, 2019 due to the adoption of the Accounting Standards Codification Topic 606, "*Revenue from Contracts with Customers*."

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 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.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2011.

San Diego, California
September 9, 2020

MEI PHARMA, INC.
BALANCE SHEETS
(In thousands, except per share amounts)

	June 30, 2020	June 30, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,331	$ 9,590
Short-term investments	170,299	64,899
Total cash, cash equivalents and short-term investments	182,630	74,489
Receivable for foreign tax withholding	20,420	—
Common stock proceeds receivable	—	5,274
Prepaid expenses and other current assets	5,594	2,435
Total current assets	208,644	82,198
Intangible assets, net	—	261
Property and equipment, net	1,084	204
Total assets	$ 209,728	$ 82,663
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,437	$ 4,787
Accrued liabilities	6,090	4,559
Deferred revenue	14,777	4,955
Total current liabilities	23,304	14,301
Deferred revenue, long-term	67,723	2,819
Warrant liability	40,483	17,613
Total liabilities	131,510	34,733
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, $0.00000002 par value; 226,000 shares authorized; 111,514 and 73,545 shares issued and outstanding at June 30, 2020 and 2019, respectively.	—	—
Additional paid-in-capital	355,452	279,148
Accumulated deficit	(277,234)	(231,218)
Total stockholders' equity	78,218	47,930
Total liabilities and stockholders' equity	$ 209,728	$ 82,663

See accompanying notes to financial statements.

MEI PHARMA, INC.
STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Years Ended June 30,		
	2020	2019	2018
Revenue	$ 28,913	$ 4,915	$ 1,622
Operating expenses:			
Cost of revenue	2,671	4,263	3,383
Research and development	34,065	32,300	17,038
General and administrative	16,717	14,597	9,787
Total operating expenses	53,453	51,160	30,208
Loss from operations	(24,540)	(46,245)	(28,586)
Other income (expense):			
Change in fair value of warrant liability	(22,870)	27,632	(9,705)
Financing costs associated with warrants	—	—	(2,367)
Interest and dividend income	1,395	1,795	591
Income tax expense	(1)	(1)	(1)
Net loss	$ (46,016)	$ (16,819)	$ (40,068)
Net loss:			
Basic	$ (46,016)	$ (16,819)	$ (40,068)
Diluted	$ (46,016)	$ (54,613)	$ (40,068)
Net loss per share:			
Basic	$ (0.51)	$ (0.24)	$ (0.97)
Diluted	$ (0.51)	$ (0.75)	$ (0.97)
Shares used in computing net loss per share:			
Basic	91,080	71,139	41,431
Diluted	91,080	72,385	41,431

See accompanying notes to financial statements.

MEI PHARMA, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Shares	Additional paid in capital	Accumulated Deficit	Total Stockholders' Equity
Balance at June 30, 2017	36,772	225,169	(174,331)	50,838
Net loss	—	—	(40,068)	(40,068)
Issuance of common stock in private placement, net (Note 8)	33,003	35,910	—	35,910
Issuance of common stock for milestone payment, net (Note 10)	167	500	—	500
Issuance of common stock for vested restricted stock units	271	(267)	—	(267)
Exercise of stock options	193	329	—	329
Share-based compensation expense	—	3,217	—	3,217
Balance at June 30, 2018	70,406	264,858	(214,399)	50,459
Net loss	—	—	(16,819)	(16,819)
Issuance of common stock, net	2,215	5,444	—	5,444
Exercise of warrants	440	2,186	—	2,186
Issuance of common stock for vested restricted stock units	246	(324)	—	(324)
Exercise of stock options	238	422	—	422
Share-based compensation expense	—	6,562	—	6,562
Balance at June 30, 2019	73,545	279,148	(231,218)	47,930
Net loss	—	—	(46,016)	(46,016)
Issuance of common stock, net	37,815	69,231	—	69,231
Exercise of stock options	154	272	—	272
Share-based compensation expense	—	6,801	—	6,801
Balance at June 30, 2020	111,514	$ 355,452	$ (277,234)	$ 78,218

See accompanying notes to financial statements.

MEI PHARMA, INC.
STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended June 30,		
	2020	2019	2018
Cash flows from operating activities:			
Net loss	$ (46,016)	$(16,819)	$ (40,068)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Change in fair value of warrant liability	22,870	(27,632)	9,705
Financing costs associated with warrants	—	—	2,367
Share-based compensation	6,801	6,562	3,217
Impairment of intangible assets	227	—	—
Depreciation and amortization	109	80	53
Changes in operating assets and liabilities:			
Receivable for foreign tax withholding	(20,420)	—	—
Prepaid expenses and other current assets	(3,159)	(849)	172
Accounts payable	(2,350)	1,144	3,058
Accrued liabilities	1,470	1,105	669
Deferred revenue	74,726	6,986	(208)
Net cash provided by (used in) operating activities	34,258	(29,423)	(21,035)
Cash flows from investing activities:			
Purchases of property and equipment	(894)	(217)	—
Purchases of short-term investments	(190,279)	(64,655)	(114,233)
Proceeds from maturity of short-term investments	84,879	89,190	69,906
Net cash (used in) provided by investing activities	(106,294)	24,318	(44,327)
Cash flows from financing activities:			
Proceeds from exercise of stock options	272	372	329
Issuance of common stock, net	69,231	220	70,151
Collection of common stock proceeds receivable	5,274	—	—
Proceeds from exercise of warrants	—	1,118	—
Payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders	—	(324)	(267)
Net cash provided by financing activities	74,777	1,386	70,213
Net increase (decrease) in cash and cash equivalents	2,741	(3,719)	4,851
Cash and cash equivalents at beginning of the period	9,590	13,309	8,458
Cash and cash equivalents at end of the period	$ 12,331	$ 9,590	$ 13,309
Supplemental cash flow information:			
Income taxes paid	$ (1)	$ (1)	$ (1)
Non-cash financing activities:			
Proceeds receivable- sale of common stock	$ —	$ 5,224	$ —
Proceeds receivable- stock option exercises	$ —	$ 50	$ —
Change in fair value of warrants exercised	$ —	$ 1,068	$ —

See accompanying notes to financial statements.

MEI PHARMA, INC.
NOTES TO FINANCIAL STATEMENTS
June 30, 2020

Note 1. The Company and Summary of Significant Accounting Policies

The Company

We are a late-stage pharmaceutical company focused on leveraging our extensive development and oncology expertise to identify and advance new therapies intended to meaningfully improve the treatment of cancer. Our portfolio of drug candidates contains four clinical-stage assets, including zandelisib (formerly known as ME-401), currently in an ongoing Phase 2 clinical trial that we intend to submit to the U.S. Food and Drug Administration ("FDA") to support accelerated approval of a marketing application. Our common stock is listed on the NASDAQ Capital Market under the symbol "MEIP".

Clinical Development Programs

Our approach to building our pipeline is to license promising cancer agents and build value in programs through development, commercialization and strategic partnerships, as appropriate. Our drug candidate pipeline includes:

- Zandelisib (formerly known as ME-401), an oral phosphatidylinositol 3-kinase ("PI3K") delta inhibitor;
- Voruciclib, an oral cyclin-dependent kinase ("CDK") inhibitor;
- ME-344, a mitochondrial inhibitor targeting the oxidative phosphorylation ("OXPHOS") complex; and
- Pracinostat, an oral histone deacetylase ("HDAC") inhibitor.

The results of pre-clinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials. The commercial opportunity will be reduced or eliminated if competitors develop and market products that are more effective, have fewer side effects or are less expensive than our drug candidates. We will need substantial additional funds to progress the clinical trial programs for the drug candidates zandelisib, voruciclib, ME-344 and pracinostat, and to develop new compounds. The actual amount of funds that will be needed are determined by a number of factors, some of which are beyond our control. Negative U.S. and global economic conditions may pose challenges to our business strategy, which relies on funding from the financial markets or collaborators.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. We use estimates that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. Actual results could materially differ from those estimates.

Liquidity

We have accumulated losses of $277.2 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of June 30, 2020, we had $182.6 million in cash and cash equivalents, and short-term investments. Additionally, we have a receivable of $20.4 million representing a tax withholding refund due to us of the $100 million upfront payment associated with the KKC Commercialization Agreement (Note 2). Of the $100 million paid by KKC, $20.4 million was remitted to the Japanese taxing authorities as a result of the U.S. Internal Revenue Service being closed due to the COVID pandemic, and therefore being unable to provide necessary documentation to support an exemption from the required foreign withholding. We believe that these resources will be sufficient to meet our obligations and fund our liquidity and capital expenditure requirements for at least the next 12 months from the issuance of these financial statements. Our current business operations are focused on continuing the clinical development of our drug candidates. Changes to our research and development plans or other changes affecting our operating expenses may affect actual future use of existing cash resources. Our research and development expenses are expected to increase in the foreseeable future. We cannot determine with certainty costs associated with ongoing and future clinical trials or the regulatory approval process. The duration, costs and timing associated with the development of our product candidates will depend on a variety of factors, including uncertainties associated with the results of our clinical trials.

To date, we have obtained cash and funded our operations primarily through equity financings and license agreements. In order to continue the development of our drug candidates, at some point in the future we expect to pursue one or more capital transactions, whether through the sale of equity securities, license agreements or entry into strategic partnerships. There can be no assurance that we will be able to continue to raise additional capital in the future.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with original maturities of three months or less when purchased. Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. We have not experienced any losses related to these balances.

Short-Term Investments

Investments that have maturities of greater than three months but less than one year are classified as short-term investments. As of June 30, 2020 and 2019, our short-term investments consisted of $170.3 million and $64.9 million, respectively, in U.S. government securities. The short-term investments held as of June 30, 2020 and 2019 had maturity dates of less than one year, are considered to be "held to maturity" and are carried at amortized cost. As of June 30, 2020 and 2019, the gross holding gains and losses were immaterial.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value is as follows:

- Level 1 — Observable inputs such as quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

We measure the following financial instruments at fair value on a recurring basis. The fair values of these financial instruments were as follows (in thousands):

	June 30, 2020			June 30, 2019		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Warrant liability	$ —	$ —	$(40,483)	$ —	$ —	$(17,613)
Total	$ —	$ —	$(40,483)	$ —	$ —	$(17,613)

The carrying amounts of financial instruments such as cash equivalents, short-term investments and accounts payable approximate the related fair values due to the short-term maturities of these instruments. We invest our excess cash in financial instruments which are readily convertible into cash, such as money market funds and U.S. government securities. Cash equivalents, where applicable, and short-term investments are classified as Level 1 as defined by the fair value hierarchy.

In May 2018, we issued warrants in connection with our private placement of shares of common stock. Pursuant to the terms of the warrants, we could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as a liability in the Balance Sheet. We recorded the fair value of the warrants upon issuance using the Black-Scholes valuation model and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our Statement of Operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities were the volatility rate and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The change in the fair value of the Level 3 warrant liability is reflected in the Statement of Operations for the years ended June 30, 2020 and 2019.

To calculate the fair value of the warrant liability, the following assumptions were used:

	June 30, 2020	June 30, 2019
Risk-free interest rate	0.2%	1.7%
Expected life (years)	2.9	3.8
Expected volatility	77.4%	56.8%
Dividend yield	0.0%	0.0%
Black-Scholes Fair Value	$ 2.52	$ 1.10

The following table sets forth a summary of changes in the estimated fair value of our Level 3 warrant liability for the years ended June 30, 2020 and 2019 (in thousands):

	Fair Value of Warrants Using Significant Unobservable Inputs (Level 3)	
	2020	2019
Balance at July 1,	$ 17,613	$ 46,313
Reclassification of derivative liability to equity upon exercise of warrants	—	(1,068)
Change in estimated fair value of liability classified warrants	22,870	(27,632)
Balance at June 30,	$ 40,483	$ 17,613

Intangible Assets

Intangible assets consist of patents acquired from S*Bio in August 2012, relating to a family of heterocyclic compounds that inhibit HDACs, including pracinostat. Capitalized amounts are amortized on a straight-line basis over the expected life of the intellectual property of 14 years from the date of acquisition. The carrying values of intangible assets are periodically reviewed to determine if the facts and circumstances suggest that a potential impairment may have occurred. As a result of Helsinn discontinuing the Phase 3 study of pracinostat in AML, we assessed the estimated future cash flows associated with the patents acquired from S*Bio and recorded an impairment charge of $0.2 million to write off the remaining book value of the intangible assets.

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets (generally three to seven years) using the straight-line method. Leasehold improvements are stated at cost and are amortized over the shorter of the estimated useful lives of the assets or the lease term.

Leases

As of July 1, 2019, we adopted Topic 842, *Leases*, using a modified retrospective basis method under which prior comparative periods are not restated. The new standard establishes a ROU model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. We elected the following as practical expedients: 1) an entity need not reassess whether any expired or existing contracts are or contain leases, 2) an entity need not reassess the lease classification for any expired or existing leases, and 3) an entity need not reassess initial direct costs for any existing leases.

Revenue Recognition

ASC Topic 606, Revenue from Contracts with Customers ("Topic 606" or the "new revenue standard")

Beginning July 1, 2018, we recognize revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. For enforceable contracts with our customers, we first identify the distinct performance obligations – or accounting units – within the contract. Performance obligations are commitments in a contract to transfer a distinct good or service to the customer.

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. At the inception of arrangements that include milestone payments, we use judgment to evaluate whether the milestones are probable of being achieved and we estimate the amount to include in the transaction price using the most likely method. If it is probable that a significant revenue reversal will not occur, the estimated amount is included in the transaction price. Milestone payments that are not within our or the licensee's control, such as regulatory approvals, are not included in the transaction price until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of development milestones and any related constraint and, as necessary, we adjust our estimate of the overall transaction price. Any adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. For the year ended June 30, 2020, we recorded a cumulative catch-up adjustment of $3.1 million related to a partially satisfied performance obligation as a result of the termination of the KKC Japan License Agreement and execution of the KKC Commercialization Agreement (Note 2).

We develop estimates of the stand-alone selling price for each distinct performance obligation. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations is allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We develop assumptions that require judgment to determine the stand-alone selling price for license-related performance obligations, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical, regulatory and commercial success. We estimate stand-alone selling price for research and development performance obligations by forecasting the expected costs of satisfying a performance obligation plus an appropriate margin.

In the case of a license that is a distinct performance obligation, we recognize revenue allocated to the license from non-refundable, up-front fees at the point in time when the license is transferred to the licensee and the licensee can use and benefit from the license. For licenses that are bundled with other distinct or combined obligations, we use judgment to assess the nature of the performance obligation to determine whether the 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. If the performance obligation is satisfied over time, we evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Revenue is recorded proportionally as costs are incurred. We generally use the cost-to-cost measure of progress because it best depicts the transfer of control to the customer which occurs as we incur costs. Under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation (an "input method" under Topic 606). We use judgment to estimate the total cost expected to complete the research and development performance obligations, which include subcontractors' costs, labor, materials, other direct costs and an allocation of indirect costs. We evaluate these cost estimates and the progress each reporting period and, as necessary, we adjust the measure of progress and related revenue recognition.

For arrangements that include sales-based or usage-based royalties, 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 sales-based royalty revenue from license agreements.

We recognized revenue associated with the following license agreements (in thousands):

	Years Ended June 30,		
	2020	2019	2018
KKC Agreements	$27,543	$2,557	$ —
Helsinn License Agreement	1,370	2,358	1,622
	$28,913	$4,915	$1,622
Timing of Revenue Recognition:			
License transferred at a point in time	$20,988	$ 879	$ —
Services performed over time	4,860	4,036	1,622
Cumulative catch-up adjustment	3,065	—	—
	$28,913	$4,915	$1,622

Based on the characteristics of the KKC Agreements (Note 2), delivery of the Ex-U.S. license and Japan License are distinct performance obligations, and we recognized related revenue of $21.0 million and $0.9 million during the years ended June 30, 2020 and June 30 2019, respectively, when the licenses were transferred to the licensee and the licensee could use and benefit from the licenses. We account for any partially unsatisfied performance obligations carried forward into the new agreement as the continuation of the previous contract, and we recorded a cumulative catch-up adjustment of $3.1 million to revenue during the year ended June 30, 2020 as a result of the termination of the KKC Japan License Agreement and execution of the KKC Commercialization Agreement. The KKC Commercialization Agreement and KKC Japan License Agreement include other distinct performance obligations that will be satisfied over time, and accordingly we recognized $6.6 million, inclusive of cumulative catch-up amounts, and $1.7 million related to our progress toward satisfying those obligations during the years ended June 30, 2020 and 2019, respectively.

Based on the characteristics of the Helsinn License Agreement, control of the remaining deliverables occurs over time and therefore we recognize revenue based on the extent of progress towards completion of the performance obligations. Accordingly we recognized $1.4 million and $2.3 million related to our progress toward satisfying those obligations during the years ended June 30, 2020 and 2019, respectively.

As of June 30, 2020, we had $82.5 million of deferred revenue associated with our remaining performance obligations under the KKC and Helsinn license agreements. We expect to recognize approximately $14.8 million of deferred revenue in the next 12 months, and an additional $67.7 million thereafter.

Contract Balances

Receivables and contract assets are included in our balance sheet in "Prepaid expenses and other current assets", and contract liabilities are included in "Deferred revenue" and "Deferred revenue long-term". The following table presents changes in contract assets and contract liabilities during the year ended June 30, 2020 and 2019 (in thousands):

	Years Ended June 30,	
	2020	2019
Receivables		
Receivables, beginning of year	$ —	$ 82
Net change	2,605	(82)
Receivables, end of year	$ 2,605	$ —
Contract assets		
Contract assets, beginning of year	$ 686	$ 312
Net change	(82)	374
Contract assets, end of year	$ 604	$ 686
Contract liabilities		
Contract liabilities, beginning of year	$ 7,774	$ 788
Net change	74,726	6,986
Contract liabilities, end of year	$82,500	$7,774

The timing of revenue recognition, invoicing and cash collections results in billed accounts receivable and unbilled receivables (contract assets), which are classified as "prepaid expenses and other current assets" on our Balance Sheet, and deferred revenue (contract liabilities). We invoice our customers in accordance with agreed-upon contractual terms, typically at periodic intervals or upon achievement of contractual milestones. Invoicing may occur subsequent to revenue recognition, resulting in contract assets. We may receive advance payments from our customers before revenue is recognized, resulting in contract liabilities. The contract assets and liabilities reported on the Balance Sheet relate to the KKC Agreements and Helsinn License Agreement. We recognized revenue of $7.8 million, $0.8 million, and $1.0 million during the years ended June 30, 2020, 2019 and 2018, respectively, related to the contract liability balance at the beginning of each respective fiscal year.

Revenues from Collaborators

We earn revenue in connection with collaboration agreements, which are detailed in Note 2, KKC Agreements, and Note 3, BeiGene Collaboration.

At contract inception, we assess whether the collaboration arrangements are within the scope of ASC Topic 808, *Collaborative Arrangements* ("Topic 808"), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed based on the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of Topic 808 that contain multiple units of account, we first determine which units of account within the arrangement are within the scope of Topic 808 and which elements are within the scope of Topic 606. For units of account within collaboration arrangements that are accounted for pursuant to Topic 808, an appropriate recognition method is determined and applied consistently, by analogy to authoritative accounting literature. For elements of collaboration arrangements that are accounted for pursuant to Topic 606, we recognize revenue as discussed above. Consideration received that does not meet the requirements to satisfy Topic 606 revenue recognition criteria is recorded as deferred revenue in the accompanying consolidated balance sheets, classified as either short-term or long-term deferred revenue based on our best estimate of when such amounts will be recognized.

Accounting Standard Codification ("ASC") Topic 605, Revenue Recognition ("Topic 605")

Revenue Recognition

Payments received under commercial arrangements, such as licensing technology rights, may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, and royalties on the sale of products. We consider a variety of factors in determining the appropriate method of accounting under our license agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting.

Multiple Element Arrangements

Deliverables under an arrangement will be separate units of accounting, provided (i) a delivered item has value to the customer on a standalone basis; and (ii) the arrangement includes a general right of return relative to the delivered item, and delivery or performance of the undelivered item is considered probable and substantially in our control.

We account for revenue arrangements with multiple elements by separating and allocating consideration according to the relative selling price of each deliverable. If an element can be separated, an amount is allocated based upon the relative selling price of each element. We determine the relative selling price of a separate deliverable using the price we charge other customers when we sell that element separately. If the element is not sold separately and third-party pricing evidence is not available, we will use our best estimate of selling price.

License Fee Revenue

Non-refundable, up-front fees that are not contingent on any future performance by us and require no consequential continuing involvement on our part are recognized as revenue when the license term commences and the licensed data, technology or product is delivered. We defer recognition of non-refundable upfront license fees if we have continuing performance obligations, without which the licensed data, technology, or product has no utility to the licensee separate and independent of our performance under the other elements of the applicable arrangement. The specific methodology for the recognition of the revenue is determined on a case-by-case basis according to the facts and circumstances of the applicable agreement.

Research and Development Revenue

Research and development revenue represents ratable recognition of fees allocated to research and development activities. We defer recognition of research and development revenue until the performance of the related research and development activities has occurred. Research and development revenue for the year ended June 30, 2018 related to services provided by third-party vendors related to research and development for activities performed under the KKC and Helsinn License Agreements (Note 2).

Cost of Revenue

Cost of revenue primarily includes external costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials, and internal compensation and related personnel expenses to support our research and development performance obligations associated with the Helsinn License Agreement.

Research and Development Costs

Research and development costs are expensed as incurred and include costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials. Clinical trial costs, including costs associated with third-party contractors, are a significant component of research and development expenses. We expense research and development costs based on work performed. In determining the amount to expense, management relies on estimates of total costs based on contract components completed, the enrollment of subjects, the completion of trials, and other events. Costs incurred related to the purchase or licensing of in-process research and development for early-stage products or products that are not commercially viable and ready for use, or have no alternative future use, are charged to expense in the period incurred.

Share-based Compensation

Share-based compensation expense for employees and directors is recognized in the Statement of Operations based on estimated amounts, including the grant date fair value and the expected service period. For stock options, we estimate the grant date fair value using a Black-Scholes valuation model, which requires the use of multiple subjective inputs including estimated future volatility, expected forfeitures and the expected term of the awards. We estimate the expected future volatility based on the stock's historical price volatility. The stock's future volatility may differ from the estimated volatility at the grant date. For restricted stock unit ("RSU") equity awards, we estimate the grant date fair value using our closing stock price on the date of grant. We recognize the effect of forfeitures in compensation expense when the forfeitures occur. The estimated forfeiture rates may differ from actual forfeiture rates which would affect the amount of expense recognized during the period. We recognize the value of the awards over the awards' requisite service or performance periods. The requisite service period is generally the time over which our share-based awards vest.

Interest and Dividend Income

Interest on cash balances is recognized when earned. Dividend income is recognized when the right to receive the payment is established.

Income Taxes

Our income tax expense consists of current and deferred income tax expense or benefit. Current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is recognized for the future tax consequences attributable to tax credits and loss carryforwards and to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. As of June 30, 2020 and 2019, we have established a valuation allowance to fully reserve our net deferred tax assets. Tax rate changes are reflected in income during the period such changes are enacted. Changes in our ownership may limit the amount of net operating loss carryforwards that can be utilized in the future to offset taxable income.

The Tax Act reduced the corporate tax rate from 34% to 21%, effective for tax years beginning January 1, 2018. We are subject to the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification 740-10, Income Taxes, which requires that the effect on deferred tax assets and liabilities of a change in tax rates be recognized in the period the tax rate change was enacted. As a result of the Tax Act, beginning with our fiscal year ending June 30, 2021, the deduction of net operating losses is limited to 80% of current year taxable income.

As a result of the Tax Act, we recorded a non-cash tax expense of $15.9 million during the year ended June 30, 2018, due to the re-measurement of our deferred tax assets and liabilities at the new U.S. federal tax rate, offset by a corresponding change to our valuation allowance.

The FASB Topic on Income Taxes prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There were no unrecognized tax benefits as of June 30, 2020 and 2019.

Net Loss Per Share

Basic and diluted net loss per share are computed using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of common stock subject to repurchase or forfeiture for the years ended June 30, 2020, 2019 and 2018. Our potentially dilutive shares, which include outstanding stock options, restricted stock units, and warrants, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. The assessment of dilution is made on a quarterly basis and therefore the annual determination of diluted net loss per share only includes those quarters in which the potential common stock equivalents were determined to be dilutive. For the years ended June 30, 2020, 2019 and 2018, we did not have any items that would be classified as other comprehensive income or losses.

The following table presents the calculation of net loss used to calculate basic and diluted loss per share (in thousands):

	Years Ended June 30,		
	2020	2019	2018
Net loss—basic	$(46,016)	$(16,819)	$(40,068)
Change in fair value of warrant liability	—	(37,794)	—
Net loss—diluted	$(46,016)	$(54,613)	$(40,068)

Shares used in calculating net loss per share was determined as follows (in thousands):

	Years Ended June 30,		
	2020	2019	2018
Weighted average shares outstanding	91,080	71,139	41,064
Effect of vested restricted stock units	—	—	367
Weighted average shares used in calculating net loss per share	91,080	71,139	41,431
Effect of potentially dilutive common shares from equity awards and liability-classified warrants	—	1,246	—
Weighted average shares used in calculating diluted loss per share	91,080	72,385	41,431

The following potentially dilutive shares (in thousands) that have been excluded from the calculation of net loss per share because of their anti-dilutive effect:

	Years Ended June 30,		
	2020	2019	2018
Stock options	11,030	8,057	5,606
Restricted stock units	—	32	336
Warrants	16,062	8,062	3,532
Total anti-dilutive shares	27,092	16,151	9,474

Recent Accounting Pronouncements

Adopted Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. We adopted the new standard on July 1, 2019 using the required modified retrospective approach and elected to apply the

adoption as of the effective date of initial application. As such, prior periods do not reflect the adoption of the new standard. The new standard is effective for fiscal years beginning after July 1, 2019, including interim periods within those fiscal years. See Note 11 for further discussion. As of June 30, 2020, our new office lease had not yet commenced, and therefore we have not recognized the associated right of use asset or liability in our balance sheet. We did not have any outstanding leases as of June 30, 2020.

Note 2. KKC Agreements

KKC License, Development and Commercialization Agreement

In April 2020, we entered into a License, Development and Commercialization Agreement with Kyowa Kirin Company (formerly "Kyowa Hakko Kirin Co., Ltd.") ("KKC") a Japanese life sciences company (the "KKC Commercialization Agreement"). We granted to KKC a co-exclusive, sublicensable, payment-bearing license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in the U.S. (the "U.S. License"), and an exclusive (subject to certain retained rights to perform obligations under the KKC Commercialization Agreement), sublicensable, payment-bearing, license under certain patents and know-how controlled by us to develop and commercialize zandelisib and any pharmaceutical product containing zandelisib for all human indications in countries outside of the United States (the "Ex-U.S.") (the "Ex-U.S. license"). KKC granted to us a co-exclusive, sublicensable, license under certain patents and know-how controlled by KKC to develop and commercialize zandelisib for all human indications in the U.S., and a co-exclusive, sublicensable, royalty-free, fully paid license under certain patents and know-how controlled by KKC to perform our obligations in the Ex-U.S. under the KKC Commercialization Agreement. KKC paid us an initial payment of $100 million in May 2020. Of the $100 million, $20.4 million was remitted to the Japanese taxing authorities as a result of the U.S. Internal Revenue Service being closed due to the COVID pandemic, and therefore being unable to provide necessary documentation to support an exemption from the required foreign withholding. We expect to receive the amount paid to the Japanese taxing authorities in fiscal year 2021. Additionally, we may earn up to approximately $582.5 million in potential development, regulatory and commercialization milestone payments, plus royalties on net sales of zandelisib in the Ex-U.S., which are tiered beginning in the teens.

KKC will be responsible for the development and commercialization of zandelisib in the Ex-U.S. and, subject to certain exceptions, will be solely responsible for all costs related thereto. We and KKC will co-develop and co-promote zandelisib in the U.S., with us recording all revenue from U.S. sales. We and KKC will share U.S. profits and costs (including development costs) on a 50-50 basis. We will also provide to KKC certain drug supplies necessary for the development and commercialization of zandelisib in the Ex-U.S., with the understanding that KKC will assume responsibility for manufacturing for the Ex-U.S. as soon as practicable.

We assessed the KKC Commercialization Agreement in accordance with Topic 808 and Topic 606 and determined that our obligations comprise the U.S. License, the Ex-U.S. License, and development services (the "Development Services"). We determined that the KKC Commercialization Agreement is a collaborative arrangement in accordance with Topic 808 that contains multiple units of account, as we and KKC are both active participants in the development and commercialization activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. The U.S. License is a unit of account under the scope of Topic 808 and is not a deliverable under Topic 606, while the Ex-U.S. License and Development Services performance obligations are also under the scope of Topic 606.

We determined that the total transaction price of $191.5 million is comprised of the upfront payment of $100.0 million, expected milestone payments of $20.0 million, estimated development cost-sharing of $66.3 million, and deferred revenue of $5.2 million from the KKC Japan License Agreement. We included the amount of estimated variable consideration that is not constrained for development cost-sharing in the transaction price, and also determined that any variable consideration related to sales-based royalties and commercial milestones related to licenses of intellectual property as it is determined when the sale or usage occurs and is therefore excluded from the transaction price. In addition, we are eligible to receive future development and regulatory milestones upon the achievement of certain criteria; however, these amounts are excluded from variable consideration as the risk of significant revenue reversal will only be resolved depending on future research and development and/or regulatory approval outcomes. We will re-evaluate the estimated variable consideration included in the transaction price and any related constraints at the end of each reporting period.

We allocated the initial transaction price to each unit of account. Variable consideration that relates specifically to our efforts to satisfy specific performance obligations are allocated entirely to those performance obligations. Other components of the transaction price are allocated based on the relative stand-alone selling price, over which management has applied significant judgment. We developed the estimated stand-alone selling price for the licenses using the risk-adjusted net present values of estimated cash flows, and the estimated stand-alone selling price of the development services performance obligations by estimating costs to be incurred, and an appropriate margin, using an income approach.

We determined that control of the U.S. License and Ex-U.S. License were transferred to KKC during the year ended June 30, 2020, and recognized revenue of $21.0 million related to the Ex-U.S. License. The $64.3 million transaction price allocated to the U.S. License obligation accounted for under Topic 808 is recorded as non-current deferred revenue and will begin to be recognized upon future commercialization as non-ASC 606 revenue. We recorded deferred revenue of $18.1 million for the transaction price allocated to the Development Services performance obligations and will recognize this revenue based on the proportional performance of these development activities, which we expect to recognize through fiscal year 2026.

KKC Japan License Agreement

In October 2018, we, as licensor, entered into a license agreement with KKC for zandelisib ("the KKC Japan License Agreement"). Under the terms of the KKC Japan License Agreement, KKC was granted the exclusive right to develop and commercialize zandelisib in Japan. We also granted KKC the right to purchase supply of zandelisib for commercial requirements at cost plus a pre-negotiated percentage, as well as manufacturing rights in Japan. In return, we received an upfront payment of $10.0 million and were eligible to receive additional development and commercialization milestones, as well as royalties on net sales of zandelisib in Japan. In April 2020, we and KKC agreed to terminate the KKC Japan License Agreement. The KKC Japan License Agreement was replaced with the KKC Commercialization Agreement. Pursuant to the terms of the KKC Commercialization Agreement, we agreed to collaborate with KKC on the development, manufacturing and commercialization of zandelisib in Japan.

We assessed the KKC Japan License Agreement in accordance with ASC 606 and determined that our performance obligations comprised the license, research and development obligations, and our obligation to provide clinical trial materials to KKC. We determined that the transaction price amounted to the upfront payment of $10.0 million.

We determined that control of the license was transferred to KKC during the year ended June 30, 2019. Revenue allocated to the research and development obligations was recognized based on the proportional performance of these research and development activities. Revenue allocated to providing clinical trial materials was recognized upon delivery.

Note 3. BeiGene Collaboration

In October 2018, we entered into a clinical collaboration with BeiGene, Ltd. ("BeiGene") to evaluate the safety and efficacy of zandelisib in combination with BeiGene's zanubrutinib, an investigational inhibitor of Bruton's tyrosine kinase ("BTK"), for the treatment of patients with B-cell malignancies. Under the terms of the clinical collaboration agreement, we amended our ongoing Phase 1b trial to include evaluation of zandelisib in combination with zanubrutinib in patients with B-cell malignancies. Study costs are being shared equally by the parties, and we agreed to supply zandelisib and BeiGene agreed to supply zanubrutinib. We record the costs reimbursed by BeiGene as a reduction of our research and development expenses. We retained full commercial rights for zandelisib and BeiGene retained full commercial rights for zanubrutinib.

Note 4. Other License Agreements

Helsinn License Agreement

In August 2016, we, as licensor, entered into an exclusive worldwide license, development, manufacturing and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical corporation ("Helsinn") for pracinostat in acute myeloid leukemia ("AML"), myelodisplastic syndrome ("MDS") and other potential indications (the "Helsinn License Agreement"). Under the terms of the agreement, Helsinn was granted a worldwide exclusive license to develop, manufacture and commercialize pracinostat, and is primarily responsible for funding its global development and commercialization. As compensation for such grant of rights, we received payments of $20.0 million.

We determined that the agreement contains multiple performance obligations for purposes of revenue recognition. Revenue related to the research and development elements of the arrangement is recognized based on the extent of progress toward completion of each performance obligation. Revenue is recognized on a gross basis as we are the primary obligor and have discretion in supplier selection. During the year ended June 30, 2020, our only remaining performance obligation under the agreement is the conduct of a Phase 2 dose-optimization study of pracinostat in combination with azacitidine in patients with high and very high risk MDS who are previously untreated with hypomethylating agents (the "POC study"), for which Helsinn has agreed to share third-party expenses.

Presage License Agreement

In September 2017, we, as licensee, entered into a license agreement with Presage Biosciences, Inc. ("Presage"). Under the terms of the license agreement, Presage granted to us exclusive worldwide rights to develop, manufacture and commercialize voruciclib, a clinical-stage, oral and selective CDK inhibitor, and related compounds. In exchange, we paid $2.9 million. With respect to the first indication, an incremental $2.0 million payment, due upon dosing of the first subject in the first registration trial will be owed to Presage, for total payments of $4.9 million prior to receipt of marketing approval of the first indication in the U.S., E.U. or Japan. Additional potential payments of up to $179 million will be due upon the achievement of certain development, regulatory and commercial milestones. We will also pay mid-single-digit tiered royalties on the net sales of any product successfully developed. As an alternative to milestone and royalty payments related to countries in which we sublicense product rights, we will pay to Presage a tiered percent (which decreases as product development progresses) of amounts received from such sublicensees.

CyDex License Agreement

We, as licensee, are party to a license agreement with CyDex Pharmaceuticals, Inc. ("CyDex"). Under the terms of the license agreement, CyDex granted to us an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with our isoflavone-based drug compounds (currently ME-344). We agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties at a low, single-digit percentage rate on future sales of our approved drugs utilizing Captisol. Contemporaneously with the license agreement, CyDex entered into a commercial supply agreement with us, pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. We may terminate both the license agreement and the supply agreement at any time upon 90 days' prior written notice.

Note 5. Intangible Assets

Intangible assets consisted of the following, in thousands:

	June 30, 2020	June 30, 2019
S*Bio Patents—Gross	$ 273	$ 500
Less: accumulated amortization	(273)	(239)
Intangible assets, net	$ —	$ 261

Amortization expense of intangible assets for the years ended June 30, 2020, 2019 and 2018 was $34,000, $35,000 and $35,000, respectively. As a result of Helsinn discontinuing the Phase 3 study of pracinostat in AML, we assessed the estimated future cash flows associated with the patents acquired from S*Bio and recorded an impairment charge of $0.2 million to write off the remaining book value of the intangible assets.

Note 6. Property and Equipment

Property and equipment consisted of the following, in thousands:

	June 30, 2020	June 30, 2019
Furniture and equipment	$ 304	$250
Leasehold improvements	842	48
	1,146	**298**
Less: accumulated depreciation	(62)	(94)
Property and equipment, net	$1,084	$204

Depreciation expense of property and equipment for the years ended June 30, 2020, 2019 and 2018 was $75,000, $45,000 and $18,000, respectively.

Note 7. Accrued Liabilities

Accrued liabilities consisted of the following, in thousands:

	June 30, 2020	June 30, 2019
Accrued pre-clinical and clinical trial expenses	$2,343	$2,014
Accrued compensation and benefits	3,410	1,973
Accrued legal and professional services expenses	226	316
Other	111	256
Total accrued liabilities	$6,090	$4,559

Note 8. Stockholders' Equity

Equity Transactions

Underwritten Registered Offering

In December 2019, we completed an underwritten registered offering of 32,343,750 shares of common stock at a price per share of $1.60. We received net cash proceeds of $48.5 million associated with the offering, after costs of $3.3 million.

At-The-Market Equity Offering

In November 2017, we entered into an At-The-Market Equity Offering Sales Agreement (the "ATM Sales Agreement"), pursuant to which we may sell an aggregate of up to $30.0 million of our common stock pursuant to the shelf registration statement. During the year ended June 30, 2020, we sold 5,471,684 shares under the ATM Sales Agreement for net proceeds of $20.7 million, after costs of $0.4 million.

Shelf Registration Statement

We have a shelf registration statement that permits us to sell, from time to time, up to $200.0 million of common stock, preferred stock and warrants. The shelf registration was filed and declared effective in May 2020, replacing our prior shelf registration statement that was filed and declared effective in May 2017, and carrying forward approximately $107.5 million of unsold securities registered under the prior shelf registration statement. Shares sold in the underwritten registered offering in December 2019 and were sold under the prior shelf registration statement. Shares sold under the ATM Sales Agreement prior to and after May 2020 were issued pursuant to the prior shelf registration statement and shelf registration statement, respectively. As of June 30, 2020, there is $178.9 million aggregate value of securities available under the shelf registration statement, including up to $3.2 million remaining available under the ATM Sales Agreement.

May 2018 Private Placement

In May 2018, we raised $70.2 million, net of transaction costs, in a private placement of common shares and warrants. We issued and sold 33,003,296 shares of common stock, as well as warrants to purchase 16,501,645 shares. The price was approximately $2.27 to purchase one share with an accompanying warrant; each warrant is for the purchase of one-half of a share. The warrants are exercisable at a price of $2.54 per share and expire in May 2023. The warrants were fully vested upon issuance in May 2018. In the event of a sale of the Company, the terms of the warrants require us to use our best efforts to ensure the holders of such warrants will have a continuing right to purchase shares of the acquirer and, if our efforts are unsuccessful, to make a payment to such warrant holders based on a Black-Scholes valuation (using variables as specified in the warrants). Therefore, we are required to account for the warrants as liabilities and record them at fair value. We recorded the fair value of the warrants of $36.6 million upon issuance using the Black-Scholes valuation model. The warrants were revalued as of June 30, 2020 and 2019 at $40.5 million and $17.6 million, respectively; the changes in fair value were recorded in our Statement of Operations. During the year ended June 30, 2019, warrants were exercised for 440,043 shares of common stock, and we received proceeds of $1.1 million. As of June 30, 2020, there were outstanding warrants to purchase 16,061,602 shares of our common stock.

Description of Capital Stock

Our total authorized share capital is 226,100,000 shares consisting of 226,000,000 shares of common stock, $0.00000002 par value per share, and 100,000 shares of preferred stock, $0.01 par value per share.

Common Stock

The holders of common stock are entitled to one vote per share. In the event of a liquidation, dissolution or winding up of our affairs, holders of the common stock will be entitled to share ratably in all our assets that are remaining after payment of our liabilities and the liquidation preference of any outstanding shares of preferred stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of holders of common stock are subject to any series of preferred stock that we have issued or that we may issue in the future. The holders of common stock have no pre-emptive rights and are not subject to future calls or assessments by us.

Preferred Stock

Our Board of Directors has the authority to issue up to 100,000 shares of preferred stock with par value of $.01 per share in one or more series and to fix the rights, preferences, privileges and restrictions in respect of that preferred stock, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption (including sinking fund provisions), redemption prices and liquidation preferences, and the number of shares constituting such series and the designation of any such series, without future vote or action by the stockholders. Therefore, the board without the approval of the stockholders could authorize the issue of preferred stock with voting, conversion and other rights that could affect the voting power, dividend and other rights of the holders of shares or that could have the effect of delaying, deferring or preventing a change of control. There were no shares of preferred stock outstanding as of June 30, 2020 or 2019.

Note 9. Share-based Compensation

We use equity-based compensation programs to provide long-term performance incentives for our employees. These incentives consist primarily of stock options and RSUs. In December 2008, we adopted the MEI Pharma, Inc. 2008 Stock Omnibus Equity Compensation Plan (“2008 Plan”), as amended and restated in 2011, 2013, 2014, 2015, 2016 and 2018, under which 19,089,794 shares of common stock are authorized for issuance. The 2008 Plan provides for the grant of options and/or other stock-based or stock-denominated awards to our non-employee directors, officers, employees and advisors. As of June 30, 2020, there were 6,437,150 shares available for future grant under the 2008 Plan.

Total share-based compensation expense for all stock awards consists of the following, in thousands:

	Years Ended June 30,		
	2020	2019	2018
Research and development	$2,777	$2,239	$1,176
General and administrative	4,024	4,323	2,041
Total share-based compensation	$6,801	$6,562	$3,217

Stock Options

Stock options granted to employees vest 25% one year from the date of grant and ratably each month thereafter for a period of 36 months and expire ten years from the date of grant. Stock options granted to directors vest ratably each month for a period of 12 months from the date of grant and expire ten years from the date of grant. As of June 30, 2020, there were a total of 11,252,976 options outstanding.

A summary of our stock option activity and related data follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2019	8,356,961	$ 3.20		
Granted	3,733,333	$ 2.50		
Exercised	(153,679)	$ 1.77		
Forfeited / Cancelled	(125,749)	$ 2.45		
Expired	(557,890)	$ 6.89		
Outstanding at June 30, 2020	11,252,976	$ 2.81	7.8	$15,290,655
Vested and exercisable at June 30, 2020	5,475,069	$ 2.66	7.0	$ 8,330,387

As of June 30, 2020, the aggregate intrinsic value of outstanding options is calculated as the difference between the exercise price of the underlying options and the closing price of our common stock of $4.13 on that date. The total fair value of options that vested during the years ended June 30, 2020, 2019 and 2018 was $5.4 million, $3.4 million and $2.4 million, respectively.

A summary of our non-vested stock option activity:

	Number of Options	Weighted-Average Grant Date Fair Value
Nonvested at June 30, 2019	4,376,928	$ 3.51
Granted	3,733,333	$ 2.50
Forfeited	(76,563)	$ 2.86
Vested	(2,255,791)	$ 3.26
Nonvested at June 30, 2020	5,777,907	$ 2.96

Unrecognized compensation expense related to non-vested stock options totaled $4.7 million as of June 30, 2020. Such compensation expense is expected to be recognized over a weighted-average period of 1.6 years. As of June 30, 2020, we expect all outstanding options to vest.

We use a Black-Scholes valuation model to estimate the grant date fair value of stock options. To calculate these fair values, the following weighted-average assumptions were used:

	Years Ended June 30,		
	2020	2019	2018
Risk-free interest rate	1.7%	2.7%	2.3%
Expected life (years)	6.0	6.0	6.0
Expected volatility	74.1%	82.5%	93.7%
Dividend yield	0.0%	0.0%	0.0%
Weighted-average grant date fair value	$1.64	$2.78	$2.40

Restricted Stock Units

In March 2013, the Compensation Committee of the Board of Directors granted 400,000 RSUs to our Chief Executive Officer. Each RSU represented the contingent right to receive one share of our common stock. The shares underlying the RSUs were delivered on March 29, 2018, and we issued 271,080 shares of common stock, net of shares withheld to cover taxes and fees. The fair value of the RSUs on the date of grant was $3.5 million.

In June 2016, we granted 364,726 RSUs to employees. Each RSU represented the contingent right to receive one share of our common stock. The RSUs were subject to performance criteria that were met in August 2016. The fair value of the RSUs was measured at $1.61 per unit on the date the performance criteria were met. The RSUs vested in August 2018, and we released 332,193 RSU shares. We issued 245,782 shares of common stock to RSU holders; 86,411 shares were surrendered to us by RSU holders as payment for the employee portion of the required withholding of associated payroll taxes.

Note 10. Commitments and Contingencies

We have contracted with various consultants and third parties to assist us in pre-clinical research and development and clinical trials work for our leading drug compounds. The contracts are terminable at any time, but obligate us to reimburse the providers for any time or costs incurred through the date of termination. We also have employment agreements with certain of our current employees that provide for severance payments and accelerated vesting for share-based awards if their employment is terminated under specified circumstances.

Presage License Agreement

As discussed in Note 2, we are party to a license agreement with Presage under which we may be required to make future payments upon the achievement of certain development, regulatory and commercial milestones, as well as potential future royalties based upon net sales. As of June 30, 2020, we have not accrued any amounts for potential future payments.

*S*Bio Purchase Agreement*

We are party to a definitive asset purchase agreement with S*Bio, pursuant to which we acquired certain assets comprised of intellectual property and technology including rights to pracinostat. We agreed to make certain milestone payments to S*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S*Bio. Milestone payments will be made to S*Bio up to an aggregate amount of $75.2 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. The first milestone payment of $200,000 plus 166,527 shares of our common stock having a value of $500,000 was paid in August 2017 upon the first dosing of a patient in a Phase 3 clinical trial. Subsequent milestone payments will be due upon certain regulatory approvals and sales-based events. As of June 30, 2020, we have not accrued any amounts for potential future payments.

CyDex License Agreement

As discussed in Note 2, we are party to a license agreement with CyDex under which we may be required to make future payments upon the achievement of certain milestones, as well as potential future royalties based upon net sales. Contemporaneously with the license agreement, CyDex entered into a commercial supply agreement with us, pursuant to which we agreed to purchase 100% of our requirements for Captisol from CyDex. As of June 30, 2020, we have not accrued any amounts for potential future payments.

COVID-19

In January 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus (the "COVID-19 outbreak") and the risks to the international community. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic based on the rapid increase in exposure globally. As a result of the ongoing and rapidly evolving COVID-19 pandemic, various public health orders and guidance measures have been implemented across much of the United States, and across the globe, including in the locations of our offices, clinical trial sites, key vendors and partners. While we continue to enroll and dose patients in our clinical trials, our clinical development program timelines have been negatively affected by COVID-19. The extent to which the ongoing pandemic continues to impact our business, including our preclinical studies, chemistry, manufacturing, and control (CMC) studies and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to minimize its economic impact.

In light of the COVID-19 outbreak, the FDA issued a number of new guidance documents. Specifically, as a result of the potential effect of the COVID-19 outbreak on many clinical trial programs in the U.S. and globally, the U.S. FDA issued guidance concerning potential impacts on clinical trial programs, changes that may be necessary to such programs if they proceed, considerations regarding trial suspensions and discontinuations, the potential need to consult with or make submissions to relevant ethics committees, IRBs, and the FDA, the use of alternative drug delivery methods, and considerations with respect the outbreak's impacts on endpoints, data collection, study procedures, and analysis. In addition, the European Medicines Agency (EMA) as well as country regulatory authorities have issued similar guidance.

CARES Act

On March 27, 2020, President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security (CARES) Act." The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. Regulatory guidance has indicated that public companies are ineligible to participate in certain of the loan programs provided by the CARES Act. We do not expect that the CARES Act will have a material impact on our financial condition, results of operation, or liquidity.

Legal Proceedings

On August 10, 2020, an individual who allegedly purchased 50 shares of our common stock filed a putative securities class action lawsuit in the United States District Court for the Southern District of California against the Company, Daniel P. Gold, and Brian G. Drazba, asserting claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder. The plaintiff seeks to sue on behalf of all purchasers of our securities from August 2, 2017 through July 1, 2020 and alleges, among other things, that we made false and misleading statements relating to pracinostat during the proposed class period. We believe that the claims are without merit, as to both the facts and the law, and intend to vigorously defend the case. At this stage, the Company cannot predict the ultimate outcome of this case or whether it will result in any loss. Accordingly, the Company has not accrued an amount for any potential loss associated with this action.

Note 11. Leases

In December 2019, we entered into a lease agreement for approximately 32,800 square feet of office space in San Diego, California. The contractual lease term is from July 2020 through March 2028. The average annual lease payments over the term of the lease will approximate $1.5 million, plus a pro rata share of certain building expenses. Our total contractual obligation over the term of the lease is approximately $11.5 million.

Note 12. Segment Information

We have one operating segment, the development of pharmaceutical compounds. All of our assets and liabilities were located in the United States of America as of June 30, 2020, 2019 and 2018.

Note 13. Income Taxes

Pre-tax loss consists of the following jurisdictions (in thousands):

	Years Ended June 30,		
	2020	2019	2018
Domestic	$(46,016)	$(16,819)	$(40,068)
Foreign	—	—	—
Pre-tax loss	$(46,016)	$(16,819)	$(40,068)

The reconciliation of income tax computed at the U.S. federal statutory tax rates to income tax expense is as follows (in thousands):

	Years Ended June 30,					
	2020		2019		2018	
	$	%	$	%	$	%
Tax benefit (expense) at U.S. statutory rates	$ 9,663	21%	$ 3,532	21%	$ 11,019	28%
State tax	9	0%	86	1%	(5,370)	-13%
Warrant liability costs	(4,803)	-10%	5,803	35%	(3,320)	-8%
Equity compensation	(2)	0%	138	1%	(837)	-2%
(Increase) decrease in valuation allowance	(4,230)	-9%	(9,082)	-54%	14,914	37%
Revaluation of deferred taxes	—	0%	—	0%	(15,870)	-40%
Other	(638)	-1%	(478)	-3%	(537)	-1%
	$ (1)	0%	$ (1)	0%	$ (1)	0%

Deferred tax liabilities and assets are comprised of the following (in thousands):

	June 30,	
	2020	2019
Deferred tax assets:		
Deferred revenue	$ 17,325	$ 1,635
Fixed and intangible assets	18,832	15,328
Share-based payments	3,834	3,081
Tax losses carried forward	2,214	18,510
Compensation accruals	709	85
Consultant and other accruals	20	41
Charitable contributions	—	22
Total deferred tax assets	42,934	38,702
Valuation allowance for deferred tax assets	(42,934)	(38,702)
Net deferred tax assets and liabilities	$ —	$ —

We evaluate the recoverability of the deferred tax assets and the amount of the required valuation allowance. Due to the uncertainty surrounding the realization of the tax deductions in future tax returns, we have recorded a valuation allowance against our net deferred tax assets as of June 30, 2020 and 2019. At such time as it is determined that it is more likely than not that the deferred tax assets will be realized, the valuation allowance would be reduced.

We had federal and state net operating loss carryforwards of approximately $4.2 million and $19.1 million as of June 30, 2020. The federal net operating losses will carryforward indefinitely until utilized. State net operating loss carryforwards will begin to expire in 2030.

Our ability to utilize our net operating loss carryforwards may be substantially limited due to ownership changes that have occurred or that could occur in the future under Section 382 of the Internal Revenue Code and similar state laws. During 2020, we completed a study to analyze whether one or more ownership changes had occurred and determined that two such ownership changes did occur. While the ownership changes do limit the amount of net operating loss we are able to use each year, all of our net operating losses are expected to be available for utilization prior to expiring. The Tax Act limits the deduction of net operating losses to 80% of current year taxable income, however, as a result of the CARES Act, the 80% limitation was temporarily repealed until our fiscal year ending June 30, 2021. Additionally, the CARES Act allows for NOLs arising from taxable years beginning after December 31, 2017 and before January 1, 2021 to be carried back to each of the five years prior to the taxable year of such losses.

None of our prior income tax returns have been selected for examination by a major taxing jurisdiction; however, the statutes of limitations for various filings remain open. The oldest filings subject to potential examination for federal and state purposes are 2016 and 2015, respectively. If we utilize a net operating loss related to a closed year, the stature for the year would re-open. We have not reduced any tax benefit on our financial statements due to uncertain tax positions as of June 30, 2020 and we are not aware of any circumstance that would significantly change this result through the end of fiscal year 2020. To the extent we incur income-tax related penalties or interest, we will recognize them as additional income tax expense.

Note 14. Selected Quarterly Financial Information (Unaudited)

The following table presents our unaudited quarterly results of operations for the years ended June 30, 2020 and 2019 (in thousands, except per share amounts).

	Quarters Ended				Year Ended
	June 30, 2020	March 31, 2020	December 31, 2019	September 30, 2019	June 30, 2020
Total revenues	$ 25,504	$ 1,244	$ 1,008	$ 1,157	$ 28,913
Net loss (1)	$(18,476)	$ (4,329)	$ (20,217)	$ (2,994)	$ (46,016)
Basic loss per share	$ (0.17)	$ (0.04)	$ (0.26)	$ (0.04)	$ (0.51)
Diluted loss per share	$ (0.17)	$ (0.04)	$ (0.26)	$ (0.04)	$ (0.51)

	Quarters Ended				Year Ended
	June 30, 2019	March 31, 2019	December 31, 2018	September 30, 2018	June 30, 2019
Total revenues	$ 1,129	$ 1,249	$ 2,049	$ 488	$ 4,915
Net income (loss) (1)	$ 3,052	$(17,354)	$ 12,025	$ (14,542)	$ (16,819)
Basic income (loss) per share	$ 0.04	$ (0.24)	$ 0.17	$ (0.21)	$ (0.24)
Diluted loss per share	$ (0.15)	$ (0.24)	$ (0.15)	$ (0.21)	$ (0.75)

(1) We have experienced large changes in our net loss which relates to the change in fair value of the warrant liability for the years ended June 30, 2020 and 2019. Refer to Note 1 for further discussion.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

(a) Disclosure Controls and Procedures

At the end of the period covered by this Annual Report on Form 10-K, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that the information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

A control system no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within the Company are detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

(b) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a - 15(f) under the Exchange Act. Our internal control was designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Management maintains a comprehensive system of controls intended to ensure that transactions are executed in accordance with management's authorization, assets are safeguarded and financial records are reliable. Management also takes steps to ensure that information and communication flows are effective, and to monitor performance, including performance of internal control procedures.

Management assessed the effectiveness of our internal control over financial reporting as of June 30, 2020, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, management believes that our internal control over financial reporting is effective as of June 30, 2020.

There were no changes in internal control over financial reporting during the quarter ended June 30, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Code of Ethics

We have adopted a Code of Business and Ethics policy that applies to our directors and employees (including our principal executive officer and our principal financial officer), and have posted the text of our policy on our website (www.meipharma.com). In addition, we intend to promptly disclose (i) the nature of any amendment to the policy that applies to our principal executive officer and principal financial officer 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 on our website in the future.

The other information required by this item is incorporated herein by reference to our proxy statement for the fiscal year ended June 30, 2020 (the "Proxy Statement").

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the Proxy Statement.

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

The information required by this item is incorporated herein by reference to the Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated herein by reference to the Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) 1. Financial Statements

Reference is made to the Financial Statements under Item 8 in Part II hereof.

2. Financial Statement Schedules

The Financial Statement Schedules have been omitted either because they are not required or because the information has been included in the financial statements or the notes thereto included in this Annual Report on Form 10-K.

3. Exhibits

Exhibit Index

3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q filed on February 7, 2019 (File No. 000-50484)).
3.5	Certificate of Designation of Series A Convertible Preferred Stock of Marshall Edwards, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on May 11, 2011 (File No. 000-50484))
3.6	Certificate of Designation of Series B Preferred Stock of Marshall Edwards, Inc. (incorporated by reference to Exhibit 4 to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 18, 2011 (File No. 000-50484))
3.7	Third Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 20, 2020 (File No. 000-50484)).
4.1	Specimen Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed on October 31, 2003 (Reg. No. 333-109129)).
4.2	Form of Warrant (incorporated by reference to Exhibit B to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 16, 2018 (File No. 000-50484)).
4.3*	Description of Capital Stock of MEI Pharma, Inc.
10.1	Employment letter dated April 23, 2010, between Marshall Edwards, Inc. and Daniel Gold (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 26, 2010 (File No. 000-50484)).
10.2	Employment letter dated June 1, 2011, between Marshall Edwards, Inc. and Robert D. Mass (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 2, 2011 (File No. 000-50484)).
10.3	Employment letter dated March 6, 2014, between MEI Pharma, Inc. and David M. Urso (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 8, 2014 (File No. 000-50484)).
10.4	Amendment No. 1, dated July 12, 2018, to the Employment Letter dated March 6, 2014, between MEI Pharma, Inc. and David M. Urso. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 16, 2018 (File No. 000-50484)).
10.5	Employment letter dated February 1, 2017, between MEI Pharma, Inc. and Brian G. Drazba (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 3, 2017 (File No. 000-50484)).
10.6	MEI Pharma, Inc. Amended and Restated 2008 Stock Omnibus Equity Compensation Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on November 30, 2018 (File No. 000-50484)).
10.7	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 29, 2011 (File No. 000-50484)).
10.8	Asset Purchase Agreement, dated as of August 7, 2012, between MEI Pharma, Inc. and S*Bio Pte Ltd. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed on August 8, 2012 (File No. 000-50484)).
10.9**	License Agreement, dated September 28, 2012, between Cydex Pharmaceuticals, Inc. and the Company (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 13, 2012 (File No. 000-50484)).
10.10**	Supply Agreement, dated September 28, 2012, between Cydex Pharmaceuticals, Inc. and the Company (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 13, 2012 (File No. 000-50484)).
10.11**	License, Development and Commercialization Agreement, dated August 5, 2016, by and between the Company and Helsinn Healthcare SA (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q/A filed on February 16, 2017 (File No. 000-50484)).

10.12	Common Stock Purchase Agreement, dated as of August 5, 2016, by and between MEI Pharma, Inc. and Helsinn Investment Fund SA (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 9, 2016 (File No. 000-50484)).
10.13**	License Agreement, dated as of September 5, 2017, by and between MEI Pharma, Inc. and Presage Biosciences, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on November 8, 2017 (File No. 000-50484)).
10.14	At-The-Market Equity Offering Sales Agreement, dated November 8, 2017 between MEI Pharma, Inc. and Stifel, Nicolaus & Company, Inc. (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on November 8, 2017 (File No. 000-50484)).
10.15	Securities Purchase Agreement, dated May 11, 2018, between MEI Pharma, Inc. and the purchasers identified in Exhibit A therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 16, 2018 (File No. 000-50484)).
10.17**	License, Development and Commercialization Agreement, dated as of October 31, 2018, by and between the Company and Kyowa Hakko Kirin Co., Ltd., now known as Kyowa Kirin Company (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on February 7, 2019 (File No. 000-50484)).
10.18***	License, Development and Commercialization Agreement, dated as of April 13, 2020, by and between the Company and Kyowa Kirin Co., Ltd. (formerly known as Kyowa Hakko Kirin Co., Ltd.)*
23.1	Consent of Independent Registered Accounting Firm*
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934*
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934*
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

(*) Filed herewith.
(**) Portions of this exhibit have been redacted pursuant to a confidential treatment request filed with the Securities and Exchange Commission.
(***) Portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, on September 9, 2020.

MEI PHARMA, INC.
A Delaware Corporation

By: /s/ Daniel P. Gold
Daniel P. Gold
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities indicated on September 9, 2020.

Signatures	Title
By: /s/ Daniel P. Gold Daniel P. Gold	President, Chief Executive Officer and Director (Principal Executive Officer)
By: /s/ Brian G. Drazba Brian G. Drazba	Secretary, Chief Financial Officer (Principal Financial and Accounting Officer)
By: /s/ Christine A. White Christine A. White	Chairman
By: /s/ Charles V. Baltic III Charles V. Baltic	Director
By: /s/ Thomas C. Reynolds Thomas C. Reynolds	Director
By: /s/ Nicholas R. Glover Nicholas R. Glover	Director
By: /s/ Kevan E. Clemens Kevan E. Clemens	Director
By: /s/ Frederick W. Driscoll Frederick W. Driscoll	Director
By: /s/ Tamar D. Howson Tamar D. Howson	Director
By: /s/ Cheryl L. Cohen Cheryl L. Cohen	Director

Description of Capital Stock of MEI Pharma, Inc.

The following is a description of the capital stock of MEI Pharma, Inc. (the "Company'). The common shares, par value $0.00000002 per share (the "Common Shares'), of the Company are registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act'); while the preferred shares, par value $0.01 per share (the "Preferred Shares'), and warrants to purchase Common Shares of the Company are not so registered. This description does not describe every aspect of the Company's capital stock and is subject to, and qualified in its entirety by reference to, the provisions of the Company's Amended and Restated Certificate of Incorporation and the Company's Second Amended and Restated By-laws, each as currently in effect, each of which is incorporated by reference as an exhibit to the Annual Report on Form 10-K for the fiscal year ended June 30, 2020, of the Company, to which this Description of Capital Stock is filed as Exhibit 4.3. This description is qualified in its entirety by reference to the provisions of the Company's Amended and Restated Certificate of Incorporation, the Company's Second Amended and Restated By-laws and applicable provisions of Delaware law.

Authorized Capital Stock

Under the Company's Amended and Restated Certificate of Incorporation, the Company's total authorized share capital is 226,100,000 shares consisting of 226,000,000 shares of common stock, $0.00000002 par value per share, and 100,000 shares of preferred stock, $0.01 par value per share. As of September 3, 2020, 112,522,001 shares of the Company's common stock and no shares of preferred stock are issued and outstanding.

Common Stock

The holders of common stock are entitled to one vote per share. In the event of a liquidation, dissolution or winding up of the Company's affairs, holders of the common stock will be entitled to share ratably in all of the Company's assets that are remaining after payment of the Company's liabilities and the liquidation preference of any outstanding shares of preferred stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of holders of common stock are subject to any series of preferred stock that we have issued or that we may issue in the future. The holders of common stock have no preemptive rights and are not subject to future calls or assessments by the Company.

Preferred Stock

The board has the authority to issue up to 100,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions in respect of that preferred stock, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption (including sinking fund provisions), redemption prices and liquidation preferences, and the number of shares constituting such series and the designation of any such series, without future vote or action by the shareholders. Therefore, the board of directors, without the approval of the shareholders, could authorize the issue of preferred stock with voting, conversion and other rights that could affect the voting power, dividend and other rights of the holders of shares or that could have the effect of delaying, deferring or preventing a change of control.

Warrants

Generally

The Company may issue warrants to purchase the Company's common stock or preferred stock. Warrants may be issued independently or together with any other securities and may be attached to, or separate from, such securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between the Company and a warrant agent. The terms of any warrants to be issued and a description of the material provisions of the applicable warrant agreement will be set forth in applicable filings with the Securities and Exchange Commission. The number of shares of the Company's common stock to be received upon the exercise of each warrant may be adjusted from time to time upon the occurrence of certain events, including but not limited to the payment of a dividend or other distribution in respect of common stock, subdivisions, reclassifications or combinations of the Company's common stock. The securities receivable upon exercise of each warrant may be adjusted in the event of any reorganization, consolidation, merger, liquidation or similar event.

Holders of the warrants may only exercise their warrants for the purchase of shares of common stock if a registration statement and current prospectus relating to these shares is then in effect and only if the shares are qualified for sale, or deemed to be exempt from qualification under applicable state securities laws.

For the term of the warrants, the holders thereof are given the opportunity to profit from an increase in the per share market price of the Company's common stock, with a resulting dilution in the interest of all other shareholders. So long as the warrants are outstanding, the terms on which the Company could obtain additional capital may be adversely affected. The holders of the warrants might be expected to exercise them at a time when the Company would, in all likelihood, be able to obtain additional capital by a new offering of securities on terms more favorable than those provided by the warrants.

Outstanding Warrants

As of September 3, 2020, the Company has outstanding warrants to purchase 16,061,602 shares of the Company's common stock. The warrants are fully vested, exercisable at a price of $2.54 per share and expire in May 2023. The Company has authorized and reserved for issuance all shares of common stock issuable upon exercise of each warrant.

Anti-Takeover Effects of Amended and Restated Certificate of Incorporation and Second Amended and Restated By-laws

Certain provisions in the Company's Amended and Restated Certificate of Incorporation and the Company's Second Amended and Restated By-laws as well as certain provision of the Delaware General Corporations Law could discourage potential takeover attempts and make attempts by shareholders to change management more difficult. A description of these provisions is set forth below.

Classified Board of Directors

Under the Company's Amended and Restated Certificate of Incorporation and Second Amended and Restated By-laws, directors are to be elected at each annual meeting of stockholders for a term of three years unless the director is removed, retires or the office is vacated earlier. The board is divided into three classes with respect to the term of office, with the terms of office of one class expiring each successive year. This classified board provision could discourage a third party from making a tender offer for the Company's shares or attempting to obtain control of the Company. It could also delay stockholders who do not agree with the policies of the Board of Directors from removing a majority of the Board of Directors for two years.

Advance Notice Requirements for Shareholder Proposals and Nominations for Election as Directors

Under the Company's by-laws, stockholders seeking to bring business before an annual meeting of stockholders or to nominate candidates for election as directors at an annual meeting must provide timely notice thereof in writing to the Company.

To be timely, a shareholder's notice with respect to business to be brought before an annual meeting must be received at the principal executive office of the Company not later than ninety 90 days, nor earlier than 120 days, prior to an annual meeting. However, in the event that no annual meeting was held in the previous year or the date of the current year's annual meeting is more than thirty (30) days before or more than sixty (60) days after the anniversary date of the previous year's annual meeting, the notice by the stockholder must be received by the Secretary at the principal executive offices of the Company not earlier than one hundred and twenty (120) days prior to the current year's annual meeting and not later than the later of ninety (90) days prior to the current year's annual meeting and ten (10) days following the date on which public announcement of the date of such annual meeting is first made. Notwithstanding anything in the preceding sentence to the contrary, in the event that the number of directors to be elected to the Board of Directors at an annual meeting is increased and there is no public announcement by the Company naming all of the nominees for director or specifying the size of the increased Board of Directors at least ninety (90) days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice shall be considered timely, but only with respect to nominees for the new positions created by such increase, if it shall be delivered to the Secretary at the principal executive offices of the Company not later than ten (10) days following the day on which the increase in the number of directors to be elected is first announced to the public by the Company.

Special Meetings of Stockholders

Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Company's notice of meeting. Directors may be elected at a special meeting of stockholders only in accordance with a determination of the Board of Directors that directors are to be elected at the special meetings. With respect to Special Meetings, nominations of persons for election as directors at that special meeting may be made (i) by the Board of Directors or (ii) by a stockholder who has given timely notice thereof in writing to the Secretary of the Company. This shall be the exclusive means for a stockholder to make nominations with regard to a special meeting of stockholders at which directors are to be elected. To be timely, a stockholder's notice must be received by the Secretary at the principal executive offices of the Company not earlier than one hundred and twenty (120) days prior to such special meeting and not later than the later of ninety (90) days prior to such special meeting or ten (10) days following the day on which public announcement of the date of the special meeting and

of the nominees proposed by the Board of Directors to be elected at such meeting is first made. In no event shall the public announcement of an adjournment or postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

Exhibit 10.18

Certain identified information has been excluded from this Exhibit 10.18 because it is both not material and would likely cause competitive harm to MEI Pharma, Inc. if publicly disclosed. The redacted portions are marked as [*CONFIDENTIAL*].

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

by and between

MEI PHARMA, INC.,

and

KYOWA KIRIN CO., LTD.

EFFECTIVE DATE:

APRIL 10, 2020

TABLE OF CONTENTS

LIST OF SCHEDULES

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This License, Development and Commercialization Agreement (this "**Agreement**"), dated as of April 10, 2020 (the "**Effective Date**"), is made by and between MEI Pharma, Inc., a Delaware corporation having an office at 3611 Valley Centre Drive STE 500, San Diego, CA 92130 ("**MEI**"), and Kyowa Kirin Co., Ltd. (formerly known as Kyowa Hakko Kirin Co., Ltd.), a Japanese corporation having an office at 1-9-2 Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan ("**KKC**"). MEI and KKC are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, MEI has certain rights to and is developing the Compounds and Products (each as defined below);

WHEREAS, KKC has extensive experience in developing, promoting and marketing pharmaceutical products throughout the world;

WHEREAS, MEI and KKC believe that a global collaboration and license arrangement between the Parties regarding the Compounds and Products would be desirable and would be of benefit to both Parties;

WHEREAS, the Parties entered into a License, Development and Commercialization Agreement dated October 31, 2018 ("**JP Agreement**") pursuant to which MEI granted a license to KKC under certain intellectual property rights related to the Compound to Develop and Commercialize the Compound and Product in Japan;

WHEREAS, MEI and KKC desire to terminate the JP Agreement in order to, among other things, expand the scope of the JP Agreement to encompass the Development and Commercialization of the Compound and Product in the U.S. and RoW (each as defined below), while maintaining substantially similar terms for Japan contained in the JP Agreement, as set forth herein; and

WHEREAS, the Parties entered into a Mutual Confidentiality Agreement dated July 1, 2019 ("**Prior CDA**") to facilitate the discussion and evaluation of a possible transaction between the Parties subsequent to the JP Agreement.

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, and for other good and valuable consideration, receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows.

ARTICLE 1
DEFINITIONS

Unless the context otherwise requires, the terms in this Agreement with initial letters capitalized, shall have the meanings set forth below, or the meaning as designated in the indicated places throughout this Agreement.

1.1 "**AAA**" has the meaning set forth in Section 14.12(b) (Dispute Resolution).

1.2 "**Acquiring Party**" has the meaning set forth in Section 14.1(b) (Non-Compete).

1.3 "**Affiliate**" means with respect to any person, any other person directly or indirectly controlling, controlled by, or under common control with such person; provided, that, for purposes of this definition, "control" (including, with correlative meanings, the terms "controlled by" and "under common control with"), as used with respect to any person, means (a) the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such person, whether through the ownership of voting securities or by contract or otherwise, or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities of such person. For purposes of this Section 1.3 (Affiliate), "person" means an individual, corporation, partnership, limited partnership, limited liability company, limited liability partnership, syndicate, person (including a "person" as defined in Section 13(d)(3) of the Securities Exchange Act of 1934, as amended, together with the rules and regulations promulgated thereunder), trust, association, entity or government or political subdivision, agency or instrumentality of a government.

1.4 "**Agreement**" has the meaning set forth in the preamble to this Agreement.

1.5 "**Alliance Managers**" has the meaning set forth in Section 2.12 (Alliance Managers).

1.6 "**Alliance Manager Expenses**" means the Commercial FTE Costs for the Alliance Manager and the Out-of-Pocket costs incurred by the Alliance Manager in performing his/her responsibilities for the U.S. in accordance with this Agreement.

1.7 "**Annual Report**" has the meaning set forth in Section 7.1(b) (Development Reports).

1.8 [*CONFIDENTIAL*] means any protein derived from **[*CONFIDENTIAL*]** that binds to or inhibits the human protein **[*CONFIDENTIAL*]**.

1.9 "**Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, and any similar anti-corruption-related Applicable Laws or Applicable Laws related to the prevention of fraud, racketeering, money laundering or terrorism.

1.10 "**Applicable Laws**" means any applicable United States federal, state or local or foreign or multinational law, statute, standard, ordinance, code, rule, regulation, resolution or promulgation, or any order, writ, judgment, injunction, decree, stipulation, ruling, determination or award entered by or with any Governmental Authority, or any license, franchise, permit or

similar right granted under any of the foregoing, or any similar provision having the force or effect of law. For the avoidance of doubt, any specific references to any Applicable Law or any portion thereof, shall be deemed to include all then-current amendments thereto or any replacement or successor law, statute, standard, ordinance, code, rule, regulation, resolution, order, writ, judgment, injunction, decree, stipulation, ruling, or determination thereto, including all applicable "good laboratory practices," "good clinical practices," "good manufacturing practices," and "good distribution practices" as such terms are most broadly defined in the industry.

1.11 "**Audit**" has the meaning set forth in Section 8.6 (Financial Records and Audit).

1.12 "**Authorized Generic**" means a listed drug as defined in §314.3 that has been approved under subsection 505(c) of the U.S. Federal Food, Drug and Cosmetic Act and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug first approved under the same Regulatory Approval.

1.13 "**Blocking Third Party Intellectual Property**" means, with respect to a Compound or Product, Patent or Know-How owned or controlled by a Third Party (but not then included in MEI Technology or KKC Technology) that Cover (with respect to Patent) or are necessary or useful to Develop, Manufacture, have Manufactured, Package, have Packaged, or Commercialize (with respect to Know-How) such Compound or Product in the Field in the U.S.

1.14 "**Blocking Third Party Intellectual Property Costs**" means Out-of-Pocket Costs comprising upfronts, milestones, royalties, and any portion of other license fees or other payments reasonably related to the Development, Manufacture, Packaging or Commercialization of a Product and paid to a Third Party who owns or controls Blocking Third Party Intellectual Property to license or acquire the relevant Patents or Know-How for the Development, Manufacture, Packaging or Commercialization of a Product in the Field in or for the U.S. For clarity, the Parties acknowledge and agree that inclusion of Blocking Third Party Intellectual Property Costs within U.S. Commercialization Costs shall be subject to Section 9.5 (Third Party Intellectual Property Rights).

1.15 "**Business Day**" means a day other than a Saturday, Sunday or a bank or other public holiday in Japan or California.

1.16 "**Calendar Quarter**" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31; provided, that, the first Calendar Quarter hereunder will be deemed to commence on the Effective Date and end on June 30, and the final Calendar Quarter will be deemed to end on the date that this Agreement expires or is terminated.

1.17 "**Calendar Year**" means each respective period of twelve (12) consecutive months ending on December 31; provided, that, the first Calendar Year hereunder will be deemed to commence on the Effective Date and end on December 31, and the final Calendar Year will be deemed to end on the date that this Agreement expires or is terminated.

1.18 "**CFR**" means the U.S. Code of Federal Regulations.

1.19 "**Change of Control**" means (a) a merger or consolidation of a Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's and its Affiliates' assets.

1.20 "**Claims**" means all Third Party demands, claims, actions, proceedings and liability (whether criminal or civil, in contract, tort or otherwise) for losses, damages, legal costs and other expenses of any nature.

1.21 "**Clinical Trial**" means any clinical study of pharmaceutical product on human subjects to assess the dosing, safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of such pharmaceutical product, including any phase I trial, phase II trial, Pivotal Study, or phase IV trial (as such trials, with the exception of Pivotal Study which is defined herein, is defined by any applicable Regulatory Authority); provided, that, post-marketing surveillance studies are not Clinical Trials.

1.22 "**CLL/SLL**" means chronic lymphocytic leukemia/small-cell lymphocytic lymphoma.

1.23 "**CMC**" means chemistry, manufacturing, and controls.

1.24 "**CMO**" means a contract manufacturing organization.

1.25 "**Co-Exclusive**" with respect to a license granted by a Party hereunder, means that: (a) the rights subject to such license shall be granted by such Party only to the other Party and not to any Third Party, and (b) such rights described in the foregoing clause (a) and any rights retained by the granting Party to the MEI Technology (in the case of MEI as the granting Party) or KKC Technology (in the case of KKC as the granting Party) shall be retained and exerciseable only by the granting Party; provided that, notwithstanding the foregoing, a Party may grant a Sublicense of a Co-Exclusive license to a Sublicensee in accordance with Section 3.3 (Sublicense Rights) or a subcontractor in accordance with Section 14.3 (Subcontractor).

1.26 "**COGS**" means, with respect to a Product, the manufacturing cost for such Product, which (a) to the extent such Product is manufactured by a Party or its Affiliates, shall approximate a reasonable definition of cost of goods sold for such Product with no markup, assuming full utilization of Manufacturing capacity, and (b) to the extent such Product is manufactured by a Third Party in an arms-length transaction, the Out-of-Pocket Costs paid to such Third Party for the manufacture of such Product.

1.27 "**Collaboration Losses**" means losses, damages, legal costs and other expenses of any nature resulting from a Claim that arise out of the performance, in good faith, of Development, Manufacture, Packaging, Commercialization or other exploitation of Products following the Effective Date in the U.S. in accordance with this Agreement.

1.28 "**Combination Product**" means any Product comprising the following, either formulated together (i.e., a fixed dose combination) or packaged together and sold for a single price: (a) a Compound and (b) at least one other active pharmaceutical ingredient that is not Controlled by MEI.

1.29 "**Commercial FTE Costs**" means the relevant Commercial FTEs times the sum of (a) the Incentive Compensation and (b) the appropriate Commercial FTE Rate, where,

(a) "**Commercial FTE**" means personnel directly engaged in performing Commercialization activities under the U.S. Commercialization Plan whose time and effort, in the aggregate, is equivalent to the time and effort of one (1) employee devoted exclusively to Commercialization activities based on 1880 person hours per year.

(b) "**Incentive Compensation**" means any cash or non-cash incentive compensation awarded to a personnel directly engaged in performing Commercialization activities under the U.S. Commercialization Plan paid or awarded pursuant to any incentive plan or arrangement maintained, contributed to or sponsored by the applicable Party, as each may be amended from time to time, and as such incentive compensation is further described in the Co-Promotion Agreement.

(c) "**Commercial FTE Rate**" means the "Commercial FTE Rate" as defined by the JCC for all roles included as billable under this Agreement with geographic adjustments as deemed appropriate by the JCC, which rates will be **[*CONFIDENTIAL*]** for each of MEI and KKC and will increase or decrease January 1 of each Calendar Year (starting with January 1, 2021) in accordance with the percentage year-over-year increase or decrease of the Mercer Human Resource Consulting Base Pay Increase for the Pharmaceutical/Biotechnology Industry.

1.30 "**Commercialization**" means to promote, market, distribute, sell (and offer for sale or contract to sell), import, conduct post-marketing surveillance, or otherwise commercially exploit or provide product support for a Product and to conduct activities, other than Development, Packaging, or Manufacturing, in preparation for conducting the foregoing activities, including activities to produce commercialization support data and to secure and maintain market access and reimbursement. "**Commercializing**" and "**Commercialization**" shall have correlative meanings.

1.31 "**Commercialization Plan**" means the U.S. Commercialization Plan, the JP Commercialization Plan, and/or the RoW Commercialization Plan, as applicable.

1.32 "**Commercially Reasonable Efforts**" means, with respect to the efforts and resources to be expended by a Party with respect to the Compound and Product hereunder, the level of efforts and resources consistent with the efforts and resources a pharmaceutical company of similar size and situation in the exercise of its reasonable business judgment typically devotes to its own product candidates of similar market potential, at a similar stage in development or

product lifecycle, taking also into account the stage of development or product lifecycle of other products in such Party's portfolio candidates, issues of safety and efficacy, product profile, the proprietary position of the Compound and Product, cost of goods, the competitiveness of the marketplace, the regulatory structure involved, the likelihood of regulatory approval, the anticipated or actual profitability of the applicable product, and other technical, legal, scientific and medical considerations; provided, that in any event each Party shall use no less than those efforts it uses with respect to its other high priority assets. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Party: (a) promptly assign responsibility for such obligation to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set objectives for carrying out such obligations, and (c) allocate resources designed to advance progress with respect to such objectives.

1.33 "**Committee**" means the JSC, JDC, JMC, JCC, and/or JFC, as applicable.

1.34 "**Competitive Program**" has the meaning set forth in Section 14.1(b) (Non-Compete).

1.35 "**Compound**" means the small molecule referred to by MEI as ME-401, generic name "zandelisib", having the structure set forth on Schedule 1.35 and **[*CONFIDENTIAL*]**.

1.36 "**Conducting Party**" has the meaning set forth in Section 4.1(e)(ii) (Exception).

1.37 "**Confidential Information**" of a Party means all Know-How, unpublished patent applications and other information and data of a financial, commercial, business, operational, scientific, clinical, medical or technical nature of such Party that is disclosed or made available by or on behalf of such Party or any of its Affiliates to the other Party or any of its Affiliates, whether made available orally, in writing or in electronic or other form, under this Agreement, the JP Agreement, or the Prior CDA. The terms of this Agreement, the JP Agreement, and the Prior CDA are the Confidential Information of both Parties.

1.38 "**Control**" and "**Controlled by**" means, with respect to any Know-How, Invention, Patent, technology, copyright, trademark or other intellectual property right, the possession by a Party or its Affiliates (whether by ownership, license grant or other means) of the legal right to grant the right to access or use, or to grant a license or a sublicense to, such Know-How, Invention, Patent, technology, copyright, trademark or other intellectual property right as provided for herein without violating the proprietary rights of any Third Party or any terms of any agreement or other arrangement between such Party (or any of its Affiliates) and any Third Party.

1.39 "**Co-Promotion Agreement**" has the meaning set forth in Section 4.3 (Co-Promotion Agreement).

1.40 "**Cover**", "**Covered**" or "**Covering**" means, with respect to a Patent, that, in the absence of a license granted to a Person under a Valid Claim included in such Patent, the Manufacture, Packaging, use, practice, distribution or sale of the subject matter of such Patent by such Person would infringe, or contribute to or induce the infringement of, such Valid Claim, or with respect to a Patent application, as if such Valid Claim was contained in an issued Patent.

1.41 "**Deductions**" has the meaning set forth in Section 1.117 (Net Sales).

1.42 "**Develop**" means to research, develop, analyze, test and conduct preclinical trials, Clinical Trials, any preclinical/clinical/CMC commitments following Regulatory Approval and all other regulatory trials, for the Compound or a Product, including new Indications, new formulations and all other activities, including regulatory activities, related to securing and maintaining Regulatory Approval, for the Compound or a Product. For the avoidance of doubt, Develop shall include activities such as conducting in vitro, in vivo or in silico studies for the purpose of determining which Indication to pursue. "**Developing**" and "**Development**" shall have correlative meanings.

1.43 "**Development Plan**" means the U.S. Development Plan, the JP Development Plan, and/or the RoW Development Plan, as applicable.

1.44 "**Direct Licensee**" means a service provider or subcontractor (including academic and medical institutions or the like) engaged by MEI as set forth in Section 14.3 for the performance of MEI's obligations under this Agreement, and which receives a license by MEI to MEI Technology solely for the purpose of performing such obligations for the benefit of MEI.

1.45 "**Disclosing Party"** has the meaning set forth in Section 10.1(a) (Duty of Confidence).

1.46 "**Distribution Costs**" means all Out-of-Pocket Costs and Commercial FTE Costs identifiable to the distribution of Products, including customer and wholesaler services, collection of data about sales to hospitals and other customers, order entry, billing, shipping, logistics, warehousing, product insurance, freight not paid by customers, credit and collection and other like activities the costs of which are includable in "Distribution Costs" in accordance with GAAP, which shall not otherwise be included in U.S. Commercialization Costs. For clarity, "Distribution Costs" shall not include costs of activities included within: (a) gross-to-net calculations included in Net Sales, (b) Marketing Expenses, (c) Medical Affairs Expenses, or (d) Selling Expenses.

1.47 "**DLBCL**" means diffuse large B-cell lymphoma.

1.48 "**Dollar**" means U.S. dollars, and "$" shall be interpreted accordingly.

1.49 "**Early Access Program**" means any program to provide patients with a Product prior to Regulatory Approval in any country in the Territory, including treatment INDs/protocols, named patient programs and compassionate use programs. For clarity, an Early Access Program with respect to a Product may continue to be performed following Regulatory Approval of such Product and costs may continue to be incurred in accordance with the performance of such Early Access Program after Regulatory Approval.

1.50 "**Early Access Program Expenses**" means the Out-of-Pocket Costs and Commercial FTE Costs to conduct Early Access Programs for the Product in accordance with this Agreement.

1.51 "**Effective Date**" has the meaning set forth in the preamble to this Agreement.

1.52 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.53 "**Excluded Claim**" has the meaning set forth in Section 14.12(g) (Dispute Resolution).

1.54 "**Executive Officer**" has the meaning set forth in Section 14.12(a) (Dispute Resolution).

1.55 "**Existing Data Agreement**" means the GDPR Joint Controller and Onward Transfer Agreement between the Parties dated October 31, 2018.

1.56 "**Expiration Date**" means, on a country-by-country basis, the latest of: (a) expiration of the last-to-expire Valid Claim of the MEI Patents that Covers the composition of matter, pharmaceutical composition, Manufacture, use or sale of a Product (or the Compound contained therein) in such country; (b) expiration of Regulatory Exclusivity for such Product in such country; or (c) **[*CONFIDENTIAL*]** after the First Commercial Sale of such Product in such country.

1.57 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.58 "**Field**" means all prophylactic, diagnostic and therapeutic uses for any human disease.

1.59 "**Financial Exhibit**" means Schedule 1.59 attached hereto, as may be amended from time to time by mutual written agreement of the Parties.

1.60 "**First Commercial Sale**" means the first shipment of the Product by or on behalf of a Party (as applicable) or its Affiliate or its Sublicensee to a Third Party in a given/applicable country in the Territory for end use or consumption of the Product after Regulatory Approval of the Product in such country or, if earlier, the invoicing of a Third Party for such shipment. Sales or transfers of reasonable quantities of the Product for Clinical Trial purposes, or for compassionate or similar use, shall not be considered a First Commercial Sale.

1.61 "**FL**" means follicular lymphoma.

1.62 "**GAAP**" means the then-current Generally Accepted Accounting Principles or International Financial Reporting Standards (IFRS), whichever is adopted as the standard financial accounting guideline in the United States for public companies, as consistently applied.

1.63 "**GDPR**" has the meaning set forth in Section 14.2 (Personally-Identifiable Data / GDPR Compliance).

1.64 "**GDPR Agreement**" has the meaning set forth in Section 14.2 (Personally-Identifiable Data / GDPR Compliance).

1.65 "**Generic Product**" means any pharmaceutical product that is distributed by a Third Party (that is not licensed or otherwise permitted by KKC or its Affiliates or its Sublicensees) in a country (a) under a Regulatory Approval approved by a Regulatory Authority in reliance, in

whole or in part, on the Regulatory Approval for the Product, including any product authorized for sale (i) in the United States pursuant to Section 505(b)(2) or 505(j) of the FD&C Act (21 U.S.C. 355(b)(2) and 355(j), respectively), (ii) in the EU pursuant to Article 10 of Directive 2001/83/EC as amended, or (iii) in other countries in the Territories all equivalents of such provisions in (i) and (ii), and (b) which product (i) contains the same active pharmaceutical ingredient(s) as the Product, (ii) is approved based in significant part upon clinical data generated and used for obtaining Regulatory Approval of the Product and (iii) is approved for at least one of the same Indication(s) as the Product in such country.

1.66 "**Government Authority**" means any United States federal, state or local, or any foreign, government or political subdivision thereof, or any multinational organization or authority, or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or Taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body. For clarity, any Regulatory Authority shall be a Governmental Authority.

1.67 "**Gross Sales**" has the meaning set forth in Section 1.117 (Net Sales).

1.68 "**Health Care Reform Fees**" means Out-of-Pocket Costs representing the annual fee paid to the U.S. government as defined in the Affordable Care Act and similar Taxes and governmental fees in the United States, in each case to the extent directly attributable to the Product. If any similar governmental fee is legislated, or analogous rule created, in any jurisdiction in the Territory, to the extent directly attributable to the Product, this shall also be included as Health Care Reform Fee.

1.69 "**IND**" means an investigational new drug application, clinical trial authorization or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority including the Clinical Trial Notification to the MHLW.

1.70 "**Indemnified Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.71 "**Indemnifying Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.72 "**Indication**" means a separate and distinct disease, disorder, illness or health condition for which **[*CONFIDENTIAL*]**.

1.73 "**Infringement Claim**" has the meaning set forth in Section 9.5(a) (Third Party Intellectual Property Rights).

1.74 "**Invention**" means any improvement, addition, refinement, modification, development, discovery or invention, whether or not patentable, that is conceived, reduced to practice or otherwise developed by either Party, or by both Parties, under this Agreement.

1.75 "**JCC**" has the meaning set forth in Section 2.5 (Joint Commercialization Committee).

1.76 "**JDC**" has the meaning set forth in Section 2.3 (Joint Development Committee).

1.77 "**JFC**" has the meaning set forth in Section 2.6 (Joint Finance Committee).

1.78 "**JMC**" has the meaning set forth in Section 2.4 (Joint Manufacturing Committee).

1.79 "**Joint Inventions**" has the meaning set forth in Section 9.1(b) (Ownership of Inventions).

1.80 "**Joint Patents**" has the meaning set forth in Section 9.1(b) (Ownership of Inventions).

1.81 "**JPY**" means the Japanese Yen (i.e., the currency in Japan).

1.82 "**JP Aggregate Annual Net Sales**" has the meaning set forth in Section 5.3(d)(i) (JP - Royalty Payments).

1.83 "**JP and RoW Quality Agreement**" has the meaning set forth in Section 7.3(b)(i) (JP and RoW – Supply Terms).

1.84 "**JP and RoW Supply Agreement**" has the meaning set forth in Section 7.3(b)(i) (JP and RoW – Supply Terms).

1.85 "**JP and RoW Supply Items**" has the meaning set forth in Section 7.3(b) (JP and RoW – Supply).

1.86 "**JP Clinical Quality Agreement**" means the quality agreement executed between the Parties dated December 21, 2018.

1.87 "**JP Clinical Supply Agreement** means the supply agreement executed between the Parties dated December 21, 2018.

1.88 "**JP Commercialization Plan**" has the meaning set forth in Section 5.2(a) (JP – Commercialization Plan).

1.89 "**JP Development Costs**" has the meaning set forth in Section 5.1(c) (JP – Development Costs).

1.90 "**JP Development Plan**" has the meaning set forth in Section 5.1(a) (JP – Development Plan).

1.91 "**JP Promotional Materials**" has the meaning set forth in Section 5.2(c) (JP – Creation of Promotional Materials).

1.92 "**JP Royalty Term**" has the meaning set forth in Section 5.3(d)(ii) (JP - Royalty Term).

1.93 "**JSC**" has the meaning set forth in Section 2.2(a) (Purpose; Formation).

1.94 "**KKC**" has the meaning set forth in the preamble to this Agreement.

1.95 "**KKC Data**" has the meaning set forth in Section 9.1(a) (Data).

1.96 "**KKC Indemnitees**" has the meaning set forth in Section 13.1 (Indemnification by MEI).

1.97 "**KKC Know-How**" means all Know-How that KKC Controls as of the Effective Date or during the Term that is necessary for the Development, Packaging, and/or Manufacture of the Compound or Product and/or Commercialization of any Product in the Field, including KKC Data. Notwithstanding the foregoing, "KKC Know-How" does not include any Know-How that is owned or in-licensed by a Third Party described in the definition of "Change of Control" or such Third Party's Affiliates (a) prior to the closing of such Change of Control, except to the extent that any such Know-How was Controlled by KKC or any of its Affiliates prior to such Change of Control, or (b) after such Change of Control (other than arising from (i) KKC's or any of its Affiliates' performance of activities hereunder or (ii) the use of any KKC Technology).

1.98 "**KKC Patents**" means all Patents that KKC Controls as of the Effective Date or during the Term that Cover the Development, Packaging, and/or Manufacture of the Compound or Product and/or Commercialization of any Product in the Field in the Territory. The KKC Patents existing as of the Effective Date are listed on Schedule 1.98; provided, that "KKC Patents" do not include any Joint Patent. Notwithstanding the foregoing, "KKC Patent" does not include any Patent that is owned or in-licensed by a Third Party described in the definition of "Change of Control" or such Third Party's Affiliates **[*CONFIDENTIAL*]**.

1.99 "**KKC Technology**" means the KKC Know-How, the KKC Patents, and KKC's interest in the Joint Patents.

1.100 "**KKC Trademarks**" has the meaning set forth in Section 9.8(b) (KKC Trademarks). For clarity, KKC Trademarks do not include KKC's name and logo.

1.101 "**Know-How**" means all secret and substantial technical, scientific, regulatory and other information, results, knowledge, techniques, in whatever form and whether or not confidential or patentable, Inventions, invention disclosures, discoveries, plans, processes, practices, methods, knowledge, trade secrets, know-how, instructions, skill, experience, ideas, concepts, data (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, safety, quality control, and preclinical and clinical data), formulae, formulations, compositions, specifications, marketing, pricing, distribution, cost, sales and Manufacturing data or descriptions. Know-How does not include any Patent claiming any of the foregoing.

1.102 "**Manufacture**" or "**Manufacturing**" or "**Manufactured**" means, with respect to the Compound and Product, the receipt, handling and storage of active pharmaceutical ingredients, drug substance or drug product and other materials, the manufacturing, processing, holding (including storage), quality assurance and quality control testing (including release) of the Compound and Product (other than quality assurance and quality control related to development of the Manufacturing process, which activities shall be considered Development activities) and

shipping of the Compound and Product. For the avoidance of doubt, Manufacturing does not include Development, Packaging, and Commercializing.

1.103 "**Manufacturing Technology Transfer Plan**" has the meaning set forth in Section 3.7(c) (Technology Transfer to KKC).

1.104 "**Marketing Authorization Application**" or "**MAA**" means an application to the appropriate Regulatory Authority for approval to market and sell the Product (but excluding Pricing Approval) in any particular country or regulatory jurisdiction.

1.105 Marketing Authorization Holder" means, on a country-by-country basis, the Party or other entity that owns the applicable Regulatory Approval following the approval of the Marketing Authorization Application for and in such country.

1.106 "**Marketing Expenses**" means Out-of-Pocket Costs and Commercial FTE Costs identifiable to the advertising, promotion and marketing of a Product in the Field, and related professional education, in each case to the extent incurred specifically with respect to a Product (and to the extent not performed by sales representatives), including:

(a) Advertising, which includes Out-of-Pocket Costs and Commercial FTE Costs associated with media costs, direct mails, production expenses, agency fees, and medical congresses and meetings and other advertising activities;

(b) Promotion, which includes Out-of-Pocket Costs and Commercial FTE Costs associated with professional samples, reimbursement of patient assistance programs, public relations and communications expenses, development of information and data for national accounts, managed care organizations and group purchasing organizations and other promotional activities;

(c) Market research, which includes Out-of-Pocket Costs and Commercial FTE Costs associated with market information, focus groups, and market research professional staff and related Out-of-Pocket Costs such as travel, and business meals;

(d) Marketing management, which includes the Out-of-Pocket Costs and Commercial FTE Costs of product management Commercial FTEs, to the extent directly performing activities with respect to the marketing and brand strategy development of Products;

(e) Reimbursement/access services, which includes Out-of-Pocket Costs incurred to manage marketing programs, marketing costs (educational material) as well as coupon or co-pay programs directly attributable to a Product; provided, however, that, if employees of MEI or KKC or any of their respective Affiliates provide this service, then the Commercial FTE Costs of such employees and the related Out-of-Pocket Costs such as travel, business meals, and entertainment will be included;

(f) Health policy/advocacy, which includes expenses reasonably necessary and identifiable to a Product, such as advocacy sponsorships for the Product's specific disease state as well as any specific policy lobbying and trade and government relations related expenses, in each case to the extent attributable to and specifically conducted with respect to such Product;

(g) Activities involving opinion leaders;

(h) Launch meetings;

(i) Conducting advisory board meetings or other consultant programs, the purpose of which is to obtain advice and feedback related to the Commercialization of a Product; and

(j) Web site (product or disease state) development, implementation and fees.

1.107 "**Medical Affairs Expenses**" means Out-of-Pocket Costs and Commercial FTE Costs reasonably necessary and identifiable to the Product incurred with respect to: medical and scientific information and response to external inquiries or complaints; pharmacovigilance, investigator initiated research if not covered in the U.S. Development Plan, medical education, Health Economics and Outcomes Research (HECOR, HEMAR), speaker programs, advisory boards, educational grants and fellowships, drug safety, local country government affairs, generating health economics and outcomes research data from patient reported outcomes, prospective observational studies and retrospective observational studies, and economic models and reimbursement dossiers; and field based medical science liaisons, medical affairs clinical trial management, medical doctors in field (separate from medical science liaisons), publications, medical communications and field medical education.

1.108 "**MEI**" has the meaning set forth in the preamble to this Agreement.

1.109 "**MEI Data**" has the meaning set forth in Section 9.1(a) (Data).

1.110 "**MEI Indemnitees**" has the meaning set forth in Section 13.2 (Indemnification by KKC).

1.111 "**MEI Know-How**" means all Know-How that MEI Controls as of the Effective Date or during the Term that is necessary for the Development, Packaging, and/or Manufacture of the Compound or Product and/or Commercialization of any Product in the Field, including MEI Data. Notwithstanding the foregoing, "MEI Know-How" does not include any Know-How that is owned or in-licensed by a Third Party described in the definition of "Change of Control" or such Third Party's Affiliates (a) prior to the closing of such Change of Control, except to the extent that any such Know-How was Controlled by MEI or any of its Affiliates prior to such Change of Control, or (b) **[*CONFIDENTIAL*]**.

1.112 "**MEI Patents**" means all Patents that MEI Controls as of the Effective Date or during the Term that Cover the Development, Packaging, and/or Manufacture of the Compound or Product and/or Commercialization of any Product in the Field in the Territory. The MEI Patents existing as of the Effective Date are listed on Schedule 1.112; provided, that "MEI Patents" do not include any Joint Patent. Notwithstanding the foregoing, "MEI Patent" does not include any Patent that is owned or in-licensed by a Third Party described in the definition of "Change of Control" or such Third Party's Affiliates (a) prior to the closing of such Change of Control, except to the extent that any such Patent was Controlled by MEI or any of its Affiliates prior to such Change of Control, or **[*CONFIDENTIAL*]**.

1.113 "**MEI Technology**" means the MEI Know-How, the MEI Patents, and MEI's interest in the Joint Patents.

1.114 "**MEI Trademarks**" means trademark(s) registered or created by MEI for use with the Product. For clarity, MEI Trademarks do not include MEI's name and logo.

1.115 "**MHLW**" means the Japanese Ministry of Health, Labor and Welfare, or a successor agency thereto.

1.116 "**MZL**" means marginal zone B-cell lymphoma.

1.117 "**Net Sales**" means, with respect to a Product, the gross amounts invoiced for sales or other dispositions of such Product by or on behalf of a Party, its Affiliates and Sublicensees ("**Selling Party**") to Third Parties in the Territory ("**Gross Sales**"), less the following deductions to the extent included in the gross invoiced sales price for such Product or otherwise paid or incurred by such Selling Party, with respect to the sale or other disposition of such Product, in each and every case solely to the extent permitted to be taken as a deduction in accordance with GAAP ("**Deductions**"):

(a) normal and customary trade and quantity discounts, allowances, and credits actually allowed and properly taken with respect to sales of such Product;

(b) credits or allowances given or made for defects, rejection, recalls or return of previously sold Products or for retroactive price reductions and billing errors;

(c) discounts, rebates, reimbursements, and chargeback payments granted to managed health care organizations or other health care institutions (including hospitals), health care administrators, patient assistance or similar programs, pharmacy benefit managers (or equivalents thereof), wholesalers and other distributors, pharmacies and other retailers, group purchasing organizations or other buying groups, health maintenance organizations, national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, any other providers of health insurance coverage, or to trade customers;

(d) transportation costs and related insurance charges actually incurred; and

(e) any Taxes levied on or with respect to such Product (excluding Taxes imposed on or with respect to net income, however, denominated).

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements shall be allocated among the relevant products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with the Selling Party's existing allocation method; provided that any such allocation to a Product shall: (i) be done in accordance with Applicable Law, including any price reporting laws, rules and regulations and (ii) subject to clause (i), in no event, be greater than a pro rata allocation, such that the portion of each of the foregoing rebates, discounts and other forms of reimbursements shall not be included as deductions from invoiced sales hereunder in any amount greater than the proportion of the number

of units of such Product sold by the Selling Party to Third Parties hereunder compared to the number of units of all the products sold by the Selling Party to Third Parties to which such foregoing rebate, discount or other form of reimbursement, as applicable, are granted.

If a Product is sold or otherwise commercially disposed of for consideration other than cash or in a transaction that is not at arm's length between the buyer and the seller, then the gross amount to be included in the calculation of Net Sales shall be the amount that would have been invoiced had the transaction been conducted at arm's length and for cash. Such amount that would have been invoiced shall be determined, wherever possible, by reference to the average selling price of the relevant Product in arm's length transactions in the relevant jurisdiction in the relevant Calendar Quarter.

Such amounts shall be determined in accordance with GAAP, consistently applied.

All deductions shall only be allowable to the extent they are commercially reasonable and shall be determined, on a jurisdiction-by-jurisdiction basis, as incurred in the ordinary course of business in type and amount consistent with the Selling Party's normal practices (as the payment is accrued by such entity); provided, however, that, if the accrued amount with respect to such deduction is determined in a subsequent Calendar Quarter to have been greater than the actual amount of such deduction, the amount over-accrued shall be included in Net Sales in such subsequent Calendar Quarter. For purposes of determining Net Sales, a Product shall be deemed to be sold when billed or invoiced and a sale shall not include transfers or dispositions of such Product for pre-clinical or clinical purposes or provided in good faith as samples or through patient assistance programs, in each case, without charge.

In the event that a Product is sold as part of a Combination Product, then Net Sales for such product shall be determined by multiplying the net sales of the Combination Product (as calculated in accordance with analogous criteria as set forth above for the "Net Sales" definition) by the fraction, A / (A+B) where A is the weighted average sale price of such Product when sold separately in finished form, and B is the weighted average sale price of the other active compound or ingredient in the Combination Product sold separately in finished form.

In the event that the weighted average sale price of a Product can be determined but the weighted average sale price of the other active compound or ingredient in the Combination Product cannot be determined, then Net Sales for such product shall be calculated by multiplying the net sales of the Combination Product (as calculated in accordance with analogous criteria as set forth above for the "Net Sales" definition) by the fraction A / C where A is the weighted average sale price of such Product when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of the other active compounds or ingredients in the Combination Product can be determined but the weighted average sale price of such Product cannot be determined, Net Sales for such product shall be calculated by multiplying the net sales of the Combination Product (as calculated in accordance with analogous criteria as set forth above for the "Net Sales" definition) by the following formula: one (1) minus B / C where B is the weighted average sale price of the other active compound or ingredient in the Combination

Product when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of both a Product and the other active compound or ingredient in the Combination Product cannot be determined in the Territory, then, the Parties shall negotiate in good faith a reasonable adjustment to Net Sales in the Territory that takes into account all factors reasonably relevant to the relative value of the Compound, on the one hand, and all of the other active ingredient(s), collectively, on the other hand.

Upon the sale or other disposal of a Product, such sale, disposal or use will be deemed to constitute a sale with the consideration for the sale being the consideration for the relevant transaction and constituting Net Sales hereunder, or if the consideration is not a monetary amount, a sale will be deemed to have occurred for a price assessed on the value of whatever consideration has been provided in exchange for the sale. Disposal of a Product for or use of a Product in Clinical Trials or as free samples will not give rise to any deemed sale under this definition. Such amounts will be determined from the books and records of the Selling Party maintained in accordance with GAAP or corresponding accounting standards in any other jurisdiction, consistently applied throughout the organization.

In no event shall any particular amount of deduction identified above be deducted more than once in calculating Net Sales (*i.e.*, no "double counting" of deductions).

1.118 "**Net Profit or Loss**" means the amount calculated in accordance with the Financial Exhibit.

1.119 "**NHI**" means the Japanese national health insurance system, or its successor system.

1.120 "**NHI Price**" means the reimbursement price of the Product for purposes of the NHI.

1.121 "**NHI Price Approval**" means approval of the NHI Price by the MHLW.

1.122 "**Non-Appointing Party**" has the meaning set forth in Section 2.10 (Appointment Not an Obligation).

1.123 "**Non-Conducting Party**" has the meaning set forth in Section 4.1(e)(ii) (Exception).

1.124 "**Other Allowable Expense**" means any Out-of-Pocket Costs and Commercial FTE Costs approved by the JSC and included in the applicable U.S. Commercialization Plan and the applicable U.S. Commercialization Budget that is not otherwise included in any other U.S. Commercialization Cost category. It is understood that Other Allowable Expenses shall not include costs associated with U.S. Development activities.

1.125 "**Other Income**" means any payment or income (other than Net Sales) received by a Party or its Affiliate from a Third Party that is attributable to a Product or is received in connection with the grant of a Sublicense or other right or activity with respect to the Products.

1.126 "**Out-of-Pocket Costs**" means amounts paid to Third Party vendors or contractors for services or materials provided by them directly in the performance of activities under the U.S. Development Plan or the U.S. Commercialization Plan, as applicable, to the extent such services or materials apply directly to a Compound or Product (or such amounts paid to Third Parties for other activities not included in determination of U.S. Development Costs or U.S. Commercialization Costs, but for which sharing of Out-of-Pocket Costs is otherwise specified in this Agreement). For clarity, Out-of-Pocket Costs do not include payments for the following internal expenses: salaries or benefits; travel expenses; facilities; utilities; general office or facility supplies; insurance; information technology, capital expenditures or the like.

1.127 "**Package**" and "**Packaging**" means all final Product labeling and packaging (whether in commercial or clinical packaging presentation), including packaging the capsules to its primary package, secondary packaging, insertion of materials such as package inserts, providing patient medication guides, professional inserts and any other written, printed or graphic materials accompanying the Product and considered to be part of the finished Product packaging and labeling, and handling storage, quality control, quality assurance, testing and release of Product with respect to a given country.

1.128 "**Partial Termination**" means, a termination of this Agreement in part with respect to a Territory (i.e., the U.S., Japan, or the entire RoW in the case of termination for material breach as set forth in Section 11.2(b)) or with respect to a country (in the case of termination for force majeure as set forth in Section 11.2(f)) (such Territory or country, as applicable, a "**Terminated Jurisdiction**").

1.129 "**Party**" and "**Parties**" have the meanings set forth in the preamble to this Agreement.

1.130 "**Patent**" means any and all (a) issued patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisionals and renewals, and all patents granted thereon, (c) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, Patent Term Extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing, and (f) United States and foreign counterparts of any of the foregoing.

1.131 "**Patent Term Extension**" means any term extensions, supplementary protection certificates and equivalents thereof offering Patent protection beyond the initial term with respect to any issued Patents.

1.132 "**Payee**" means the Party receiving the payment under this Agreement.

1.133 "**Payor**" means the Party making the payment under this Agreement.

1.134 "**Person**" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association or other entity.

1.135 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 7.5 (Pharmacovigilance).

1.136 "**Pivotal Study**" means a human clinical trial (a) on a sufficient number of subjects that is designed to establish that the compound or product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with the compound or product in the dosage range to be prescribed, and to support Regulatory Approval of the compound or product for an Indication or label expansion of the compound or product, (b) that would otherwise satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations) or any equivalent regulations in the countries in the Territory, regardless of where such clinical trial is conducted, or (c) that the data from which is actually used for registration purposes.

1.137 "**PMDA**" means the Pharmaceuticals and Medical Devices Agency of Japan, which is an extra-ministerial bureau of the MHLW and is responsible for, among other things, the evaluation of new drugs, and offers face-to-face consultation services, or a successor agency thereto.

1.138 "**Pricing Approval**" means, with respect to any country where a Governmental Authority authorizes reimbursement or access, or approves or determines pricing, for pharmaceutical products, receipt of such reimbursement or access authorization or pricing approval or determination (as the case may be), including the NHI Price Approval.

1.139 "**Process Validation**" means the development of a Manufacturing process for the applicable Compound and Product that, when operated within established parameters, performs effectively and reproducibly to allow commercial Manufacture the Compound and Product meeting the Specifications in accordance with Applicable Laws. For clarity, Process Validation is limited to process qualification and does not include continued process verification, as these terms are defined in FDA Guidance for Industry (Process Validation: General Principles and Practices, January 2011).

1.140 "**Product**" means any pharmaceutical product, containing the Compound, whether or not as the sole active ingredient, and in any dosage, form or formulation. For clarity, (a) the Compound in drug substance form (as opposed to the drug dosage form) shall constitute the Compound, but not the Product, and (b) the term "Product" shall not be construed to include any proprietary compounds of MEI or any of its Affiliates other than the Compound.

1.141 "**Product Agreements**" has the meaning set forth in Section 11.3(g) (Effect of Termination).

1.142 "**Product Infringement**" has the meaning set forth in Section 9.4(a) (Notice).

1.143 "**Product Liability**" means any liability in respect of any personal injury or death (or risk of personal injury or death) arising from, relating to or otherwise in respect of, the use or ingestion of, or exposure to, a Product, whether based on negligence, strict product liability or any other product liability theory, including liability predicated on any alleged or actual

Manufacturing, design or formulation defect or failure to warn or any breach of any express or implied warranties.

1.144 "**Product Liability Claims**" means any and all Claims in respect of Product Liability or alleged Product Liability in the Territory.

1.145 "**Product Trademark Costs**" means all costs of establishment, maintenance and enforcement efforts relating to MEI Trademarks in the U.S.

1.146 "**Profit Reconciliation Procedures**" has the meaning set forth in Section 4.4(b)(i) (Net Profit or Loss).

1.147 "**Publication**" has the meaning set forth in Section 10.4(b) (Publication).

1.148 "**Recall Expenses**" means Out-of-Pocket Costs and Commercial FTE Costs directly associated with notification, retrieval and return of a Product, destruction of such returned Product, replacement Product and distribution of the replacement Product, in each case that are incurred with respect to a recall conducted in accordance with Section 7.2(d) (Remedial Actions) of this Agreement. The Parties acknowledge that if the recall was not anticipated at the time the applicable U.S. Commercialization Budget was established for a Calendar Year, then the Recall Expenses shall not be included for determining whether the Party conducting such recall has exceeded the amounts budgeted to be incurred by such Party in such Calendar Year for U.S. Commercialization Costs. Notwithstanding the foregoing, for clarity, Recall Expenses that are entitled to indemnification under Article 13 (Indemnification; Liability) shall be solely borne by the relevant Indemnifying Party, and shall not be shared hereunder.

1.149 "**Receiving Party"** has the meaning set forth in Section 10.1(a) (Duty of Confidence).

1.150 "**Reconciliation Procedures**" has the meaning set forth in Section 4.4(b)(i) (Net Profit or Loss).

1.151 "**Regulatory Approval**" means, with respect to any pharmaceutical product in any regulatory jurisdiction for a given Indication, approval from the applicable Regulatory Authority permitting the distribution, use and sale of such pharmaceutical product in such regulatory jurisdiction for such Indication in accordance with Applicable Law.

1.152 "**Regulatory Authority**" means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or Pricing Approval of a pharmaceutical product in such country or regulatory jurisdiction.

1.153 "**Regulatory Data**" means any and all research data, pharmacology data, preclinical data, clinical data and all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with regulatory filings for the Product (including any applicable Drug Master Files, CMC data, CDISC electronic data and relevant documents, or similar documentation).

1.154 "**Regulatory Exclusivity**" means, with respect to each Product in any jurisdiction in the Territory, any period of data, market or other regulatory exclusivity (other than Patent exclusivity) granted or afforded by Applicable Law or by a Regulatory Authority in such jurisdiction that confers exclusive marketing rights with respect to such Product in such jurisdiction or prevents another Person from using or otherwise relying on any data supporting the approval of the Marketing Authorization Application with respect to such Product in such jurisdiction without the prior written consent of the Marketing Authorization Holder, as applicable, including orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, or pediatric exclusivity.

1.155 "**Regulatory Maintenance Costs**" means Out-of-Pocket Costs and Commercial FTE Costs for maintenance fees relating to Regulatory Approval for the Products in the Field, personnel engaged in the filing and maintenance of Regulatory Approval and incurred to establish, maintain and enforce the MEI Trademarks.

1.156 "**Regulatory Materials**" means regulatory applications, submissions, notifications, communications, correspondence, discussion/meeting minutes, registrations, Regulatory Approvals and/or other filings made or related to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, Manufacture, have Manufactured, Package, have Packaged, obtain marketing authorization, market, sell or otherwise Commercialize the Product in a particular country or regulatory jurisdiction. Regulatory Materials include INDs, presentations, responses, and applications for other Regulatory Approvals.

1.157 "**Remedial Action**" has the meaning set forth in Section 7.2(d) (Remedial Actions).

1.158 "**RoW**" means worldwide, but excluding Japan and the U.S.

1.159 "**RoW Aggregate Annual Net Sales**" has the meaning set forth in Section 6.3(c)(i) (RoW - Royalty Rates).

1.160 "**RoW Commercialization Plan**" has the meaning set forth in Section 6.2(a) (RoW – Commercialization Plan).

1.161 "**RoW Development Plan**" has the meaning set forth in Section 6.1(a) (RoW – Development Plan).

1.162 "**RoW Promotional Materials**" has the meaning set forth in Section 6.2(c) (RoW – Creation of Promotional Materials).

1.163 "**r/r**" means relapsed or refractory.

1.164 "**Selling Expenses**" means Out-of-Pocket Costs and Commercial FTE Costs reasonably necessary and identifiable to the Product incurred with respect to: sales representatives, sales managers, sales deployment planning, sales training, customer tracking and targeting, payor and reimbursement activities, hospital and managed health care activities, performance reporting, and sales incentive planning. Costs for sales force automation (SFA) tools and hardware, such as laptops or tablets used to track activity, are not Selling Expenses, and not billable costs under this Agreement unless shared systems are developed and mutually agreed as a billable cost.

1.165 "**Selling Party**" has the meaning set forth in Section 1.117 (Net Sales).

1.166 "**Sole Inventions**" has the meaning set forth in Section 9.1(b) (Ownership of Inventions).

1.167 "**Sublicense**" means a sublicense granted by a Party to a Third Party or an Affiliate of such Party of any rights granted hereunder to such Party by the other Party, including, without limitation, the right to Develop, Manufacture, have Manufactured, Package, have Packaged, or Commercialize any Compound or Product.

1.168 "**Sublicensee**" means with respect to a Party, a Third Party or Affiliate to whom such Party has granted a Sublicense in accordance with the terms of this Agreement.

1.169 "**Tax**" or "**Taxes**" means any (a) all federal, provincial, territorial, state, municipal, local, foreign or other Taxes, imposts, rates, levies, assessments and other charges in the nature of a Tax (and all interest and penalties thereon and additions thereto imposed by any Government Authority), including all income, excise, franchise, gains, capital, real property, goods and services, transfer, value added, gross receipts, windfall profits, severance, ad valorem, personal property, production, sales, use, license, stamp, documentary stamp, mortgage recording, employment, payroll, social security, unemployment, disability, escheat, estimated or withholding Taxes, and all customs and import duties, together with all interest, penalties and additions thereto imposed with respect to such amounts, in each case whether disputed or not; (b) any liability for the payment of any amounts of the type described in clause (a) as a result of being or having been a member of an affiliated, consolidated, combined or unitary group; and (c) any liability for the payment of any amounts as a result of being party to any Tax sharing agreement or arrangement or as a result of any express or implied obligation to indemnify any other person with respect to the payment of any amounts of the type described in clause (a) or (b).

1.170 "**Term**" has the meaning set forth in Section 11.1 (Term).

1.171 "**Terminated Jurisdiction**" has the meaning set forth in Section 1.128.

1.172 "**Territory**" means collectively or individually, as applicable, U.S., Japan, and/or the RoW.

1.173 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.174 "**Third Party Patent**" has the meaning set forth in Section 9.5(c)(i) (Third Party Intellectual Property Rights).

1.175 "**Trademark Infringement**" has the meaning set forth in Section 9.8(c) (Trademarks).

1.176 "**United States**" or "**U.S.**" means the United States of America including its territories and possessions.

1.177 "**Update Report**" has the meaning set forth in Section 7.1(b) (Development Reports).

1.178 "**U.S. Commercialization Budget**" means the budget for conducting Commercialization activities for the Products in the Field for the U.S. pursuant to the U.S. Commercialization Plan for the relevant Calendar Years, as developed, approved and amended concurrently with the U.S. Commercialization Plan in accordance with this Agreement.

1.179 "**U.S. Commercialization Costs**" means the sum of the following costs and expenses incurred following the Effective Date by the Parties or their Affiliates, in the course of Manufacturing, Packaging or Commercialization of the Products in or for the U.S. in accordance with this Agreement during the applicable Calendar Quarter or the applicable Calendar Year, in each case, that are incurred in accordance with the U.S. Commercialization Budget:

(a) Blocking Third Party Intellectual Property Costs;

(b) Distribution Costs;

(c) Early Access Program Expenses;

(d) Health Care Reform Fees;

(e) Marketing Expenses;

(f) Medical Affairs Expenses;

(g) Other Allowable Expenses;

(h) [*CONFIDENTIAL*]

(i) Recall Expenses;

(j) Regulatory Maintenance Costs;

(k) Selling Expenses;

(l) Alliance Manager Expenses; and

(m) COGS of Products for Commercialization.

For clarity, it is understood that U.S. Commercialization Costs shall include only Out-of-Pocket Costs and Commercial FTE Costs, and that internal costs of a Party and its Affiliates shall be reimbursed only as reflected in Commercial FTE Costs. Notwithstanding anything to the contrary in this Agreement (or the Financial Exhibit), to the extent that any activity is conducted (or an Out-of-Pocket Cost or Commercial FTE Cost is incurred) in support of both a Product and other products, services or efforts of a Party, or are not solely attributable to a Product, then the Out-of-Pocket Costs and Commercial FTE Costs thereof shall be included in U.S. Commercialization Costs only to the extent included in the applicable U.S. Commercialization Budget, or expressly and specifically included under the Financial Exhibit. In connection with the JCC's review of a proposed U.S. Commercialization Budget for approval, upon request by either Party, the JCC shall review the methodology used to allocate to the U.S. Commercialization Costs

the Commercial FTE Costs and Out-of-Pocket Costs of such combined activity, and if the JCC does not approve such methodology, the matter shall be resolved by the JSC.

1.180 "**U.S. Commercialization Plan**" has the meaning set forth in Section 4.2(a) (U.S. – Commercialization Plan).

1.181 "**U.S. Development Budget**" means the budget for conducting Development of Compounds and Products pursuant to the U.S. Development Plan for the relevant Calendar Years, as developed, approved and amended concurrently with the U.S. Development Plan in accordance with this Agreement.

1.182 "**U.S. Development Costs**" means Development FTE Costs and Out-of-Pocket Costs incurred by the Parties and their Affiliates in Developing the Products in the Field in or for the U.S. (including costs incurred in connection with U.S. Global Studies), in each case to the extent incurred in accordance with this Agreement, the U.S. Development Plan and the U.S. Development Budget, including:

(a) "**Development FTE Costs**", which equals the relevant Development FTEs times the applicable Development FTE Rate, where:

(i) a "**Development FTE**" means a scientific, medical, technical, or other individual directly engaged in performing Development activities under the U.S. Development Plan, whose time and effort, in the aggregate, is equivalent to the time and effort of one (1) employee devoted exclusively to Development activities based on 1880 person hours per year.

(ii) "**Development FTE Rate**" means the "Development FTE Rate" as defined by the JDC for all roles included as billable under this Agreement with geographic adjustments as deemed appropriate by the JDC, which rates will be **[*CONFIDENTIAL*]** for each of MEI and KKC and will increase or decrease January 1 of each Calendar Year (starting with January 1, 2021) in accordance with the percentage year-over-year increase or decrease of the Mercer Human Resource Consulting Base Pay Increase for the Pharmaceutical/Biotechnology Industry;

(b) Out-of-Pocket Costs (if not otherwise captured above) of Manufacturing or having Manufactured clinical supplies for such efforts as set forth in the U.S. Development Plan, including, as applicable, (i) the COGS of clinical supply of the Products; (ii) costs and expenses incurred to purchase or package Third Party comparator or Third Party combination drugs or devices; and (iii) costs and expenses of disposal of clinical samples;

(c) Out-of-Pocket Costs representing fees incurred in connection with regulatory filings with respect to Products in the Field;

(d) Out-of-Pocket Costs (if not otherwise captured above) associated with pre- and post-approval commitments mandated by Governmental Authorities, to the extent incurred with respect to Products;

(e) Out-of-Pocket Costs (if not otherwise captured above) incurred in connection with CMC Development or qualification and validation of Third Party contract manufacturers, and if a Party or an Affiliate of a Party is established as a supplier, the Out-of-Pocket Costs and Development FTE Costs to do so, including the Parties' costs for transfer of process and manufacturing technology and analytical methods, scale up, process and equipment validation, and initial manufacturing licenses, approvals and inspections;

(f) Out-of-Pocket Costs paid to contract research organizations;

(g) Out-of-Pocket Costs (if not otherwise captured above) identifiable to establishing, updating and maintaining a global safety database for Products;

(h) Out-of-Pocket Costs (if not otherwise captured above) associated with diagnostic products, if applicable to the Development of a Product;

(i) [*CONFIDENTIAL*] costs specified as "U.S. Development Costs" in **[*CONFIDENTIAL*]**; and

(j) any other Out-of-Pocket Costs incurred for activities specified in the U.S. Development Plan and included in the U.S. Development Budget.

For clarity, U.S. Development Costs shall exclude all of the payments set forth in Section 4.4 (U.S. – Financial Terms) 5.3 (JP – Financial Terms), and 6.3 (RoW – Financial Terms), and U.S. Commercialization Costs as defined in the Financial Exhibit and capital expenditures, and costs attributable to general corporate activities, executive management, investor relations, treasury services, business development, corporate government relations, external financial reporting and other overhead activities.

1.183 "**U.S. Development Plan**" has the meaning set forth in Section 4.1(a) (U.S. – Development Plan).

1.184 "**U.S. Development Reconciliation Procedures**" has the meaning set forth in Section 4.1(e)(iii) (U.S. Development Cost Reports).

1.185 "**U.S. Global Study**" means a Clinical Trial that (a) is intended to generate data that will be submitted to the relevant Regulatory Authorities in the United States and (b) is conducted, in whole or in part, in Japan and/or the RoW; provided, that U.S. Global Studies shall not include any Clinical Trial that is required by one or more Regulatory Authorities in Japan or the RoW but is not required by relevant Regulatory Authorities in the United States.

1.186 "**U.S. Supply Items**" has the meaning set forth in Section 7.3(a) (U.S. – Supply).

1.187 "**Valid Claim**" means, with respect to a country, a claim of (a) an issued and unexpired Patent in such country which has not been revoked, held unenforceable, unpatentable or invalid by an administrative agency, court or other governmental agency of a competent jurisdiction in a final and non-appealable decision (or decision unappealed within the time allowed for appeal), and which has not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) a pending Patent application in such country that is being prosecuted

in good faith and has not been pending for more than **[*CONFIDENTIAL*]** from the first office action date with respect to such Patent application (for clarity, a Patent application pending longer than such **[*CONFIDENTIAL*]** period would become a Valid Claim after such period upon the issuance of the relevant Patent).

1.188 "**VAT**" has the meaning set forth in Section 8.5(b) (VAT).

1.189 "**Working Group**" has the meaning set forth in Section 2.7 (Working Group).

ARTICLE 2
MANAGEMENT OF COLLABORATIVE ACTIVITIES

2.1 Overview of Collaboration. Prior to the Effective Date, MEI has initiated Clinical Trials of Product containing the Compound, including in conjunction with KKC under the JP Agreement. The Parties have agreed to Develop and Commercialize Products in the Field in the Territory under the terms of this Agreement in accordance with Development Plan(s) and Commercialization Plan(s), as applicable.

2.2 Joint Steering Committee.

(a) Purpose; Formation. The Parties acknowledge and agree that the joint steering committee established under the JP Agreement is hereby disbanded in connection with the termination of the JP Agreement pursuant to Section 14.6(b) (Entire Agreement; Modification; JP Agreement and Prior CDA). Within **[*CONFIDENTIAL*]** after the Effective Date, the Parties shall establish a new joint steering committee (the "**JSC**"), composed of **[*CONFIDENTIAL*]** of each Party (or such other equal number of representative from each Party as the Parties may agree in writing from time-to-time), to coordinate and oversee the activities of the Parties under this Agreement. Each JSC representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. The purposes of the JSC shall be (i) to serve as a forum to review, discuss and oversee (which, for clarity, shall not include approval rights except as explicitly set forth below in subsections (ii) and (iii)) the overall Development, Manufacture, Packaging and Commercialization strategies with respect to the Compounds and Products in the applicable Territories pursuant to this Agreement, (ii) to review, discuss and oversee the Development, Manufacture, Packaging and Commercialization strategies, plans and budgets in or for the U.S. (including in connection with U.S. Global Studies) by reviewing and approving the U.S. Development Plan, U.S. Development Budgets, U.S. Commercialization Plan and U.S. Commercialization Budgets, (iii) to review, discuss and oversee the Development strategies and plans with respect to the Compounds and Products in or for Japan or RoW by reviewing and approving the JP Development Plan and RoW Development Plan, (iv) to review, discuss and oversee the Manufacturing, Packaging, and Commercialization of Products in the Field in or for Japan and RoW, including by reviewing the Manufacturing, Packaging, and Commercialization strategy for Japan and RoW, reviewing the JP Commercialization Plan and RoW Commercialization Plan and amendments and updates to such plans, (v) to oversee the JDC, JMC, JCC and JFC, and the Working Groups which report to the JSC, and (vi) in accordance with

Section 2.8 (Committee Decision Making), to resolve matters on which the JDC, JMC, JCC or JFC are unable to reach consensus. The Parties agree that the JSC will not be involved in day-to-day implementation of activities under this Agreement, and, for clarity, a Party assigned responsibility for a task will have control over day-to-day decisions related to operationalizing such task.

(b) Specific Responsibilities of the JSC. In addition to its overall responsibility for monitoring and providing a forum to discuss and coordinate the Parties' activities under this Agreement, the JSC shall in particular:

(i) oversee the collaborative activities of the Parties under this Agreement;

(ii) review and discuss, as necessary, performance of each Party, Affiliate or Sublicensee in performing the activities under the Development Plans or the Commercialization Plans, including compliance with Applicable Laws and any agreed-upon standards for conduct of such activities and progress of the Clinical Trials then on-going;

(iii) review and approve publication and communication strategies, global brand positioning or global trademarks proposed by the JDC and/or JCC, in each case when requested by the chairpersons of the JSC;

(iv) review strategies for obtaining, maintaining, defending and enforcing patent and trademark protection for Products in the Territory;

(v) review and approve each Development Plan and the U.S. Commercialization Plan, including budgets contained therein, and amendments thereto, as such are referred to the JSC by the JDC and JCC, as applicable;

(vi) review and discuss the JP Commercialization Plan and RoW Commercialization Plan and amendments thereto;

(vii) monitor progress and evaluate performance of the Parties under this Agreement, including a review of actual financial results versus budget or plan;

(viii) oversee any Working Group that reports into the JSC;

(ix) attempt to resolve disputes within the JDC, JMC, JCC, JFC and any other Working Group that reports to the JSC; and

(x) perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement as agreed to in writing by the Parties.

(c) JSC Membership and Meetings.

(i) **JSC Members.** Each Party shall designate one of its JSC representatives to act as co-chairpersons of the JSC. Each Party may replace its JSC representatives (and its chairperson) on written notice to the other Party, but each Party shall strive

to maintain continuity. The JSC members shall jointly prepare an agenda and shall direct the preparation of reasonably detailed minutes for each JSC meeting, respectively, which shall be circulated within **[*CONFIDENTIAL*]** of such meeting and thereafter be approved by both Parties as soon as possible; provided, that in the event of any disagreement it shall be noted in the minutes and finalized with such notation(s).

(ii) **JSC Meetings.** The JSC will hold its first meeting as soon as practicable but no **[*CONFIDENTIAL*]** of Effective Date. Thereafter, the JSC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than **[*CONFIDENTIAL*]**. Meetings may be held in person, or by audio or video teleconference; provided, that unless otherwise agreed by both Parties, at **[*CONFIDENTIAL*]** per Calendar Year shall be held in person, and all in-person JSC meetings shall be held at locations mutually agreed upon by the Parties. Each Party shall be responsible for all of its own expenses of participating in JSC meetings.

(iii) **Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representative, to attend JSC meetings in a non-voting capacity; provided, that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide at least **[*CONFIDENTIAL*]** prior written notice (to the extent practicable, and otherwise as soon as possible) to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld, conditioned or delayed. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

2.3 Joint Development Committee. Within **[*CONFIDENTIAL*]** after the Effective Date, the Parties shall establish a joint Development committee (the "**JDC**"), composed of three (3) representatives of each Party (or such other equal number of representative from each Party as the Parties may agree in writing from time-to-time), to coordinate and oversee the Development of the Compound and Products in the Field in or for the U.S., Japan, and RoW. Each JDC representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the JDC's responsibilities.

(a) Specific Responsibilities of the JDC. In addition to its general responsibilities, the JDC shall in particular:

(i) review and discuss applicable Development Plans and material amendments and updates to such Development Plans, including, with respect to the U.S., the U.S. Development Budget, and strategy for Development set forth therein, and present such Development Plans to the JSC for the JSC's review and approval;

(ii) work with the JFC to develop and review budgets for Development Plans;

(iii) provide regular reports to the JSC regarding the Development of the Products;

(iv) discuss and manage the implementation of the initial Development Plans;

(v) oversee the conduct of Development in the Territory, including all Clinical Trials and nonclinical studies;

(vi) create, implement and review the design of all Clinical Trials and nonclinical studies conducted under each Development Plan;

(vii) establish trial/project-specific addenda to the U.S. Development Plan that will set forth applicable Development FTE Rates and an allocation of time by such Development FTEs to be spent on such activities;

(viii) decide whether and when to initiate or discontinue any Clinical Trial and any nonclinical study under each Development Plan;

(ix) determine the amount of Product to be distributed free of charge annually for regulatory or Clinical Trials, including investigator-initiated trials;

(x) allocate budgeted resources and determine priorities for each Clinical Trial and nonclinical study under each Development Plan;

(xi) facilitate the flow of information between the Parties with respect to the Development of Products, including with respect to obtaining Regulatory Approval for Products;

(xii) discuss whether to Develop Products for new Indications and propose any such Indications to the JSC;

(xiii) allocate primary responsibility as between the Parties for tasks relating to Development of Products in or for the U.S. where not already specified in the Development Plan;

(xiv) discuss the requirements for Regulatory Approval in the Territory and oversee regulatory matters, including regulatory communication strategies with respect to Products in the Territory in conjunction with the regulatory department of the Party which holds or will hold the relevant Regulatory Approval;

(xv) establish a publication strategy for publications and presentations related to the Product in the Territory in cooperation with the JCC; and

(xvi) perform such other functions as may be appropriate to further the purposes of this Agreement, as directed by the JSC.

(b) JDC Membership and Meetings.

(i) **JDC Members.** Each Party shall designate one of its JDC representatives to act as co-chairpersons of the JDC. Each Party may replace its JDC

representatives (and its chairperson) on written notice to the other Party, but each Party shall strive to maintain continuity. The JDC members shall jointly prepare an agenda and shall direct the preparation of reasonably detailed minutes for each JDC meeting, respectively, which shall be circulated within **[*CONFIDENTIAL*]** of such meeting and thereafter be approved by both Parties as soon as possible; provided, that in the event of any disagreement it shall be noted in the minutes and finalized with such notation(s).

(ii) **JDC Meetings.** The JDC will hold its first meeting as soon as practicable but no later than **[*CONFIDENTIAL*]** of Effective Date. Thereafter, the JDC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than **[*CONFIDENTIAL*]**. Meetings may be held in person, or by audio or video teleconference; provided, that unless otherwise agreed by both Parties, at least **[*CONFIDENTIAL*]** per Calendar Year shall be held in person, and all in-person JDC meetings shall be held at locations mutually agreed upon by the Parties. Each Party shall be responsible for all of its own expenses of participating in JDC meetings.

(iii) **Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representative, to attend JDC meetings in a non-voting capacity; provided, that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide at least **[*CONFIDENTIAL*]** prior written notice (to the extent practicable, and otherwise as soon as possible) to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld, conditioned or delayed. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

2.4 Joint Manufacturing Committee. Within **[*CONFIDENTIAL*]** after the Effective Date, the Parties shall establish a joint Manufacturing committee (the "**JMC**"), composed of three (3) representatives of each Party (or such other equal number of representative from each Party as the Parties may agree in writing from time-to-time), to coordinate and oversee the Manufacturing of the Compound and Products in the Field in the U.S., Japan, and RoW. Each JMC representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the JMC's responsibilities.

(a) Specific Responsibilities of the JMC. In addition to its general responsibilities, the JMC shall in particular:

(i) oversee clinical and commercial supply of the Products (in accordance with any supply or quality agreements entered into connection with this Agreement);

(ii) oversee any CMC related development activities, e.g. stability studies or packaging development, in the Territory;

(iii) review capital investments relating to the Compound and Products;

(iv) review, in conjunction with the JSC and JFC, COGS, including yields, success rates and other relevant production statistics;

(v) review other operational issues relating to the manufacture or supply of the Compound and Products (including health, safety and environmental issues related thereto);

(vi) review and approve any updates to the Manufacturing Technology Transfer Plan from time-to-time, including amendments to timelines;

(vii) coordinate the transition of Manufacturing from MEI to KKC for Japan and the RoW;

(viii) develop and implement a supply chain assurance plan, pursuant to which each Party shall act as a back-up supplier of Compound and Product for the other Party (i.e., MEI shall act as a back-up supplier for KKC for Japan and RoW, and KKC shall act as a back-up supplier for MEI for the U.S.);

(ix) make recommendations regarding results of regulatory inspections related to the Compound and Products and review steps to be taken by either Party to address any deficiencies noted;

(x) make recommendations regarding capacity planning, supply plans and supply continuity planning for each Product for consistency with the forecasts, including consultation with the JDC regarding clinical supply Manufacturing;

(xi) make recommendations regarding changes in Manufacturing sites, testing sites, and responsibilities in the supply chain for each Compound and Product, it being understood that decisions regarding selection of which of internal or Third Party manufacturing and testing sites shall be used to manufacture the Compound and Product shall remain in the sole control of MEI, with respect to the U.S., and KKC, with respect to Japan and RoW;

(xii) make recommendations regarding Product enhancements through lifecycle management process;

(xiii) make recommendations regarding any material quality-related issues concerning any Compound and Product; and

(xiv) perform such other functions as appropriate to further the purposes of this Agreement, as directed by the JSC.

(b) JMC Membership and Meetings.

(i) **JMC Members.** Each Party shall designate one of its JMC representatives to act as co-chairpersons of the JMC. Each Party may replace its JMC representatives (and its chairperson) on written notice to the other Party, but each Party shall strive to maintain continuity. The JMC members shall jointly prepare an agenda and shall direct the preparation of reasonably detailed minutes for each JMC meeting, respectively, which shall be circulated within **[*CONFIDENTIAL*]** of such meeting and thereafter be approved by both Parties as soon as possible; provided, that in the event of any disagreement it shall be noted in the minutes and finalized with such notation(s).

(ii) **JMC Meetings.** The JMC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than **[*CONFIDENTIAL*]** per Calendar Year. Meetings may be held in person, or by audio or video teleconference; provided, that unless otherwise agreed by both Parties, at least **[*CONFIDENTIAL*]** per Calendar Year shall be held in person, and all in-person JMC meetings shall be held at locations mutually agreed upon by the Parties. Each Party shall be responsible for all of its own expenses of participating in JMC meetings.

(iii) **Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representative, to attend JMC meetings in a non-voting capacity; provided, that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide at least **[*CONFIDENTIAL*]** prior written notice (to the extent practicable, and otherwise as soon as possible) to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld, conditioned or delayed. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

2.5 Joint Commercialization Committee. Within **[*CONFIDENTIAL*]** after the Effective Date, the Parties shall establish a joint Commercialization committee (the "**JCC**"), composed of three (3) representatives of each Party (or such other equal number of representative from each Party as the Parties may agree in writing from time-to-time), to coordinate and oversee the Commercialization of the Compound and Products in the Field in or for the U.S., Japan, and RoW. Each JCC representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the JCC's responsibilities.

(a) Specific Responsibilities of the JCC. In addition to its general responsibilities, the JCC shall in particular:

(i) review and discuss applicable Commercialization Plans and material amendments and updates to such Commercialization Plans, including, with respect to the U.S., the U.S. Commercialization Budget, and strategy for Commercialization set forth therein, and present such Commercialization Plans to the JSC for the JSC's review and, with respect to the U.S. Commercialization Plan, for the JSC's approval;

(ii) work with the JFC to develop and review budgets for Commercialization Plans;

(iii) oversee implementation of the Commercialization Plan(s);

(iv) establish and oversee a Commercialization strategy in the Territory, including pricing strategies for Product and MEI Trademark and KKC Trademark (to the extent applicable);

(v) regularly report to the JSC regarding the Commercialization strategy for the Product;

(vi) establish a publication strategy for publications and presentations related to the Product in the Territory in cooperation with the JDC;

(vii) coordinate the global Commercialization strategy and activities of MEI and KKC with respect to Products, including pre-launch and post-launch activities to build and establish a global brand; and

(viii) perform such other functions as appropriate to further the purposes of this Agreement, as directed by the JSC.

(b) JCC Membership and Meetings.

(i) **JCC Members.** Each Party shall designate one of its JCC representatives to act as co-chairpersons of the JCC. Each Party may replace its JCC representatives (and its chairperson) on written notice to the other Party, but each Party shall strive to maintain continuity. The JCC members shall jointly prepare an agenda and shall direct the preparation of reasonably detailed minutes for each JCC meeting, respectively, which shall be circulated within **[*CONFIDENTIAL*]** of such meeting and thereafter be approved by both Parties as soon as possible; provided, that in the event of any disagreement it shall be noted in the minutes and finalized with such notation(s).

(ii) **JCC Meetings.** The JCC shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than **[*CONFIDENTIAL*]** per Calendar Year. Meetings may be held in person, or by audio or video teleconference; provided, that unless otherwise agreed by both Parties, at least **[*CONFIDENTIAL*]** per Calendar Year shall be held in person, and all in-person JCC meetings shall be held at locations mutually agreed upon by the Parties. Each Party shall be responsible for all of its own expenses of participating in JCC meetings.

(iii) **Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representative, to attend JCC meetings in a non-voting capacity; provided, that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide at least **[*CONFIDENTIAL*]** prior written notice (to the extent practicable, and otherwise as soon as possible) to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld, conditioned or delayed. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

2.6 Joint Finance Committee. Within **[*CONFIDENTIAL*]** after the Effective Date, the Parties shall establish a joint finance committee (the "**JFC**"), composed of three (3) representatives of each Party (or such other equal number of representative from each Party as the Parties may agree in writing from time-to-time), to provide support to all other Committees with respect to accounting and financial matters relating to the activities under this Agreement. Each JFC representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the JFC's responsibilities.

(a) Specific Responsibilities of the JFC. In addition to its general responsibilities, the JFC shall in particular:

(i) work with the other Committees to assist in financial, forecasting, budgeting and planning matters as required, including (A) assisting in the preparation, for approval by the JSC, of such reports on financial matters as are requested by the JSC for the implementation of the financial aspects of the activities under this Agreement, (B) overseeing the preparation by the Parties of the budgets in U.S. Development Plan and U.S. Commercialization Plan for submission to the JSC for review and approval, (C) assisting in the preparation of other budgets and annual and long-term plans for JSC approval, (D) as requested by a Party, coordinating the preparation of Calendar Quarterly updates to annual budgets, (E) assisting the JCC in developing the long-range forecast for commercial supply of the Compounds and Products, (F) supporting the development of the revenue forecast model or methodology and (G) supporting development and review of the Product revenue forecasts at each official submission and update;

(ii) recommend, for approval by the Parties, procedures, formats and timelines consistent with this Agreement for reporting financial data and assist in resolving differences that relate to the financial terms of this Agreement;

(iii) recommend any changes to or additional items to be included within U.S. Development Costs, Out-of-Pocket Costs, COGS, Deductions, and U.S. Commercialization Costs accounted for under this Agreement;

(iv) review calculations of the amount of any payments to be made by the Parties (or their Affiliates) hereunder, review the reconciliation of payments and provide guidance regarding the most appropriate and Tax effective methods of cost sharing and determination and distribution of the Net Profit or Loss to a Party or its Affiliates consistent with this Agreement;

(v) on an annual basis, review the Development FTE Rates and Commercial FTE Rates and discuss and approve (if applicable) any modifications thereof;

(vi) coordinate audits of data where appropriate and required or allowed by this Agreement;

(vii) coordinate with the other Committees as appropriate and applicable;

(viii) perform such other duties as are expressly assigned to the JFC in this Agreement; and

(ix) perform such other functions as appropriate to further the purposes of this Agreement, as directed by the JSC.

2.7 Working Group. The Parties may establish under the JSC, JDC, JMC, JCC, or JFC one or more working groups to focus on discussions, information sharing and day-to-day conduct of activities concerning Development, Commercialization, Packaging, and Manufacturing and supply of the Product or any other areas of concern (the "**Working Group**"). Each Party may appoint its own members of working group with expertise and responsibilities of the areas relevant

to the purpose of the Working Group and such member may be replaced from time to time. For clarity, any Committee may decide to establish a Working Group; provided, that, once established, Working Groups will report to the Committee it is established under, and any disagreements within a Working Group not resolved within **[*CONFIDENTIAL*]** may be referred to such Committee for resolution as provided in Section 2.8(a) (Within Operating Committees).

2.8 Committee Decision Making.

(a) Within Operating Committees. All decisions within any Committee other than the JSC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before such Committee, the representatives of the Parties cannot reach an agreement within **[*CONFIDENTIAL*]**, then either Party may cause such matter to be referred to the JSC for resolution as provided in Section 2.8(b) (Within the JSC).

(b) Within the JSC. In addition to resolving issues specifically delegated to it, the JSC shall have the authority to resolve any disputes within the Parties' collaboration not resolved by any other Committees, except where expressly specified elsewhere in this Agreement. Subject to the exceptions specified below in this Section 2.8(b) (Within the JSC), all decisions within the JSC (whether originating there, or referred to it by an operating Committee) shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. A Party's representative may indicate that its vote on an issue within the JSC is on a contingent basis pending internal approval of the applicable Party regarding the vote; provided, however, that such Party shall as promptly as possible report back to the JSC the outcome of such internal approval process and the meeting minutes shall reflect the ultimate vote. If a matter is referred by an operating Committee to the JSC, it shall use good faith efforts to resolve promptly such matter. If the JSC is unable to reach consensus on any issue for which it is responsible, within **[*CONFIDENTIAL*]** after a Party affirmatively states that a decision needs to be made, either Party may invoke the dispute resolution provisions of Section 14.12 (Dispute Resolution) and the status quo shall be maintained until resolution is reached.

2.9 General Committee Authority. Each Committee shall have solely the powers expressly assigned to it in this Article 2 (Management of Collaborative Activities) and elsewhere in this Agreement. No Committee shall have any right, power or authority: (a) to determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (b) to amend, modify, or waive compliance with this Agreement. It is expressly understood and agreed that the control of decision-making authority by MEI or KKC, as applicable, pursuant to Section 2.8 (Committee Decision Making), so as to resolve a disagreement or deadlock on a Committee for any matter will not authorize either Party to perform any function not delegated to a Committee, and that neither MEI nor KKC shall have any right to unilaterally modify or amend, or waive its own compliance with, the terms of this Agreement or any other agreement between the Parties.

2.10 Appointment Not an Obligation. The appointment of members to a Committee is a right of each Party and not an obligation and shall not be a "deliverable" as defined in EITF Issue No. 00-21. Each Party shall be free to determine not to appoint members to the Committee. If a Party (the "N**on-Appointing Party**") does not appoint members to a Committee, it shall not

be a breach of this Agreement, nor shall any consideration be required to be returned, and the other Party shall have the votes and the decision-making power of the Non-Appointing Party unless and until such members are appointed by the Non-Appointing Party.

2.11 Discontinuation; Disbandment. Once established, each Committee shall continue to exist until the Parties mutually agree to disband the Committee. Upon the occurrence of the foregoing, (a) such Committee shall disband, have no further responsibilities or authority under this Agreement and will be considered dissolved by the Parties and (b) any requirement of a Party to provide information or other materials to the Committee shall be deemed a requirement to provide such information or other materials to the other Party and the Parties shall retain their respective decision making authority in accordance with Section 2.8 (Committee Decision Making) over matters that are subject to the review or approval by the Committee hereunder; provided that MEI shall have final decision making authority with respect to the U.S. and KKC shall have final decision making authority with respect to Japan and RoW so long as MEI is Commercializing Product in the U.S., and KKC is Commercializing Product in Japan and Row, as applicable.

2.12 Alliance Managers. Each Party has appointed a representative to act as its alliance manager under the JP Agreement, who shall, as of the Effective Date, act as such Party's alliance manager under this Agreement (the "**Alliance Manager**"). The Alliance Managers shall serve as a key contact point between the Parties to facilitate the collaboration hereunder. A Party may replace its Alliance Managers at any time by providing notice in writing to the other Party.

ARTICLE 3
LICENSES

3.1 Licenses to KKC. Subject to the terms and conditions of this Agreement, MEI hereby grants to KKC:

(a) U.S. a Co-Exclusive (solely with MEI and subject to Section 11.3(a) (Effect of Termination)) license, with the right to grant Sublicenses (through multiple tiers) in accordance with Section 3.3 (Sublicense Rights) and with the right to grant subcontracts in accordance with Section 14.3 (Subcontractor), under the MEI Technology to Develop and use Compound and Product, and Commercialize Product, in the Field in or for the U.S. to the extent applicable to the activities delegated to KKC under this Agreement (including any ancillary agreement entered in connection with this Agreement).

(b) JP and RoW. (i) a Co-Exclusive (solely with MEI and subject to Section 11.3(a) (Effect of Termination)) license, with the right to grant Sublicenses (through multiple tiers) in accordance with Section 3.3 (Sublicense Rights) and with the right to grant subcontracts in accordance with Section 14.3 (Subcontractor), under the MEI Technology to Develop, Manufacture, have Manufactured, Package, have Packaged and use Compound and Product in the Field in Japan and in the RoW to the extent applicable to the activities delegated to MEI under this Agreement (including any ancillary agreement entered in connection with this Agreement), and (ii) an exclusive (subject to Section 11.3(a) (Effect of Termination)), royalty-bearing license, with the right to grant Sublicenses (through multiple tiers) in accordance with Section 3.3 (Sublicense Rights), under MEI Technology to Commercialize Product, in the Field in Japan and in the RoW.

3.2 Licenses to MEI. Subject to the terms and conditions of this Agreement, KKC hereby grants to MEI:

(a) U.S. a Co-Exclusive (solely with KKC) license, with the right to grant Sublicenses (through multiple tiers) in accordance with Section 3.3 (Sublicense Rights) and with the right to grant subcontracts in accordance with Section 14.3 (Subcontractor), under the KKC Technology to Develop, Manufacture, have Manufactured, Package, have Packaged, use, and Commercialize Compound and Product, in the Field in or for the U.S.

(b) JP and RoW. a Co-Exclusive (solely with KKC) license, with the right to grant Sublicenses (through multiple tiers) in accordance with Section 3.3 (Sublicense Rights) and with the right to grant subcontracts in accordance with Section 14.3 (Subcontractor), under the KKC Technology to Develop, Manufacture, have Manufactured, Package, have Packaged, and use Compound and Product in the Field in Japan and in the RoW to the extent applicable to the activities delegated to MEI under this Agreement (including any ancillary agreement entered in connection with this Agreement).

3.3 Sublicense Rights.

(a) Subject to the terms of this Section 3.3 (Sublicense Rights), each Party as applicable licensee may grant a Sublicense of the licenses granted to it in Section 3.1 (Licenses to KKC), Section 3.2 (Licenses to MEI), or Section 3.4 (Rights of Reference), as applicable, to an Affiliate of such Party without notice to or the prior consent of the other Party. Upon [*CONFIDENTIAL*]

(b) Each authorized Sublicense granted under this Section 3.3 (Sublicense Rights), if any, whether to an Affiliate or Sublicensee, shall be in writing and shall incorporate terms and conditions sufficient to enable the sublicensing Party to comply with this Agreement. The sublicensing Party shall remain responsible for the performance by any of its Sublicensees and shall cause its Sublicensees to comply with the provisions of this Agreement in connection with such performance, including the non-compete, reporting, audit, inspection and confidentiality provisions hereunder, and shall terminate all relevant agreements with any such Sublicensee in the case of any uncured material breach of such terms and conditions by such Sublicensee. For the avoidance of doubt, the sublicensing Party will remain directly responsible for all amounts owed to the other Party under this Agreement and such sublicensing Party hereby expressly waives any requirement that such other Party exhaust any right, power or remedy, or proceed against a Sublicensee for any obligation or performance hereunder prior to proceeding directly against the sublicensing Party.

3.4 Rights of Reference. MEI hereby grants KKC the right to use and reference all Regulatory Materials (including data contained therein) Controlled by MEI, and all Regulatory Approvals for the Compound and Products submitted by or on behalf of MEI, its Affiliates or Sublicensees, which right may be used by KKC **[*CONFIDENTIAL*]**. MEI shall use Commercially Reasonable Efforts to cause all relevant Sublicensees of MEI to grant such cross reference rights, with right to sublicense (through multiple tiers) to KKC. KKC hereby grants MEI the right to use and reference all Regulatory Materials (including data contained therein) Controlled by KKC, and all Regulatory Approvals for the Compound and Products submitted by

or on behalf of KKC, its Affiliates or Sublicensees which right may be used by MEI with **[*CONFIDENTIAL*]**. KKC shall cause all relevant Sublicensees of KKC to grant such cross reference rights, with right to sublicense (through multiple tiers) to MEI. Each Party shall execute any documentation that is reasonably requested by the other Party to facilitate the exercise of such rights of reference.

3.5 Retained Rights. MEI retains the right under the MEI Technology, and KKC retains the right under the KKC Technology, in each case, to exercise its rights and perform its obligations under this Agreement, including, for clarity, in connection with undertaking any U.S. Global Studies for the Compound and Product.

3.6 No Implied Licenses; Negative Covenant. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any Know-How, Patents, trademarks or other intellectual property rights owned or controlled by the other Party. Each Party hereby covenants not to practice, and not to permit or cause any of its Affiliate or any Third Party to practice, any MEI Technology or any KKC Technology (as the case may be) for any purpose other than as expressly authorized in this Agreement, including Developing and Commercializing Products in accordance with the applicable Development Plan or Commercialization Plan, as applicable.

3.7 Technology Transfer to KKC.

(a) The Parties acknowledge and agree that, prior to the Effective Date, MEI has disclosed and made available to KKC, and KKC has received, the MEI Know-How and materials pursuant to the JP Agreement.

(b) If, during the Term, (i) MEI becomes aware of any Know-How or Patents MEI Controls that are necessary for KKC to Develop, Manufacture, have Manufactured, Package, have Packaged, and use Compound and Product, and Commercialize Product, MEI shall promptly notify KKC; and (ii) upon reasonable request by KKC, MEI shall disclose such MEI Know-How or MEI Patents and make available such Know-How or Patents to KKC with no additional cost and shall use Commercially Reasonable Efforts to provide reasonable technical assistance, subject to Section 3.7(c) (Technology Transfer to KKC), including making appropriate employees available at reasonably agreed times and frequency, for the purpose of assisting KKC to understand and use such Know-How in connection with KKC's Product-related activities.

(c) The Parties shall conduct Manufacturing technology transfer of the Compound and Products in accordance with a Manufacturing technology transfer plan (as amended in accordance with this Agreement, the "**Manufacturing Technology Transfer Plan**"), including the timelines set forth therein, the initial version of which is attached to this Agreement as Schedule 3.7(c), provided that in the event of any inconsistency between the Manufacturing Technology Transfer Plan and this Agreement, the terms of this Agreement shall prevail. MEI shall provide assistance for each of KKC's CMOs in compliance with Section 7.3(b)(ii) (Third Party Manufacturer) until such CMO completes Process Validation. MEI shall provide support for the Manufacturing technology transfer in accordance with the Manufacturing Technology Transfer Plan for **[*CONFIDENTIAL*]**. For clarity, subject to the foregoing obligation to provide assistance and other terms and conditions of this Agreement, KKC shall be solely responsible for

any costs associated with its CMO(s), including the costs of any "bridging study(ies)" that are needed to establish the interchangeability of any such CMO(s)'s Manufacturing sites for regulatory purposes.

(d) The Parties acknowledge and agree that none of the technology transfer assistance required by this Section 3.7 (Technology Transfer to KKC) will require either Party to provide such assistance in person.

3.8

(a) KKC shall make the KKC Technology available to MEI at no additional cost and shall use Commercially Reasonable Efforts to provide reasonable technical assistance, including making appropriate employees available at reasonably agreed times and frequency, for the purpose of assisting MEI to understand and use such Know-How in connection with MEI's Product-related activities; provided, that KKC shall have no obligation under this Section 3.8(a) (Technology Transfer to MEI) to provide such assistance in excess of **[*CONFIDENTIAL*]** and any such assistance provided by KKC in excess of **[*CONFIDENTIAL*]** at a rate of **[*CONFIDENTIAL*]**.

(b) Notwithstanding the foregoing Section 3.8(a) (Technology Transfer to MEI), during the Term, with no additional costs to MEI, KKC shall, as soon as reasonably practicable following reasonable request by MEI, provide MEI with copies of all data, as well as all other information requested by MEI, generated by KKC in the conduct of any Clinical Trials involving the Compound and Product (including all of KKC's Regulatory Data and KKC Data) that MEI determines would be necessary or useful to Package, have Packaged, Manufacture, have Manufactured, Develop or Commercialize the Products in or for the U.S.

(c) The Parties acknowledge and agree that none of the technology transfer assistance required by this Section 3.8 (Technology Transfer to MEI) will require either Party to provide such assistance in person.

ARTICLE 4
U.S. SPECIFIC TERMS

4.1 U.S. – Development. Subject to the terms and conditions of this Agreement, the Parties shall be jointly responsible for the Development of the Compound and Products in the Field in or for the U.S., and for U.S. Global Studies, including conduct of preclinical studies and Clinical Trials that are required by Regulatory Authority(ies) in the U.S. to support Regulatory Approval of the Compound and Products in the Field in the U.S.

(a) U.S. – Development Plan. The Parties shall conduct all Development of the Compound and Products in the Field in or for the U.S., and all U.S. Global Studies, in accordance with a comprehensive development plan (as amended in accordance with this Agreement, the "**U.S. Development Plan**"), including the timelines set forth therein, the initial version of which is attached to this Agreement as Schedule 4.1(a). For clarity, the Parties acknowledge and agree that such attachment may be subject to further discussion and updates, as agreed upon by the Parties through the JDC and approved by the JSC, following the execution of

this Agreement. The U.S. Development Plan will include, among other things, the Indications for which the Product is to be Developed, allocation of responsibilities between the Parties, critical activities to be undertaken, certain timelines, go/no go decision points and relevant decision criteria, and feedback from the FDA, EMA and/or PMDA (which, to the extent applicable, FDA, EMA and/or PMDA feedback will be reflected in a promptly updated U.S. Development Plan, including applicable updates to U.S. Global Studies, that is reviewed and discussed by the JDC, and presented to the JSC for final approval), if applicable. The Parties may also discuss and consider the feedbacks from the other Regulatory Authorities with respect to the U.S. Development Plan. The U.S. Development Plan shall be focused on efficiently obtaining Regulatory Approval for the Product in the Field in the U.S., but may consider its impact on Regulatory Approval for the Product in EU and Japan. The U.S. Development Plan will be associated with the U.S. Development Budget. Each U.S. Development Plan shall include a three (3) Calendar Year plan for Developing the Products and shall be prepared in good faith; provided, however that the Parties acknowledge and agree that the initial U.S. Development Plan does not include a corresponding U.S. Development Budget, and that the initial U.S. Development Budget shall be deemed to equal and include any costs incurred for activities to be undertaken after the Effective Date by MEI under such initial U.S. Development Plan and any such costs shall, accordingly, be deemed to be U.S. Development Costs that are subject to Section 4.1(e)(iv) (U.S. – Development Costs) until such time as the Parties approve a U.S. Development Budget through the JSC in accordance with applicable provisions of this Agreement. In the event of any inconsistency between the U.S. Development Plan and this Agreement, the terms of this Agreement shall prevail.

(b) Amendments to the U.S. Development Plan. On an annual basis (no later than September 30th of the preceding Calendar Year), or more often as the Parties deem appropriate, the JDC shall prepare amendments to the then-current U.S. Development Plan and U.S. Development Budget for approval by the JSC. Each such amended U.S. Development Plan shall specify, with a reasonable level of detail, the items described in Section 4.1(a) (U.S. – Development Plan). Such amended U.S. Development Plan shall cover the next three (3) Calendar Years (and additional periods as reasonably determined by the Parties) and shall contain a corresponding U.S. Development Budget. Such updated and amended U.S. Development Plan shall reflect any changes, re-prioritization of studies within, reallocation of resources with respect to, or additions to the then-current U.S. Development Plan. In addition, the JDC may prepare amendments for approval by the JSC to the U.S. Development Plan and corresponding U.S. Development Budget from time to time during the Calendar Year in order to reflect changes in such plan and budget for applicable Calendar Years, in each case, in accordance with the foregoing. Each Party may, **[*CONFIDENTIAL*]**, propose necessary amendments to the U.S. Development Budget to the JSC for approval. Once approved by the JSC, the amended U.S. Development Plan and U.S. Development Budget shall become effective for the applicable period on the date approved by the JSC (or such other date as the JSC shall specify). Any JSC-approved amended U.S. Development Plan and U.S. Development Budget shall supersede the previous U.S. Development Plan and U.S. Development Budget for the applicable period.

(c) U.S. – Development Diligence. The Parties, directly and/or with or through Affiliates or Sublicensees (or Direct Licensees with respect to MEI), shall use Commercially Reasonable Efforts to Develop, and to obtain Regulatory Approval for, the Compound and Product in the Field in the U.S. in accordance with the then-current U.S. Development Plan for the

Indications of **[*CONFIDENTIAL*]** in accordance with the U.S. Development Plan shall be deemed to be a material breach (which, for clarity, shall be subject to the terms of Section 11.2(b) including the cure period thereunder) of such Party's Development diligence obligations under this Section 4.1(c) (U.S. - Development Diligence).

(d) U.S. - Development Budget. The U.S. Development Budget shall set forth the budgeted amounts for U.S. Development Costs with respect to activities allocated to the Parties under the U.S. Development Plan, and shall include for each Party a budget for U.S. Development Costs for the Development activities allocated to such Party, broken down by Calendar Quarter with respect to at least the then-current Calendar Year. The U.S. Development Budget shall also include a breakout of costs by functional area or category as determined by the JDC. Concurrently with the annual update of the U.S. Development Plan in accordance with Section 4.1(b) (Amendments to the U.S. Development Plan), the Parties shall also prepare, and the JSC shall review and approve, an updated U.S. Development Budget.

(e) U.S. - Development Costs.

(i) **Cost Sharing.** Subject to Section 4.1(e)(ii) (Exception), U.S. Development Costs incurred for activities to be undertaken after the Effective Date by a Party shall be borne **[*CONFIDENTIAL*]**. For the avoidance of double-counting, the Parties acknowledge and agree that (A) U.S. Development Costs shall not be included in U.S. Commercialization Costs for purposes of calculating Net Profit or Loss in accordance with the Financial Exhibit (and, likewise, that any amounts included in U.S. Commercialization Costs shall not be included in U.S. Development Costs), and (B) in the case of **[*CONFIDENTIAL*]** and be deducted from the total cost of the U.S. Development Costs, and the remaining cost shall be borne **[*CONFIDENTIAL*]**.

(ii) **Exception.** If one Party ("**Conducting Party**") desires to conduct a Clinical Trial of the Product for an Indication outside the scope of the then-current U.S. Development Plan that the other Party ("**Non-Conducting Party**") does not, and the Parties are unable to reach an agreement under the JDC, and under the JSC following escalation, then such Conducting Party shall be permitted to conduct such Clinical Trial at its sole cost and expense (i.e., such costs for conducting such Clinical Trial shall not be considered a U.S. Development Cost), provided that:

(1) if the Non-Conducting Party subsequently agrees in writing to the Parties' conducting a Pivotal Study of the Product for such Indication prior to initial submission of the study protocol of such Pivotal Study to the relevant Regulatory Authority, then the Non-Conducting Party shall be obligated to reimburse the **[*CONFIDENTIAL*]** of the cost of such earlier Clinical Trial that was not agreed upon, and the costs for conducting such Pivotal Study shall be considered a U.S. Development Cost subject to cost sharing as provided in Section 4.1(e)(i) (Cost Sharing); and

(2) if a Regulatory Approval is obtained for the Product for such Indication without the Non-Conducting Party agreeing as provided in Section 4.1(e)(ii)(1) (Exception), then the Non-Conducting Party shall be obligated to reimburse **[*CONFIDENTIAL*]** of the cost of the related earlier Clinical Trial that was not agreed upon. Without limiting the foregoing, (A) in the case of MEI conducting such Pivotal Study at its own cost and expense as a Conducting Party, any Development milestone associated with such Indication as provided in Section 4.4(a) **[*CONFIDENTIAL*]**; and (B) in the case of KKC conducting Pivotal Study at its own cost and expense as a Conducting Party, any **[*CONFIDENTIAL*]**.

(iii) **U.S. Development Cost Reports.** U.S. Development Costs shall initially be borne by the Party incurring the cost or expense, subject to reimbursement as provided in Section 4.1(e)(iv) (Reimbursement of U.S. Development Costs). Each Party shall calculate and maintain records of U.S. Development Costs incurred by it and its Affiliates in accordance with procedures to be established by the JFC and approved by the JSC, and the procedures for monthly reporting of actual results, monthly review and discussion of potential discrepancies, quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to U.S. Development Costs will be determined by the JSC (the "**U.S. Development Reconciliation Procedures**"). Such procedures will provide the ability to comply with financial reporting requirements of each Party under Applicable Laws. Without limiting the foregoing, the JFC shall establish reasonable procedures for the Parties to share estimated U.S. Development Costs for each Calendar Quarter prior to the end of such Calendar Quarter, to enable each Party to appropriately accrue its share of U.S. Development Costs for financial reporting purposes.

(iv) **Reimbursement of U.S. Development Costs.**

(1) The U.S. Development Reconciliation Procedures shall provide (A) for each Party to provide a monthly written report to the other Party setting forth in reasonable detail the total actual U.S. Development Costs for the Products incurred by such Party, and (B) that, within **[*CONFIDENTIAL*]** after the end of each Calendar Quarter, each Party shall submit to the JDC a report, in such reasonable detail and format as is established by the JDC, of all U.S. Development Costs incurred by such Party during such Calendar Quarter. Within **[*CONFIDENTIAL*]** following the receipt of such report by the JDC, each Party shall have the right to request reasonable additional information related to the other Party's and its Affiliates' U.S. Development Costs during such Calendar Quarter in order to confirm that such other Party's spending is in conformance with the approved U.S. Development Budget.

(2) The Party (with its Affiliates) that incurs more than its share of the total actual U.S. Development Costs for the Products shall be paid by the other Party an amount of cash sufficient to reconcile to its agreed percentage of actual U.S. Development Costs in each Calendar Quarter. Notwithstanding the foregoing, on a Calendar Year basis, the Parties shall not share any U.S. Development Costs in excess of the amounts allocated for such Calendar Year in the U.S. Development Budget and each Party will be solely responsible for U.S. Development Costs it incurs in excess of the amounts set forth in the U.S. Development Budget; provided, however, that U.S. Development Costs in excess of the U.S. Development Budget shall be included in the calculation of U.S. Development Costs to be shared by the

Parties if (A) such excess U.S. Development Costs do not exceed by more than **[*CONFIDENTIAL*]** the total U.S. Development Costs allocated to be incurred by such Party and its Affiliates in the applicable Calendar Year in accordance with the applicable U.S. Development Budget for such Calendar Year, or (B) the JSC approves such excess U.S. Development Costs (either before or after they are incurred) (to the extent exceeding the limit set forth in the forgoing clause (A)), which approval shall not be unreasonably withheld to the extent the U.S. Development Costs in excess of the U.S. Development Budget were not within the reasonable control of the Party (or Affiliate) incurring such expense.

(3) The U.S. Development Reconciliation Procedures shall provide for the JFC to develop a written report setting forth in reasonable detail the calculation of any net amount owed by KKC to MEI or by MEI to KKC, as the case may be, as necessary to accomplish the sharing of U.S. Development Costs set forth in Section 4.1(e)(i) (Cost Sharing) and this Section 4.1(e)(iv) (Reimbursement of U.S. Development Costs), and to prepare such report promptly following delivery of the report described in Section 4.1(e)(iii) (U.S. Development Cost Reports) and in a reasonable time (to be defined in the U.S. Development Reconciliation Procedures) in advance of payment. The net amount payable to accomplish the sharing of U.S. Development Costs as provided under this Agreement shall be paid by MEI or KKC, as the case may be, within **[*CONFIDENTIAL*]** after the end of the applicable Calendar Quarter. In the event of any dispute regarding the reconciliation payments due from one Party to the other, the Parties shall work together in good faith to resolve such dispute as expeditiously as possible.

(f) U.S. - Regulatory Responsibilities. MEI shall be responsible for all regulatory activities necessary to obtain and maintain Regulatory Approval of Products in the Field in the U.S. as the Marketing Authorization Holder. MEI shall keep KKC informed of regulatory developments related to the Compound and Products in the Field in or for the U.S. both via the JDC and MEI's reports pursuant to Section 7.1(b) (Development Reports), including by keeping KKC informed of scheduled MEI regulatory strategy discussions and meetings with Regulatory Authorities. MEI shall allow (i) to the extent permitted by Regulatory Authorities and without reducing the number of representatives of MEI and/or its Affiliates, up to three (3) representative(s) of KKC and/or its Affiliates to attend any such meetings as a silent observer (without any obligation on KKC to do so) with Regulatory Authorities, and (ii) representative(s) of KKC and/or its Affiliates to participate in MEI's internal meeting preparation process.

(g) U.S. - Regulatory Materials. MEI shall prepare and submit all Regulatory Materials for Products in the Field in the U.S. and shall own all Regulatory Materials and Regulatory Approvals for Products in the Field in the U.S. MEI shall timely notify KKC of all material submissions, filings with any Regulatory Authority and all material notices, correspondences, communications, or other filings received from any Regulatory Authority that are related to any Product in the U.S. Moreover, with respect to submission of (i) Marketing Authorization Application in the U.S., MEI will provide KKC with drafts of such filing not less than **[*CONFIDENTIAL*]** prior to submission so that KKC may review and comment, and (ii) other Regulatory Materials to any Regulatory Authority in the U.S., MEI will provide KKC with drafts of such submissions not **[*CONFIDENTIAL*]** (except in exigent circumstances) prior to document finalization so that KKC may review and comment on them; provided, that any failure by KKC to provide comments within the applicable review period shall not delay MEI's submission date. MEI shall consider all comments of KKC in good faith, taking into account the

best interests of the Development and/or Commercialization of the Product in the U.S. MEI shall also provide to KKC copies of the final submitted version of each Regulatory Material and each granted Regulatory Approval in the U.S. In addition, upon reasonable request by KKC, MEI shall also provide KKC with any Regulatory Material(s) not previously provided under this Section 4.1(g) (U.S. - Regulatory Materials). Upon request by MEI, KKC shall assist MEI in seeking and obtaining Regulatory Approvals with respect to Product in the U.S., including through: **[*CONFIDENTIAL*]**.

(h) U.S. - Regulatory Inspections. If a Regulatory Authority in the U.S. desires to conduct an inspection or audit of KKC's facilities or facilities under contract with KKC with regard to Manufacturing of the Compound or Product, KKC shall cooperate with such Regulatory Authority during such inspection or audit and shall **[*CONFIDENTIAL*]**. As reasonably requested by MEI in a timely manner KKC shall allow representative(s), details of which shall be discussed under quality agreement governing KKC's supply of Compound and Product to MEI, from MEI to attend any inspection or audit required by Regulatory Authority (as and to the extent permitted by such Regulatory Authority and any applicable CMOs) as a silent observer. MEI shall reimburse KKC for **[*CONFIDENTIAL*]** of any costs KKC incurs under this Section 4.1(h) (U.S. - Regulatory Inspections) promptly following receipt of an invoice for any such costs. Notwithstanding anything to the contrary herein, and without limiting Section 13.5 (Special Indirect and Other Losses), KKC's liability toward MEI caused by such a CMO's failure to perform its obligation under this Section 4.1(h) (U.S. - Regulatory Inspections) **[*CONFIDENTIAL*]** shall be limited to **[*CONFIDENTIAL*]**. For the avoidance of any doubt, this limitation of liability in the previous sentence shall not affect KKC's liability toward MEI under any other Sections of this Agreement.

(i) Authorized Generic. During the Term, if MEI determines to Develop an Authorized Generic of the Product for the U.S., then MEI shall promptly notify KKC thereof and the Parties shall negotiate exclusively in good faith regarding a potential commercial partnership for **[*CONFIDENTIAL*]** following such notification.

4.2 U.S. – Commercialization. Subject to the terms and conditions of this Agreement, and the Co-Promotion Agreement (as and to the extent applicable), the JCC shall oversee the Commercialization of Products in the Field in the U.S.

(a) U.S. - Commercialization Plan. The Parties shall conduct all Commercialization of Products in the Field in the U.S. in accordance with a comprehensive commercialization plan that is consistent with this Agreement (as amended in accordance with this Agreement, the "**U.S. Commercialization Plan**"), the initial version of which MEI will prepare and provide to the JCC for review and discussion (and subsequently present to the JSC for final approval), **[*CONFIDENTIAL*]** prior to the anticipated Regulatory Approval of Product in the Field in the U.S. From time to time, but at least once every Calendar Year, the JCC will update the U.S. Commercialization Plan and submit such updated plan to the JSC for final

approval. Notwithstanding anything to the contrary herein, if the terms of the U.S. Commercialization Plan contradict, or create actual or potential inconsistencies with, the terms of this Agreement, then the terms of this Agreement shall govern and the Parties shall perform relevant activities in accordance with this Agreement and not the U.S. Commercialization Plan to the extent of such conflict. The U.S. Commercialization Plan will be associated with the U.S. Commercialization Budget.

(b) U.S. - Commercialization Budget. The U.S. Commercialization Budget associated with a U.S. Commercialization Plan shall set forth the budgeted amounts for costs with respect to activities allocated to the Parties under such U.S. Commercialization Plan, and shall include for both Parties a budget for applicable Commercial FTE Costs and Out-of-Pocket Costs, broken down by Calendar Quarter for the then-current Calendar Year. The Commercialization Budget shall also include a breakout of costs by functional area or category as determined by the JCC.

(c) U.S. - Commercialization Costs. Subject to Section 4.4(b)(i) (Net Profit or Loss), U.S. Commercialization Costs incurred after the Effective Date by a Party shall be borne **[*CONFIDENTIAL*]**.

(d) U.S. - Commercial Diligence. The Parties, directly and/or with or through Affiliates or Sublicensees (or Direct Licensees with respect to MEI), shall use Commercially Reasonable Efforts to Commercialize, and optimize the commercial potential for, the Products that received Regulatory Approval in the Field in the U.S., and shall use Commercially Reasonable Efforts to execute and to perform, or cause to be performed, the activities assigned to it under the U.S. Commercialization Plan.

4.3 Co-Promotion Agreement. Following submission of the first MAA for a Product in the U.S. or at such earlier time as either Party may request, the Parties will negotiate in good faith and enter into an agreement governing the Parties' conduct of activities for co-promoting Products in the Field in the U.S. (the "**Co-Promotion Agreement**"). The Co-Promotion Agreement will be consistent with the terms of Schedule 4.3 (provided that primary responsibilities of each Party described in Schedule 4.3 may be reviewed and discussed under the JCC and may be revised, amended, added or deleted from time to time and then presented to the JSC for final approval), the U.S. Commercialization Plan most recently approved by the JSC, other terms agreed by the Parties, and other customary terms for such an agreement.

4.4 US – Financial Terms.

(a) U.S. - Milestone Payments. Within **[*CONFIDENTIAL*]** after a Party becomes aware that the milestone event below by or on behalf of MEI, KKC or any of their respective Affiliates or Sublicensees (or Direct Licensees with respect to MEI), has been first achieved, it shall notify the other Party thereof in writing. After receipt of such notice, MEI shall submit an invoice to KKC with respect to the corresponding milestone payment, and within **[*CONFIDENTIAL*]** after the receipt of such invoice, KKC shall pay to MEI the applicable non-refundable, non-creditable milestone payment corresponding to such milestone event as shown below.

Milestone Events	Milestone Payments (in U.S. Dollars)
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**

[*CONFIDENTIAL*]

[*CONFIDENTIAL*]

(b) U.S. – Net Profit or Loss.

(i) **Net Profit or Loss**. Each Party shall bear (and be entitled to) **[*CONFIDENTIAL*]**. The JCC shall establish procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters, to the extent not set forth in the Financial Exhibit (the "**Profit Reconciliation Procedures**," and together with the Development Reconciliation Procedures, the "**Reconciliation Procedures**"). Such procedures shall be designed to provide each Party with the ability to comply with its financial reporting requirements and should be consistent with the reporting and reconciliation process described in Section 4.4(b)(ii) (Quarterly Reconciliation and Payments).

(ii) **Quarterly Reconciliation and Payments**. Except to the extent otherwise agreed by the JCC, the Profit Reconciliation Procedures shall provide that within **[*CONFIDENTIAL*]** after the end of each Calendar Quarter, each Party shall submit to the JCC and JFC a report, in such reasonable detail and format as is established by the JFC, of all Gross Sales, Net Sales and U.S. Commercialization Costs and other amounts necessary to calculate Net Profit or Loss. Following receipt of such report, each Party shall reasonably cooperate to provide additional information as necessary to permit calculation and reconciliation of Net Profit or Loss for the applicable Calendar Quarter, and to confirm that, to the extent applicable, the U.S. Commercialization Costs are in conformance with the applicable U.S. Commercialization Budget. The Profit Reconciliation Procedures shall provide for the JCC to develop a written report setting forth in reasonable detail the calculation of Net Profit or Loss for the applicable month, amounts owed by one Party to the other as necessary to accomplish the sharing of Net Profit or Loss for the applicable month in accordance with Section 4.4(b)(i) (Net Profit or Loss), and to prepare such report promptly following delivery of the reports from the Parties as described above in this Section 4.4(b)(ii) (Quarterly Reconciliation and Payments) and in a reasonable time (to be defined in the Profit Reconciliation Procedures) in advance of applicable payments to accomplish the sharing of Net Profit or Loss for the applicable month. Payments to reconcile Net Profit or Loss such that the relevant reconciliation amounts shall be paid within **[*CONFIDENTIAL*]** after the end of each Calendar Quarter.

(iii) **Net Profit or Loss Term.** Net Profit or Loss shall be allocated and shared under this Section 4.4(b) (U.S. – Net Profit or Loss) on a Product-by-Product basis from the Effective Date until the Expiration Date for such Product in the U.S.

ARTICLE 5
JAPAN SPECIFIC TERMS

5.1 JP – Development. Subject to the terms and conditions of this Agreement, KKC shall be responsible for the Development of the Compound and Products in the Field in Japan, including conduct of preclinical studies and Clinical Trials that are required by Regulatory Authority in Japan to support Regulatory Approval of the Compound and Products in the Field in Japan.

(a) JP - Development Plan. KKC shall conduct all Development of the Compound and Products in the Field in Japan in accordance with a comprehensive development plan (as amended in accordance with this Agreement, the "**JP Development Plan**"), including the timelines set forth therein, the current version of which is attached to this Agreement as Schedule 5.1(a). The JP Development Plan shall be focused on efficiently obtaining Regulatory Approval for the Product in the Field in Japan, while taking into consideration actual and potential Development, Regulatory Approval or commercial impacts on the Product outside of Japan and/or the Field. During the Term, KKC will review the JP Development Plan from time to time, not less than **[*CONFIDENTIAL*]**, and amend such JP Development Plan on an ongoing basis as necessary. Any such amendment to the JP Development Plan will be reviewed and discussed by the JDC, and presented to the JSC for final approval; provided, that, (i) under no circumstances shall KKC conduct any Development activities as part of a JP Development Plan that would reasonably be expected to have a material adverse safety effect on the Development or Commercialization of the Compound in the U.S. and (ii) if the terms of the JP Development Plan contradict, or create actual or potential inconsistencies with, the terms of this Agreement, then the terms of this Agreement shall govern and KKC shall perform relevant activities in accordance with this Agreement and not the JP Development Plan. The then-current JP Development Plan will at all times contain at least that level of detail and cover at least the same matters (to the extent applicable) as the prior iteration of the JP Development Plan.

(b) JP - Development Diligence. KKC, directly and/or with or through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Develop, and to obtain Regulatory Approval for the Compound and Product in the Field in Japan in accordance with the JP Development Plan for the Indications of **[*CONFIDENTIAL*]**. The Parties acknowledge and agree that KKC's failure to undertake any Development activities for a period **[*CONFIDENTIAL*]** shall be deemed to be a material breach (which, for clarity, shall be subject to the terms of Section 11.2(b) including the cure period thereunder) of this Agreement to the extent that there are no unexpected material delays in U.S. Global Studies conducted by MEI that affect KKC's Development in Japan.

(c) JP - Development Costs. Subject to the terms and conditions of this Agreement, KKC shall be solely responsible for the cost for the Development of Compounds and Products in the Field in Japan, including all of the costs in connection with seeking Regulatory

Approval of the Product in Japan and as otherwise set forth in Section 7.3(b) (JP and RoW - Supply) of this Agreement. For clarity, in the case of KKC joining **[*CONFIDENTIAL*]** or its designees, KKC shall **[*CONFIDENTIAL*]**. In such case, MEI shall invoice KKC from time-to-time in connection with JP Development Costs incurred in connection with the foregoing, and KKC shall pay such invoices within **[*CONFIDENTIAL*]** of receipt of an invoice thereof.

(d) JP - Regulatory Responsibilities. KKC shall be responsible for all regulatory activities necessary to obtain and maintain Regulatory Approval of Products in the Field in Japan as the Marketing Authorization Holder. KKC shall keep MEI informed of regulatory developments related to the Compound and Products in the Field in Japan both via the JDC and KKC's reports pursuant to Section 7.1(b). (Development Reports).

(e) JP - Regulatory Materials. KKC shall prepare and submit all Regulatory Materials for Products in the Field in Japan and shall own all Regulatory Materials and Regulatory Approvals for Products in the Field in Japan. KKC shall timely notify MEI of all material submissions, filings with any Regulatory Authority and all material notices, correspondences, communications, or other filings received from any Regulatory Authority that are related to any Product in Japan. Moreover, with respect to submission of (i) Marketing Authorization Application in Japan, KKC will provide MEI with drafts of such filing and a reasonable English summary of such filing (which summary will include key information) not less than **[*CONFIDENTIAL*]** prior to submission so that MEI may review and comment, and (ii) other Regulatory Materials to any Regulatory Authority in Japan, KKC will provide MEI with drafts of such submissions and reasonable English summaries of such submissions (which summaries will include key information) not **[*CONFIDENTIAL*]** (except in exigent circumstances) prior to document finalization so that MEI may review and comment on them; provided, that any failure by MEI to provide comments within the applicable review period shall not delay KKC's submission date. KKC shall consider all comments of MEI in good faith, taking into account the best interests of the Development and/or Commercialization of the Product. For clarity, such English summaries to be provided prior to document submission or finalization, as applicable, shall include **[*CONFIDENTIAL*]**. KKC shall also provide to MEI copies of the final submitted version of each Regulatory Material and each granted Regulatory Approval in Japan and an English translation of such Regulatory Approval. In addition, upon reasonable request by MEI, KKC shall also provide MEI with any Regulatory Material(s) not previously provided under this Section 5.1(e) (JP - Regulatory Materials). Upon request by KKC, MEI shall, subject to the reasonable availability of MEI's relevant personnel, assist KKC in seeking and obtaining Regulatory Approvals with respect to Product in Japan, including through: **[*CONFIDENTIAL*]**, and shall, subject to the reasonable availability of MEI's relevant personnel, use Commercially Reasonable Efforts to provide additional support requested by KKC thereafter, at a rate of **[*CONFIDENTIAL*]** per hour in excess of **[*CONFIDENTIAL*]**.

(f) JP - Regulatory Inspections. If a Regulatory Authority in Japan desires to conduct an inspection or audit of MEI's facilities or facilities under contract with MEI with regard to Manufacturing of the Compound or Product, MEI shall cooperate with such Regulatory Authority during such inspection or audit and shall **[*CONFIDENTIAL*]**. As reasonably requested by KKC in a timely manner MEI shall allow representative(s), details of which shall be discussed under the JP and RoW Quality Agreement, from KKC to attend any inspection or audit required by Regulatory Authority (as and to the extent permitted by such Regulatory Authority

and any applicable CMOs) as a silent observer. KKC shall reimburse MEI for any costs MEI incurs under this Section 5.1(f) (JP - Regulatory Inspections) promptly following receipt of an invoice for any such costs. Notwithstanding anything to the contrary herein, and without limiting Section 13.5 (Special Indirect and Other Losses), MEI's liability toward KKC caused by such a CMO's failure to perform its obligation under this Section 5.1(f) (JP - Regulatory Inspections) **[*CONFIDENTIAL*] (shall be limited to [*CONFIDENTIAL*]. For the avoidance of any doubt, this limitation of liability in the previous sentence shall not affect MEI's liability toward KKC under any other Sections of this Agreement.**

(g) JP - Pricing Approval Documentation. Upon MEI's reasonable request, from time-to-time, KKC shall provide to MEI KKC's, its Affiliates', and its Sublicensees' materials, including correspondence and submissions, related to negotiating for, obtaining, and maintaining Pricing Approval in Japan and shall discuss the same with MEI upon MEI's request.

5.2 JP - Commercialization. Subject to the terms and conditions of this Agreement, KKC shall be responsible for all aspects of the Commercialization of the Products in the Field in Japan, including, solely with respect to the Products in the Field in Japan: (a) developing and executing a commercial launch and pre-launch plan; (b) negotiating with applicable Government Authorities in Japan regarding the price and reimbursement status of the Products and obtaining and maintaining the NHI Price Approvals; (c) marketing, medical affairs, and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to Applicable Law relating to the marketing, detailing and promotion of Products in the Field in Japan. As between the Parties, KKC shall be solely responsible for the costs and expenses of Commercialization of the Products in the Field in Japan.

(a) JP - Commercialization Plan. KKC shall conduct all Commercialization of Products in the Field in Japan in accordance with a comprehensive commercialization plan that is consistent with this Agreement (as amended in accordance with this Agreement, the "**JP Commercialization Plan**"), the initial version of which KKC will prepare and provide to the JCC for review and discussion, and subsequent presentation to the JSC for review, no later than **[*CONFIDENTIAL*]** after initial submission of the Marketing Authorization Application of Product in the Field in Japan, and such plan will include a pricing strategy for the Product; provided, however, that KKC shall have ultimate decision-making authority and control over the content of the JP Commercialization Plan, subject to KKC under no circumstances conducting any Commercialization activities that would reasonably be expected to have a material adverse effect on the Commercialization of the Product in the U.S. From time to time, but at least **[*CONFIDENTIAL*]**, KKC will update the JP Commercialization Plan and submit such updated plan to the JCC for review and discussion, and subsequent presentation to the JSC for review and discussion; provided, that, (i) the JP Commercialization Plan shall be consistent with, and not adversely affect, with respect to the Product, global brand positioning, global trademarks, or the U.S. Commercialization Plan, and (ii) if the terms of the JP Commercialization Plan contradict, or create actual or potential inconsistencies with, the terms of this Agreement, then the terms of this Agreement shall govern and KKC shall perform relevant activities in accordance with this Agreement and not the JP Commercialization Plan.

(b) JP - Commercial Diligence. KKC, directly and/or with or through Affiliates or, subject to Section 3.3 (Sublicense Rights), Sublicensees, shall use Commercially Reasonable Efforts to Commercialize, and optimize the commercial potential for, the Products that received Regulatory Approval in the Field in Japan. Without limiting the foregoing, in connection with the Commercialization of Products in the Field in Japan:

(i) KKC shall promote Products in a professional, diligent and honest manner in accordance with Applicable Law and industry standards;

(ii) KKC shall not (A) sell any Product as part of a bundle with any other products, (B) utilize deceptive, misleading or unethical business practices or (C) take any action or inaction that would reasonably be likely to prejudice the value of any Product;

(iii) KKC shall seek a daily NHI Price equal to or greater than **[*CONFIDENTIAL*]**; and

(iv) KKC shall undertake a First Commercial Sale within **[*CONFIDENTIAL*]** of the NHI Price listing for a Product in Japan.

(c) JP - Creation of Promotional Materials. KKC will create and develop materials for marketing, advertising and promoting the Products in the Field in Japan ("**JP Promotional Materials**") in accordance with the Regulatory Approvals and Applicable Laws and at KKC's sole cost and expense. To the extent KKC includes any MEI corporate trademarks in the JP Promotional Materials for Japan, KKC shall comply with MEI's then current guidelines for trademark usage. KKC will review all JP Promotional Materials and programs in connection with the Commercialization of Products prior to use thereof to ensure that all are in accordance with the JP Commercialization Plan, the Regulatory Approvals and Applicable Laws. KKC shall provide MEI with copies of final versions of material JP Promotional Materials through the JCC which (i) are prepared in connection with the First Commercial Sale of the Product and that KKC is intending to use in connection with Commercialization the Products, or (ii) introduce any change to the key message(s) contained in such JP Promotional Materials.

5.3 JP – Financial Terms.

(a) JP - Upfront Payment. The Parties acknowledge and agree that KKC has satisfied its requirement under the JP Agreement to pay to MEI a one-time, non-refundable and non-creditable upfront payment of ten million Dollars ($10,000,000).

(b) JP - Milestone Payments. Within **[*CONFIDENTIAL*]** after the first achievement of each milestone event below by or on behalf of KKC or any of its Affiliates or Sublicensees, KKC shall notify MEI of the achievement of such milestone event. After receipt of such notice, MEI shall submit an invoice to KKC with respect to the corresponding milestone payment, and within **[*CONFIDENTIAL*]** after receipt of such invoice, KKC shall pay to MEI the applicable non-refundable, non-creditable milestone payment corresponding to such milestone event as shown below.

Milestone Events	Milestone Payments (in U.S. Dollars)
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**

[*CONFIDENTIAL*].

*** [*CONFIDENTIAL*].**

**** [*CONFIDENTIAL*].**

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(c) JP - Commercial Milestones.

(i) Within **[*CONFIDENTIAL*]** after the annual Net Sales in Japan for a Calendar Year reach any threshold indicated in the milestone events listed below, KKC shall notify MEI of the achievement of such milestone event and pay to MEI the corresponding non-refundable, non-creditable milestone payment set forth below.

Annual Net Sales Milestone Events	Milestone Payments
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**

(ii) For purposes of determining whether a Net Sales milestone event has been achieved, Net Sales of all Products in Japan shall be aggregated. For clarity, the annual Net Sales milestone payments set forth in this Section 5.3(c) (JP - Commercial Milestones) shall be payable only once for all Products with respect to Japan, upon the first achievement of the applicable milestone event.

(iii) If a Milestone Event in this Section 5.3(c) (JP - Commercial Milestones) is achieved and payment with respect to any previous milestone event has not been made, then such previous milestone event shall be deemed achieved, MEI shall invoice KKC for such unpaid previous milestone event(s) and KKC shall pay MEI such unpaid previous milestone payment(s) within **[*CONFIDENTIAL*]** of receipt of such invoice.

(d) JP - Royalty Payments.

(i) **JP – Royalty Rates.** KKC shall pay to MEI non-refundable, non-creditable royalties on aggregate annual Net Sales of all Products in Japan in each Calendar Year ("**JP Aggregate Annual Net Sales**") at the applicable rate(s) set forth below, with such royalties to be calculated by multiplying the applicable incremental amount of JP Aggregate Annual Net Sales in such Calendar Year by the corresponding royalty rate set forth in the table below:

JP Aggregate Annual Calendar Year Net Sales of the Products	Royalty Rates
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**

(ii) **JP - Royalty Term.** Royalties under this Section 5.3(d) (JP - Royalty Payments) shall be payable on a **[*CONFIDENTIAL*]** from the First Commercial Sale of such Product in Japan until the Expiration Date for such Product in Japan (the "**JP Royalty Term**" for such Product).

(iii) **JP - Royalty Reports and Payment.** KKC shall calculate all Royalty Payments payable to MEI pursuant to this Section 5.3(d) (JP - Royalty Payments) with respect to Net Sales at the end of each Calendar Quarter, which amounts shall be converted to Dollars at such time in accordance with Section 8.3 (Currency Conversion). KKC shall pay to MEI the royalty payment due for Net Sales during a given Calendar Quarter within **[*CONFIDENTIAL*]** after the end of such Calendar Quarter. Each royalty payment due shall be accompanied by (A) a statement of the amount of Gross Sales of each Product during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars), (B) an itemized calculation of Net Sales showing deductions from Gross Sales provided for in the definition of "Net Sales" during such Calendar Quarter, and (C) a statement of the prices and the number of units of Products sold. KKC shall be responsible for the proper accounting of Net Sales by or on behalf of its Affiliates and Sublicensees.

(e) JP - Royalty Adjustments. Except as otherwise set forth in this Agreement, royalties due hereunder with respect to Japan are subject to adjustment as set forth below (such adjustments to be prorated for the Calendar Quarter in which the adjustment becomes applicable), provided, however, that the royalties payable under Section 5.3(d)(i) (JP - Royalty Payments) shall not be reduced by more than **[*CONFIDENTIAL*]** of the amounts set forth in Section 5.3(d)(i) (JP - Royalty Payments) by any or all reasons of the adjustments set forth below.

(i) **JP - Royalty Adjustment for Third Party License Payments.** If a license to any Third Party Patent is entered under Section 9.5 (Third Party Intellectual Property Rights), then the amount of royalties payable under Section 5.3(d)(i) (JP - Royalty Payments) with respect to Japan shall be adjusted in accordance with Section 9.5 (Third Party Intellectual Property Rights).

(ii) **JP - Royalty Adjustment for Generic Competition.** If a Generic Product receives Regulatory Approval and is sold in Japan, then for so long as such Generic Product is being sold in Japan the royalties payable to MEI on the sales of such Product shall be reduced by **[*CONFIDENTIAL*]**.

(iii) **JP - Royalty Adjustment for Pricing.** If the JP Royalty Term is continuing with respect to a given Product on or after the date that is **[*CONFIDENTIAL*]** after the date that the NHI Price is first listed for such Product in Japan, then the royalties payable to MEI on the sales of such Product shall be reduced by **[*CONFIDENTIAL*]**.

(f) JP - Financial Adjustments. In case it appears likely that the **[*CONFIDENTIAL*]**, the Parties shall discuss and negotiate in good faith regarding potential adjustments to **[*CONFIDENTIAL*]**; provided, that, in no event shall any such newly negotiated financial terms be less favorable to MEI in their totality and in no event shall either Party be obligated to agree to any such adjustments.

ARTICLE 6
RoW SPECIFIC TERMS

6.1 RoW – Development. Subject to the terms and conditions of this Agreement, KKC shall be responsible for the Development of the Compound and Products in the Field in the RoW, including conduct of preclinical studies and Clinical Trials that are required by Regulatory Authority in the RoW to support Regulatory Approval of the Compound and Products in the Field in the RoW.

(a) RoW - Development Plan. KKC shall conduct all Development of the Compound and Products in the Field in the RoW in accordance with a comprehensive development plan (as amended in accordance with this Agreement, the "**RoW Development Plan**"), including the timelines set forth therein, the initial version of which shall be generated by KKC and delivered to the JDC no later than **[*CONFIDENTIAL*]** after the Effective Date for review and discussion, and subsequently presented to the JSC for final approval. The RoW Development Plan shall be focused on efficiently obtaining Regulatory Approval for the Product in the Field in the RoW, while taking into consideration actual and potential Development, Regulatory Approval or commercial impacts on the Product outside of the RoW and/or the Field. During the Term, KKC will review the RoW Development Plan from time to time, not less than **[*CONFIDENTIAL*]**, and amend such RoW Development Plan on an ongoing basis as necessary. Any such amendment to the RoW Development Plan will be reviewed and discussed by the JDC, and presented to the JSC for final approval; provided, that, (i) under no circumstances shall KKC conduct any Development activities as part of a RoW Development Plan that would reasonably be expected to have a material adverse safety effect on the Development or Commercialization of the Compound in the U.S. and (ii) if the terms of the RoW Development Plan contradict, or create actual or potential inconsistencies with, the terms of this Agreement, then the terms of this Agreement shall govern and KKC shall perform relevant activities in accordance with this Agreement and not the RoW Development Plan. The then-current RoW Development Plan will at all times contain at least that level of detail and cover at least the same matters (to the extent applicable) as the prior iteration of the RoW Development Plan.

(b) RoW - Development Diligence. KKC, directly and/or with or through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Develop, and to obtain Regulatory Approval for the Compound and Product in the Field in **[*CONFIDENTIAL*]** in accordance with the then-current RoW Development

Plan for the Indications of **[*CONFIDENTIAL*]** shall be deemed to be a material breach (which, for clarity, shall be subject to the terms of Section 11.2(b) including the cure period thereunder) of this Agreement to the extent that there are no unexpected material delays in U.S. Global Studies conducted by MEI that affect KKC's Development in **[*CONFIDENTIAL*]**, as applicable.

(c) RoW - Development Costs. KKC shall be solely responsible for the cost for the Development of Compounds and Products in the Field in the RoW, including all of the costs in connection with seeking Regulatory Approval of the Product in the RoW and as otherwise set forth in Section 7.3(b) (JP and RoW – Supply) of this Agreement. For clarity, in the case of KKC joining **[*CONFIDENTIAL*]**.

(d) RoW - Regulatory Responsibilities. KKC shall be responsible for all regulatory activities necessary to obtain and maintain Regulatory Approval of Products in the Field in the RoW as the Marketing Authorization Holder; provided that **[*CONFIDENTIAL*]** and the Parties will cooperate to facilitate such activities. For clarity, Regulatory Materials relating to **[*CONFIDENTIAL*]**. KKC shall keep MEI informed of regulatory developments related to the Compound and Products in the Field in the RoW both via the JDC and KKC's reports pursuant to Section 7.1(b) (Development Reports).

(e) RoW - Regulatory Materials. KKC shall prepare and submit all Regulatory Materials for Products in the Field in the countries within the RoW where KKC Develops or Commercializes and shall own all Regulatory Materials and Regulatory Approvals for Products in the Field in the RoW, subject to Section 6.1(d) (RoW – Regulatory Responsibilities). KKC shall timely notify MEI of all material submissions, filings with any Regulatory Authority and all material notices, correspondences, communications, or other filings received from any Regulatory Authority that are related to any Product in such countries. Moreover, with respect to submission of (i) Marketing Authorization Application, KKC will provide MEI with drafts of such filing and a reasonable English summary of such filing (which summary will include key information) not less **[*CONFIDENTIAL*]** prior to submission so that MEI may review and comment, and (ii) other Regulatory Materials to any Regulatory Authority, KKC will provide MEI with drafts of such submissions and reasonable English summaries of such submissions (which summaries will include key information) not **[*CONFIDENTIAL*]** (except in exigent circumstances) prior to document finalization so that MEI may review and comment on

them; provided, that (1) any failure by MEI to provide comments within the applicable review period shall not delay KKC's submission date; and (2) any obligation by KKC to provide drafts of submissions to MEI pursuant to (i) and (ii) above shall apply to **[*CONFIDENTIAL*]**, and KKC's obligation pursuant to (i) and (ii) above with respect to **[*CONFIDENTIAL*]** shall be subject to prior discussion and mutual agreement under the JDC regarding the applicable countries for which KKC will provide MEI with such submissions. KKC shall consider all comments of MEI in good faith, taking into account the best interests of the Development and/or Commercialization of the Product. For clarity, such English summaries to be provided prior to document submission or finalization, as applicable, **[*CONFIDENTIAL*]**. Upon reasonable request by MEI, KKC shall also provide to MEI copies of the final submitted version of each Regulatory Material and each granted Regulatory Approval in the RoW and an English translation of such Regulatory Approval; provided that countries to provide such copies of Regulatory Materials and granted Regulatory Approvals **[*CONFIDENTIAL*]**. In addition, upon reasonable request by MEI, KKC shall also provide MEI with any Regulatory Material(s) not previously provided under this Section 6.1(e) (RoW - Regulatory Materials). Upon request by KKC, MEI shall, subject to the reasonable availability of MEI's relevant personnel, assist KKC in seeking and obtaining Regulatory Approvals with respect to Product in the RoW, including through: **[*CONFIDENTIAL*]**. MEI will provide such support to assist KKC with respect to regulatory matters under this Section 6.1(e) (RoW – Regulatory Materials) or under Section 5.1(e) (JP - Regulatory Materials) at no cost for the **[*CONFIDENTIAL*]**, and shall, subject to the reasonable availability of MEI's relevant personnel, use Commercially Reasonable Efforts to provide additional support requested by KKC thereafter, at a rate of **[*CONFIDENTIAL*]** per hour in excess of such limit thereafter, payable by KKC to MEI.

(f) RoW - Regulatory Inspections. If a Regulatory Authority in RoW desires to conduct an inspection or audit of MEI's facilities or facilities under contract with MEI with regard to Manufacturing of the Compound or Product, MEI shall cooperate with such Regulatory Authority during such inspection or audit and shall **[*CONFIDENTIAL*]** details of which shall be discussed under the JP and RoW Quality Agreement. KKC shall

reimburse MEI for any costs MEI incurs under this Section 6.1(f) (RoW - Regulatory Inspections) promptly following receipt of an invoice for any such costs. Notwithstanding anything to the contrary herein, and without limiting Section 13.5 (Special Indirect and Other Losses), MEI's liability toward KKC caused by such a CMO's failure to perform its obligation under this Section 6.1(f) (RoW - Regulatory Inspections) **[*CONFIDENTIAL*]**. For the avoidance of any doubt, this limitation of liability in the previous sentence shall not affect MEI's liability toward KKC under any other Sections of this Agreement.

(g) RoW - Pricing Approval Information. KKC shall provide to MEI, KKC's, its Affiliates' and its Sublicensees' pricing strategies related to Pricing Approvals of RoW through the JCC, provided that upon MEI's reasonable request, from time-to-time, KKC will **[*CONFIDENTIAL*]**, and shall discuss the same with MEI.

6.2 RoW – Commercialization. Subject to the terms and conditions of this Agreement, KKC shall be responsible for all aspects of the Commercialization of the Products in the Field in the RoW, including, solely with respect to the Products in the Field in the RoW: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Government Authorities in the RoW regarding the price and reimbursement status of the Products and obtaining and maintaining the Pricing Approvals; (c) marketing, medical affairs, and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to Applicable Law relating to the marketing, detailing and promotion of Products in the Field in the RoW. As between the Parties, KKC shall be solely responsible for the costs and expenses of Commercialization of the Products in the Field in the RoW.

(a) RoW - Commercialization Plan. KKC shall conduct all Commercialization of Products in the Field in the RoW in accordance with a comprehensive commercialization plan that is consistent with this Agreement (as amended in accordance with this Agreement, the "**RoW Commercialization Plan**"), the initial version of which KKC will prepare and provide to the JCC for review and discussion, and subsequent presentation to the JSC for review, no later than **[*CONFIDENTIAL*]** after initial submission of the Marketing Authorization Application of Product in the Field in a first country in RoW, and such plan will include a pricing strategy for the Product; provided, however, that KKC shall have ultimate decision-making authority and control over the content of the RoW Commercialization Plan, subject to KKC under no circumstances conducting any Commercialization activities that would reasonably be expected to have a material adverse effect on the Commercialization of the Product in the U.S. From time to time, but at least once every **[*CONFIDENTIAL*]**, KKC will update the RoW Commercialization Plan and submit such updated plan to the JCC for review and discussion, and subsequent presentation to the JSC for review and discussion; provided, that, (i)

the RoW Commercialization Plan shall be consistent with, and not adversely affect, with respect to the Product, global brand positioning, global trademarks, or the U.S. Commercialization Plan, and (ii) if the terms of the RoW Commercialization Plan contradict, or create actual or potential inconsistencies with, the terms of this Agreement, then the terms of this Agreement shall govern and KKC shall perform relevant activities in accordance with this Agreement and not the RoW Commercialization Plan

(b) RoW - Commercial Diligence. KKC, directly and/or with or through Affiliates or, subject to Section 3.3 (Sublicense Rights), Sublicensees, shall use Commercially Reasonable Efforts to Commercialize, and optimize the commercial potential for, the Products that received Regulatory Approval in the Field in the RoW in accordance with the RoW Commercialization Plan. Without limiting the foregoing, in connection with the Commercialization of Products in the Field in a country(ies) within the RoW:

(i) KKC shall promote Products in a professional, diligent and honest manner in accordance with Applicable Law and industry standards;

(ii) KKC shall not (A) sell any Product as part of a bundle with any other products, (B) utilize deceptive, misleading or unethical business practices or (C) take any action or inaction that would reasonably be likely to prejudice the value of any Product; and

(iii) KKC shall use Commercially Reasonable Effort to undertake a First Commercial Sale of a given Product in a country within **[*CONFIDENTIAL*]** of receipt of the first grant of any necessary Pricing Approvals for such Product in the applicable country, provided that in case of any delay in First Commercial Sale of such country, KKC shall promptly inform JCC on the reasons of such delay.

(c) RoW - Creation of Promotional Materials. KKC will create and develop materials for marketing, advertising and promoting the Products in the Field in the RoW ("**RoW Promotional Materials**") in accordance with the Regulatory Approvals and Applicable Laws and at KKC's sole cost and expense. To the extent KKC includes any MEI corporate trademarks in the RoW Promotional Materials for the RoW, KKC shall comply with MEI's then current guidelines for trademark usage. KKC will review all RoW Promotional Materials and programs in connection with the Commercialization of Products prior to use thereof to ensure that all are in accordance with the RoW Commercialization Plan, the Regulatory Approvals and Applicable Laws. Upon MEI's reasonable request, KKC shall provide MEI with copies of final versions of material RoW Promotional Materials through the JCC which (i) are prepared in connection with the First Commercial Sale of the Product and that KKC is intending to use in connection with Commercialization the Products, or (ii) introduce any change to the key message(s) contained in such RoW Promotional Materials.

6.3 RoW - Financial Terms.

(a) RoW - Milestone Payments. Within **[*CONFIDENTIAL*]** after the first achievement of each milestone event below by or on behalf of KKC or any of its Affiliates or Sublicensees, KKC shall notify MEI of the achievement of such milestone event. After receipt of such notice, MEI shall submit an invoice to KKC with respect to the corresponding milestone

payment, and within **[*CONFIDENTIAL*]** after receipt of such invoice, KKC shall pay to MEI the applicable non-refundable, non-creditable milestone payment corresponding to such milestone event as shown below.

Milestone Events	Milestone Payments (in U.S. Dollars)
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**

[*CONFIDENTIAL*]

[*CONFIDENTIAL*] [*CONFIDENTIAL*]

(b) RoW - Commercial Milestones.

Within **[*CONFIDENTIAL*]** after the annual Net Sales in the RoW for a Calendar Year reach any threshold indicated in the milestone events listed below, KKC shall notify MEI of the achievement of such milestone event and pay to MEI the corresponding non-refundable, non-creditable milestone payment set forth below.

Annual Net Sales Milestone Events	Milestone Payments
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**

(i) For purposes of determining whether a Net Sales milestone event has been achieved, Net Sales of all Products in the RoW shall be aggregated. For clarity, the annual Net Sales milestone payments set forth in this Section 6.3(b) (RoW - Commercial Milestones) shall be payable only once for all Products in the RoW, upon the first achievement of the applicable milestone event.

(ii) If a Milestone Event in this Section 6.3(b) (RoW - Commercial Milestones) is achieved and payment with respect to any previous milestone event has not been made, then such previous milestone event shall be deemed achieved, MEI shall invoice KKC for

such unpaid previous milestone event(s) and KKC shall pay MEI such unpaid previous milestone payment(s) within **[*CONFIDENTIAL*]** of receipt of such invoice.

(c) RoW - Royalty Payments.

(i) **RoW – Royalty Rates.** KKC shall pay to MEI non-refundable, non-creditable royalties on aggregate annual Net Sales of all Products in the RoW in each Calendar Year ("**RoW Aggregate Annual Net Sales**") at the applicable rate(s) set forth below, with such royalties to be calculated by multiplying the applicable incremental amount of RoW Aggregate Annual Net Sales in such Calendar Year by the corresponding royalty rate set forth in the table below:

RoW Aggregate Annual Calendar Year Net Sales of the Products	Royalty Rates
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**

(ii) **RoW - Royalty Term.** Royalties under this Section 6.3(c) (RoW - Royalty Payments) shall be payable on a Product-by-Product and country-by-country basis from the First Commercial Sale of such Product in a given country in the RoW until the Expiration Date for such Product in such country.

(iii) **RoW - Royalty Reports and Payment.** KKC shall calculate all Royalty Payments payable to MEI pursuant to this Section 6.3(c) (RoW - Royalty Payments) with respect to Net Sales at the end of each Calendar Quarter, which amounts shall be converted to Dollars at such time in accordance with Section 8.3 (Currency Conversion). KKC shall pay to MEI the royalty payment due for Net Sales during a given Calendar Quarter within **[*CONFIDENTIAL*]**. Each royalty payment due shall be accompanied by (A) a statement of the amount of Gross Sales of each Product during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars), (B) an itemized calculation of Net Sales showing deductions from Gross Sales provided for in the definition of "Net Sales" during such Calendar Quarter, and (C) a statement of the prices and the number of units of Products sold. KKC shall be responsible for the proper accounting of Net Sales by or on behalf of its Affiliates and Sublicensees.

(d) RoW - Royalty Adjustments. Except as otherwise set forth in this Agreement, royalties due hereunder with respect to RoW are subject to adjustment as set forth below (such adjustments to be prorated for the Calendar Quarter in which the adjustment becomes applicable), provided, however, that the royalties payable under Section 6.3(c)(i) (RoW - Royalty Rates) shall not be reduced by more than **[*CONFIDENTIAL*]** of the amounts set forth in Section 6.3(c)(i) (RoW - Royalty Rates) by any or all reasons of the adjustments set forth below.

(i) **RoW - Royalty Adjustment for Third Party License Payments.** If a license to any Third Party Patent is entered under Section 9.5 (Third Party Intellectual Property Rights), then the amount of royalties payable under Section 6.3(c)(i) (RoW - Royalty Rates) with

respect to the RoW shall be adjusted in accordance with Section 9.5 (Third Party Intellectual Property Rights).

(ii) **RoW - Royalty Adjustment for Generic Competition.** On a country-by-country basis with respect to the RoW, if a Generic Product receives Regulatory Approval and is sold in such country, then the royalties payable to MEI on the sales of such Product shall be reduced by **[*CONFIDENTIAL*]** thereafter.

(iii) **RoW - Sui Generis Royalty Adjustment.** The Parties shall discuss in good faith a possible reduction of the royalty rates set forth in Section 6.3(c)(i) (RoW – Royalty Rates) for a country in the RoW if the Parties agree **[*CONFIDENTIAL*]**.

ARTICLE 7
GENERAL DEVELOPMENT, REGULATORY, SUPPLY AND COMMERCIAL PROVISIONS

7.1 Development.

(a) Development Records. Each Party shall, and shall cause its Affiliates and Sublicensees to, maintain, in good scientific manner, complete and accurate books and records pertaining to Development of the Compound and Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall (i) be appropriate for patent and regulatory purposes, (ii) be in compliance with Applicable Law, (iii) properly reflect all work done and results achieved in the performance of Development activities hereunder, (iv) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement, and (v) be retained by each Party for at least **[*CONFIDENTIAL*]** after the expiration or termination of this Agreement or for such longer period as may be required by Applicable Law, and during such period, neither Party shall dispose of any such books and records without the prior written consent of the other Party. Both Parties shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such books and records maintained pursuant to this Section 7.1(a) (Development Records), provided that requesting Party shall bear all the costs for such inspection.

(b) Development Reports. Without limiting Section 7.1(a) (Development Records), at least **[*CONFIDENTIAL*]** prior to each meeting of the JDC each Party shall provide the JDC with an update report of such Development activities it has performed, or caused to be performed, since the preceding report, its Development activities in process, and the future activities it expects to initiate during the following **[*CONFIDENTIAL*]** period (each an "**Update Report**"). In addition, within **[*CONFIDENTIAL*]** after the end of each Calendar Year, each Party shall provide the JDC with a detailed written report summarizing all Development activities it has undertaken in the preceding Calendar Year (each an "**Annual Report**"). Each

such Update Report and Annual Report shall contain sufficient detail to enable the JDC to assess each Party's compliance with its obligations set forth in Sections 4.1(a) (U.S. - Development Plan), 4.1(c) (U.S. - Development Diligence), 5.1(a) (JP - Development Plan), 5.1(b) (JP - Development Diligence), 6.1(a) (RoW - Development Plan), and 6.1(b) (RoW - Development Diligence), including: (i) each Party's, or its Affiliates' or Sublicensees' activities with respect to achieving Regulatory Approvals of Products in the Territory; (ii) results of Clinical Trials and other Development activities not otherwise provided under subsection (i) above; and (iii) the Regulatory Approvals that the Parties or any of its Affiliates reasonably expect to make, seek or attempt to obtain in the Territory.

7.2 Regulatory.

(a) Cooperation for Regulatory Activities. Upon a reasonable request from the Party obligated to the regulatory activity in each Territory, the other Party shall cooperate in good faith to obtain and maintain Regulatory Approval of Products in the Field in the Territory; provided, that MEI's obligations under this Section 7.2(a) shall be subject to, and performed in accordance with, Section 5.1(e) (JP – Regulatory Materials) and 6.1(e) (RoW – Regulatory Materials).

(b) Inspections for Improper Activities. If any Regulatory Authority (i) contacts a Party or any of its Affiliates or any Sublicensee with respect to the alleged improper Development, Packaging, Manufacture or Commercialization of any Product, (ii) conducts, or gives notice of its intent to conduct, an inspection at such Party's or its Affiliate's or a Sublicensee's (including the facilities of any subcontractor(s) of any of the foregoing) facilities used in the Development, Packaging or Manufacturing of Products, or (iii) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of such Party or its Affiliates or a Sublicensee that could reasonably be expected to adversely affect any Development, Packaging, Manufacture or Commercialization activities with respect to the Product, then such Party will (A) promptly notify the other Party of such contact, inspection or notice and (B) provide copies of all reports and correspondence received from or provided to any such Regulatory Authority in connection with any of the matters identified in the foregoing clauses (i), (ii) or (iii). In addition, the other Party shall have the right to attend any such meetings or inspections to the extent not prohibited by such Regulatory Authority.

(c) Sharing of Regulatory Data and Filings.

(i) **MEI.** MEI shall make available MEI's, its Affiliates' and its Sublicensee's material Regulatory Data and material Regulatory Materials to KKC, its Affiliates, and its Sublicensees, for no additional consideration, for use solely in the Development, Manufacturing, Packaging, and Commercialization of the Compound and the Products in the Field in the Territory. MEI shall ensure that all Sublicensees of MEI shall be required to provide such material Regulatory Data and material Regulatory Materials to MEI for use by KKC.

(ii) **KKC.** KKC shall make available KKC's, its Affiliates', and its Sublicensees' material Regulatory Data and material Regulatory Materials to MEI, its Affiliates, and Sublicensees, for no additional consideration, for use solely in the Development, Manufacturing, Packaging, and Commercialization of the Compound and the Products. KKC shall

ensure that all Sublicensees of KKC shall be required to provide such material Regulatory Data and material Regulatory Materials to KKC for use by MEI.

(iii) **Maintenance.** Each Party shall provide its Regulatory Data and Regulatory Materials, and each Party shall receive and maintain the other Party's Regulatory Data and Regulatory Materials, in conformity with all Applicable Laws (including data privacy laws) and in a good scientific manner appropriate for patent and regulatory purposes. The Parties acknowledge and agree that it may be necessary to amend and supplement this Agreement, or to enter into one or more separate agreements, in order to facilitate compliance with applicable data privacy laws.

(d) Remedial Actions. Each Party will notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that a Product may be subject to any recall, withdrawal, corrective action or other regulatory action with respect to the Product taken by virtue of Applicable Laws (a "**Remedial Action**"). The Parties will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. KKC shall have the sole discretion with respect to any matters relating to any Remedial Action with respect to any Product in the Field in Japan and the RoW, including the decision to commence such Remedial Action and the control over the conduct of such Remedial Action, provided that KKC shall notify MEI prior to making any public disclosure of Remedial Action and shall keep MEI regularly informed regarding any such Remedial Action. KKC shall be solely responsible for the cost and expense of any such Remedial Action in the Field in Japan and the RoW. **[*CONFIDENTIAL*]** MEI and KKC shall be jointly responsible for the cost and expense of any such Remedial Action in the U.S. (including for Recall Expenses), which shall be borne **[*CONFIDENTIAL*]** in accordance with the Financial Exhibit to the extent applicable. Notwithstanding anything to the contrary in this Section 7.2(d) (Remedial Actions), (i) to the extent that the Remedial Action is caused by: (1) the negligence or willful misconduct of one of the Parties or its Affiliates; or (2) a breach by one of the Parties (or its Affiliates) of one or more of its obligations under this Agreement or related agreements, such Party shall bear all costs of such Remedial Action, and (ii) the Parties acknowledge and agree that supply and/or quality agreements between the Parties may vary and/or augment the rights and responsibilities of the Parties with respect to Remedial Actions.

7.3 Supply.

(a) U.S. - Supply. MEI shall **[*CONFIDENTIAL*]** the Product, Compound, placebo and other related materials (including empty capsules, empty bottles and caps for the bottles, reference standards and impurities) (collectively, "**U.S. Supply Items**") for use in the Development and Commercialization of the Product in and for the U.S. In the event that MEI determines that it will be unable to timely supply the U.S., MEI shall notify KKC thereof as soon as practicable following MEI's determination. Such notification shall include the reasons and the expected duration of MEI's inability or anticipated inability to supply. Upon receipt of such

notification, KKC shall use Commercially Reasonable Efforts to supply such U.S. Supply Items for Development and/or Commercialization in the U.S. in accordance with the back-up structure discussed and agreed upon by the JMC pursuant to Section 2.4(a)(viii) (Specific Responsibilities of the JMC).

(b) JP and RoW - Supply. MEI shall be **[*CONFIDENTIAL*]** for supplying to KKC the Product, Compound, placebo and other related materials (including empty capsules, empty bottles and caps for the bottles, reference standards and impurities) (collectively, "**JP and RoW Supply Items**") in accordance with the JP and RoW Supply Agreement: (1) without further consideration and **[*CONFIDENTIAL*]** for KKC's use in the Development of the Product in Japan; (2) at a price equal to MEI's COGS plus **[*CONFIDENTIAL*]** for KKC's use in the Development of the Product in the RoW and for use in the Commercialization of the Product in Japan and the RoW; and (3) for KKC's use in the Manufacturing technology transfer of the Compound and Products in accordance with Section 3.7(c) (Technology Transfer to KKC), which JP and RoW Supply Items shall, for this subclause (3), (i) include the starting materials for the technology transfer of the Compound, and the Compound for technology transfer of the Product, and (ii) be supplied at a **[*CONFIDENTIAL*]**; provided, that the Parties intend (y) to transition responsibility for the Manufacture and supply of such JP and RoW Supply Items to KKC (or a Third Party Manufacturer in compliance with Section 7.3(b)(ii) (Third Party Manufacturer)) as soon as practicable, and (z) that KKC (or a Third Party Manufacturer in compliance with Section 7.3(b)(ii) (Third Party Manufacturer)) **[*CONFIDENTIAL*]**, in each case, excluding any Compound or Product for use in U.S. Global Studies (which U.S. Global Study-supplies shall be supplied by MEI).

(i) **JP and RoW – Supply Terms.** Within **[*CONFIDENTIAL*]** after the Effective Date, the Parties shall amend and restate the JP Clinical Supply Agreement to include customary provisions to address the forecasting, order, delivery, and other customary provisions applicable to the supply of the JP and RoW Supply Items for Development and Commercialization purposes in Japan and the RoW (the "**JP and RoW Supply Agreement**"); provided, that the Parties acknowledge and agree that the JP and RoW Supply Agreement may need to be further revised or replaced in conjunction with transitioning from Development to Commercialization. At the same time that the Parties enter into the Japan and RoW Supply Agreement, the Parties shall enter into a new quality agreement which shall include customary provisions to address the quality of the Product and related regulatory issues, Parties' audit rights relating thereto, product specifications and other customary provisions applicable to the supply of the pharmaceuticals for Japan and the RoW (the "**JP and RoW Quality Agreement**"), which shall supersede the JP Clinical Quality Agreement, and which JP Clinical Quality Agreement shall therefrom be deemed terminated; provided, that the Parties acknowledge and agree that the JP and RoW Quality Agreement may need to be further revised or replaced in conjunction with transitioning from Development to Commercialization. Prior to such time as KKC (or a Third Party Manufacturer in compliance with Section 7.3(b)(ii) (Third Party Manufacturer)) assumes responsibility for Manufacturing and supply of such JP and RoW Supply Items, MEI shall **[*CONFIDENTIAL*]** the JP and RoW Supply Items to KKC with the amounts and in the forms, and on the timing set forth in JP and RoW Supply Agreement, which KKC agrees to accept in accordance with the JP

and RoW Quality Agreement. MEI shall **[*CONFIDENTIAL*]** Supply Items with appropriate documentation (i.e., appropriate certificates of analysis and/or compliance, as applicable in accordance with the JP and RoW Quality Agreement) following receipt of a written request therefor from KKC that specifies the quantities and forms desired.

(ii) **Third Party Manufacturer.** After Manufacturing technology transfer in accordance with Section 3.7(c) (Technology Transfer to KKC) and KKC's CMO completes Process Validation, KKC shall be responsible for **[*CONFIDENTIAL*]** and at the election of KKC, KKC may subcontract such activities to CMO(s) reasonably acceptable to MEI; provided that **[*CONFIDENTIAL*]**. For clarity, the Parties acknowledge and agree that **[*CONFIDENTIAL*]**.

(iii) **JP and RoW - Packaging; Certain Other Manufacturing Activities.** KKC or its designated Third Party shall be responsible (at its sole cost and expense) for all final Product Packaging (with respect to Japan and the RoW). For clarity, KKC's Packaging responsibilities apply to the Product supplied by MEI under the JP and RoW Supply Agreement. KKC or its designated Third Party shall ensure that all such Packaging complies with Applicable Laws and the Regulatory Approvals for the Product. To the extent that a Third Party is involved in Packaging or other activities described in this Section 7.3(b)(iii) (JP and RoW - Packaging; Certain Other Manufacturing Activities), KKC shall be wholly responsible for, and bear **[*CONFIDENTIAL*]** of the costs related to, qualifying such Third Party to perform such activities. Notwithstanding the foregoing, MEI shall be responsible for the physical performance of Packaging for U.S. Global Studies, including the portion of any such Clinical Trials in Japan or the RoW; provided, that KKC shall be responsible **[*CONFIDENTIAL*]**.

(iv) **JP and RoW - Back-Up Manufacturer.** After **[*CONFIDENTIAL*]** and in the event that KKC determines that it will be unable to **[*CONFIDENTIAL*]**, KKC shall notify MEI thereof as soon as practicable following KKC's determination. Such notification shall include the reasons and the expected duration of KKC's inability or anticipated inability to supply. Upon receipt of such notification, MEI shall use Commercially Reasonable Efforts to supply such JP and RoW Supply Items for Development and/or Commercialization in Japan or RoW in accordance with the back-up structure discussed and agreed upon by the JMC pursuant to Section 2.4(a)(viii) (Specific Responsibilities of the JMC).

7.4 Commercial.

(a) Commercialization Reports. [*CONFIDENTIAL*], commencing upon a Party's, any of its Affiliates' or any Sublicensee's first filing for Marketing Authorization

Application of a Product in such country and thereafter, (i) KKC for Japan or countries in the RoW, or (ii) both Parties for the U.S., shall provide to the JCC with detailed written reports of such Commercialization activities it, any of its Affiliates or any Sublicensee has performed, or caused to be performed, since the preceding report and the future activities it expects to initiate during the following **[*CONFIDENTIAL*]** period. Each such report shall contain sufficient detail to enable the JCC to assess the applicable Party's compliance with its obligations set forth in Sections 4.2(a) (U.S. - Commercialization Plan), 4.2(c) (U.S. - Commercial Diligence), 5.2(a) (JP - Commercialization Plan), 5.2(b) (JP - Commercial Diligence), 6.2(a) (RoW - Commercialization Plan), and 6.2(b) (RoW - Commercial Diligence).

(b) Compliance with Applicable Law. With respect to (i) Japan and the RoW, KKC, and (ii) the U.S., each Party, shall, and shall ensure that its Affiliates and Sublicensees shall, in all material respects conform their practices and procedures relating to the Commercialization of the Products in the Territory and educating the medical community in the Territory with respect to the Products to any applicable industry association regulations, policies and guidelines, as the same may be amended from time to time, and Applicable Law.

(c) Training. KKC shall be solely responsible for training, and all costs associated with such training, its employees and representatives engaged in activities under this Agreement with respect to Japan and the RoW. Such training shall be in accordance with Applicable Laws, including with respect to timely reporting of any adverse events with respect to the Products. Training for U.S. Commercialization shall be governed under Co-Promotion Agreement set forth under Section 4.3 (Co-Promotion Agreement).

7.5 Pharmacovigilance. As soon as practicable, but in any case within **[*CONFIDENTIAL*]** from the Effective Date, the Parties shall define and finalize the actions that the Parties shall employ with respect to Development of the Compound and Products to protect patients and promote their well-being in the U.S., Japan, and RoW, by amending the Safety Data Exchange Agreement **[*CONFIDENTIAL*]**, which was entered into by the Parties pursuant to the JP Agreement (the "**Pharmacovigilance Agreement**"), with MEI (or its designee) as the global safety database holder. Absent the amendment and execution of a Pharmacovigilance Agreement, MEI shall not ship Product to any clinical study site in Japan or the RoW. The Parties acknowledge and agree that such Pharmacovigilance Agreement shall be further amended by the Parties prior to commercial launch of the Product, to define and finalize the actions that the Parties shall employ with respect to Commercialization of the Compound and Products to protect patients and promote their well-being in the U.S., Japan, and RoW, with MEI (or its designee) as the global safety database holder. The Pharmacovigilance Agreement shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports and any other information concerning the safety of the Compound and Products and shall ensure that adverse event associated with the Products and other safety information is exchanged according to a schedule that will permit each Party (and its designees) to comply with Applicable Laws and regulatory requirements in applicable Territories. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under Applicable Laws and regulations.

ARTICLE 8
GENERAL PAYMENT PROVISIONS

8.1 Upfront Payment. Within **[*CONFIDENTIAL*]** after receipt of an invoice therefor, KKC shall pay to MEI a one-time, non-refundable and non-creditable upfront payment of **[*CONFIDENTIAL*]** subject to Section 8.5(c); provided that, if MEI desires for KKC to reduce applicable withholding taxes to be withheld by KKC, then such invoice shall be accompanied by any Tax forms that may be reasonably necessary in order for KKC not to withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income Tax treaty in accordance with Section 8.5(d).

8.2 Blended Royalty. KKC acknowledges that (i) the MEI Know-How and the information included in MEI's Regulatory Materials licensed to KKC are proprietary and valuable and that without the MEI Know-How and such information, KKC would not be able to obtain and maintain Regulatory Approvals with respect to the Products, (ii) such Regulatory Approvals will allow KKC to obtain and maintain Regulatory Exclusivity with respect to the Products in the Field in Japan and the RoW, (iii) access to the MEI Know-How and the rights with respect to the MEI's Regulatory Materials will have provided KKC with a competitive advantage in the marketplace beyond the exclusivity afforded by the MEI Patents and Regulatory Exclusivity and (iv) the upfront payment and royalties set forth in Sections 8.1 (Upfront Payment), 5.3(a) (JP - Upfront Payment), 5.3(d) (JP - Royalty Payments), and 6.3(c) (RoW – Royalty Payments), respectively, are, in part, intended to compensate MEI for such exclusivity and such competitive advantage. The Parties agree that the royalty rate set forth in Section 5.3(d) (JP - Royalty Payments) and Section 6.3(c) (RoW – Royalty Payments) each reflects an efficient and reasonable blended allocation of the value provided by MEI to KKC.

8.3 Currency Conversion. All payments hereunder shall be made in United States Dollars. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), any amount expressed in a foreign currency shall be converted into Dollars in a manner consistent with Payor's normal practices used to prepare its audited financial statements for external reporting purposes, in accordance with GAAP, consistently applied, or by using the Wall Street Journal or Reuters, at Payor's discretion.

8.4 Late Payments. Any amount required to be paid by Payor hereunder which is not paid on the date due shall accrue interest from the date due at the rate of the one-month Secured Overnight Financing Rate as quoted by the Federal Reserve Bank of New York (or if it no longer exists, similarly authoritative source) plus **[*CONFIDENTIAL*]**; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Payee from exercising any other rights it may have as a consequence of the lateness of any payment. Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent.

8.5 Taxes and Withholding.

(a) Taxes on Income. Notwithstanding anything else set forth in this Section 8.5 (Taxes and Withholding), each Party shall solely bear and pay all Taxes imposed on

such Party's net income (however denominated) franchise Taxes, and branch profits Taxes, in each case, imposed as a result of such Party being organized under the laws of, or having an permanent establishment or office located in, the jurisdiction imposing such Tax (or any political subdivision thereof).

(b) VAT. The Parties agree to cooperate with one another and use reasonable efforts to ensure that any value added Tax or similar payment ("**VAT**") in respect of any payments made by Payor to Payee under this Agreement does not represent an unnecessary cost in respect of payments made under this Agreement; provided, that the Parties further agree that as of the Effective Date it is not anticipated that VAT will apply in connection with payments under this Agreement. For purposes of clarity, all sums payable under this Agreement shall be exclusive of VAT. In the event that any VAT is owing in any jurisdiction in respect of any such payment, Payor shall pay such VAT, and (i) if such VAT is owing as a result of any action by Payor, including any assignment or sublicense (including assignment to, or payment hereunder by, a Payor-related entity or Affiliate), or any failure on the part of Payor or its Affiliates to comply with applicable Tax laws or filing or record retention requirements, that has the effect of modifying the Tax treatment of the Parties hereto, then the payment in respect of which such VAT is owing shall be made without deduction for or on account of such VAT to ensure that Payee receives a sum equal to the sum which it would have received had such VAT not been due or (ii) otherwise, such payment shall be made after deduction of such VAT. In the event that any deducted VAT is later recovered by Payor, Payor shall promptly reimburse Payee for the deducted amount. For the sake of clarity, any increase in payments to Payee under this Section 8.5(b) (VAT) shall reflect only the incremental increase in VAT directly resulting from clause (i) above. In the event that any VAT is owing in any jurisdiction in respect of any such payment, Payee will provide to Payor Tax invoices showing the correct amount of VAT in respect of such payments hereunder.

(c) Withholding Tax Matters. If Payor is required to make a payment to Payee subject to a deduction of Tax or withholding Tax, the sum payable by Payor (in respect of which such deduction or withholding is required to be made) shall be made to Payee after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted to the appropriate Governmental Authority in accordance with Applicable Laws. Any such withholding Taxes required under Applicable Laws to be paid or withheld shall be an expense of, and borne solely by Payee.

(d) Tax Cooperation. To the extent Payor is required to deduct and withhold Taxes on any payments to Payee, Payor shall pay the amounts of such Taxes to the proper Governmental Authority in a timely manner and promptly transmit to Payee an official Tax certificate or other evidence of such withholding reasonably sufficient to enable Payee to claim such payments of Taxes. At Payee's discretion, Payee shall provide to Payor any Tax forms that may be reasonably necessary in order for Payor not to withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income Tax treaty. Payee shall use reasonable efforts to provide any such Tax forms to Payor at least **[*CONFIDENTIAL*]** prior to the due date for any payments for which the Payee desires that Payor apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery or reduction, as permitted by Applicable Laws, of withholding Taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding Tax or VAT.

8.6 Financial Records and Audit. Each Party shall keep full, true and accurate records and books of account containing all particulars that may be necessary for the purpose of confirming the accuracy of, and calculating, as applicable, all royalty payments and other amounts due to MEI hereunder (including records of Net Sales), Development Costs, U.S. Commercialization Costs, Net Profit or Loss, and the other elements thereof required to prepare the reports or calculate payments required under this Agreement and the Reconciliation Procedures, and any other payments under this Agreement, during the Term and for **[*CONFIDENTIAL*]** thereafter or such longer period as required by Applicable Laws. Each Party shall have a right to request **[*CONFIDENTIAL*]** audit of the other Party **[*CONFIDENTIAL*]** throughout the Term in order to confirm the accuracy of the foregoing (an "**Audit**"); provided, that, such **[*CONFIDENTIAL*]** audit per Calendar Year limitation shall not apply in the event of any subsequent "for cause" audit. Upon the written request by a Party to Audit the other Party, such auditing Party shall have the right to engage an independent, internationally recognized accounting firm reasonably acceptable to the other Party and which will be subject to appropriate written obligations of confidentiality, to perform a review as is reasonably necessary to enable such accounting firm to calculate or otherwise confirm the accuracy of any of the foregoing for the Calendar Year(s) requested by such auditing Party. The audited Party, shall make personnel reasonably available during regular business hours to answer queries on all such books and records required for the purpose of the Audit. The accountants shall deliver a copy of their findings to each of the Parties within **[*CONFIDENTIAL*]** of the completion of the review, and, in the absence of fraud or manifest error, the findings of such accountant shall be final and binding on each of the Parties. Any underpayments by a Party shall be paid to the other Party within **[*CONFIDENTIAL*]** of notification of the results of such Audit. Any overpayments made by a Party shall be refunded by the other Party within **[*CONFIDENTIAL*]** of notification of the results of such Audit. The cost of the accountants shall be the responsibility of the auditing Party unless the accountants' calculation shows that the actual royalties payable, Net Sales and/or any other applicable amount Audited hereunder (in the aggregate with respect to the entire period audited) to be different, by more than **[*CONFIDENTIAL*]**, than the amounts as paid and reported by the audited Party for the period subject to the Audit, in which case the audited Party shall bear the costs of the accountants. Any information obtained during such audit shall be treated as Confidential Information of the audited Party. In the event that a Party has a good faith basis, which shall be shared with the other Party, for believing that a Sublicensee of such other Party is not accurately reporting Net Sales (and thus that such other Party is not making appropriate royalty payments hereunder), then at the inquiring Party's request, the other Party shall enforce its audit rights with respect to any such Sublicensee and such other Party shall report back to the inquiring Party regarding the outcome of any such audit.

ARTICLE 9
INTELLECTUAL PROPERTY RIGHTS

9.1 Ownership.

(a) Data. All data generated in connection with any Development, Manufacturing, Commercialization or Packaging activities with respect to any Compound or Product conducted by or on behalf of MEI or its Affiliates, Direct Licensees, or Sublicensees without the involvement of KKC (the "**MEI Data**") shall be the sole and exclusive property of

MEI or of its Affiliates, Direct Licensees, or Sublicensees, as applicable. All data generated in connection with any Development, Manufacturing, Commercialization or Packaging activities with respect to any Compound or Product conducted by or on behalf of KKC or its Affiliates or Sublicensees without the involvement of MEI (the "**KKC Data**") shall be the sole and exclusive property of KKC or of its Affiliates or Sublicensees, as applicable. All data generated in connection with any Development, Manufacturing, Commercialization or Packaging activities with respect to any Compound or Product conducted by or on behalf of both (i) MEI or its Affiliates, Direct Licensees, or Sublicensees, and (ii) KKC or its Affiliates or Sublicensees shall be the joint property of MEI and KKC (or of their respective Affiliates or Sublicensees (or Direct Licensees with respect to MEI), as applicable).

(b) Ownership of Inventions. Ownership of all Inventions shall be based on inventorship, as determined in accordance with the rules of inventorship under United States patent laws. Each Party shall solely own any Inventions made solely by its or its Affiliates' employees, agents or independent contractors ("**Sole Inventions**"). The Parties shall jointly own any Inventions that are made jointly by employees, agents or independent contractors of one Party or its Affiliates together with employees, agents or independent contractors of the other Party or its Affiliates ("**Joint Inventions**"). All Patents claiming Joint Inventions shall be referred to herein as "**Joint Patents**". Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice, license, assign and otherwise exploit the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party, and each Party hereby waives any right it may have under the laws of any country to require any such accounting or consent.

(c) Disclosure of Inventions. Each Party shall promptly disclose to the other Party all Sole Inventions of such Party and all Joint Inventions, including any invention disclosures or other similar documents submitted to such Party by its employees, agents or independent contractors describing such Inventions, and shall promptly respond to reasonable requests from the other Party for additional information relating to such Inventions.

9.2 Patent Prosecution and Maintenance.

(a) MEI Patents and Joint Patents.

(i) MEI shall have the first right, but not the obligation, to control the preparation, filing (including any filing relating to patent term extension), prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all MEI Patents and Joint Patents by counsel of its own choice; provided that MEI shall be solely responsible for the cost and expense of all MEI Patents **[*CONFIDENTIAL*]**. MEI shall consult with KKC and keep KKC reasonably informed of the status of such Patents and shall promptly provide KKC with all material correspondence received from any patent authority in connection therewith. In addition, MEI shall promptly provide KKC with drafts of all proposed material filings and correspondence to any patent authority with respect to such Joint Patents in the U.S., Japan, the European Union and United Kingdom. Upon KKC's request, MEI shall promptly notify KKC of

the latest status of any material filings and correspondences for countries other than those listed above, and KKC shall have the opportunity to review and comment prior to the submission of such proposed filings and correspondences. MEI shall confer with KKC and consider in good faith KKC's comments prior to submitting such filings and correspondence, provided that KKC provides such comments within **[*CONFIDENTIAL*]** of receiving the draft filings and correspondence from MEI.

(ii) In the event that MEI desires to abandon or cease prosecution or maintenance of any MEI Patent or any Joint Patent, MEI shall provide reasonable prior written notice to KKC of such intention to abandon (which notice shall be given no later than ninety (90) days prior to the next deadline for any action that must be taken with respect to any such Patent in the relevant patent office). In such case, upon KKC's written election provided no later than **[*CONFIDENTIAL*]** after such notice from MEI, KKC shall have the right to **[*CONFIDENTIAL*]**. If KKC does not provide such election during such **[*CONFIDENTIAL*]** period, MEI may, in its sole discretion, continue prosecution and maintenance of such Patent or discontinue prosecution and maintenance of such Patent.

(b) KKC Patents.

(i) KKC shall have the first right, but not the obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of all KKC Patents, at its sole cost and expense and by counsel of its own choice; provided that the Parties shall be jointly responsible for the cost and expense of all KKC Patents in the U.S., **[*CONFIDENTIAL*]**. KKC shall consult with MEI and keep MEI reasonably informed of the status of such Patents and shall promptly provide MEI with all material correspondence received from any patent authority in connection therewith. KKC shall confer with MEI and consider in good faith MEI's comments prior to submitting such filings and correspondence, provided that MEI provides such comments within **[*CONFIDENTIAL*]** of receiving the draft filings and correspondence from KKC.

(ii) In the event that KKC desires to abandon or cease prosecution or maintenance of any KKC Patent, KKC shall provide reasonable prior written notice to MEI of such intention to abandon (which notice shall be given no later **[*CONFIDENTIAL*]** prior to the next deadline for any action that must be taken with respect to any such Patent in the relevant patent office). In such case, upon MEI's written election provided no later **[*CONFIDENTIAL*]** after such notice from KKC, MEI shall have the right to **[*CONFIDENTIAL*]**. If MEI does not provide such election within **[*CONFIDENTIAL*]** after such notice from KKC, KKC may, in its sole discretion, continue prosecution and maintenance of such KKC Patent or discontinue prosecution and maintenance of such KKC Patent.

9.3 Cooperation of the Parties. Each Party agrees to reasonably cooperate in the preparation, filing, prosecution and maintenance of Patents under Section 9.2 (Patent Prosecution and Maintenance), at its own cost, and such cooperation includes: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to enable the other Party to apply for and to prosecute patent applications in any country as permitted by Section 9.2 (Patent Prosecution and Maintenance); and (b) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

9.4 Infringement by Third Parties.

(a) Notice. In the event that either MEI or KKC becomes aware of any infringement or threatened infringement by a Third Party of any MEI Patent, KKC Patent or Joint Patent, or the submission to a Party or a Regulatory Authority in any Territory of an application for a product referencing a Product, or any declaratory judgment or equivalent action challenging any MEI Patent, KKC Patent or Joint Patent in any Territory in connection with any such infringement (each, a "**Product Infringement**"), it will promptly notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement, or declaratory judgment or equivalent action, by such Third Party.

(b) Enforcement of MEI Patents, KKC Patents and Joint Patents.

(i) MEI shall have the first right, as between KKC and MEI, but not the obligation, to bring an appropriate suit or take other action against any Person engaged in, or to defend against, a Product Infringement in the Field of any MEI Patent or Joint Patent, at its own expense and by counsel of its own choice. KKC shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and KKC and its counsel will reasonably cooperate with MEI and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If MEI fails to bring an action or proceeding with respect to such Product Infringement of any MEI Patent or Joint Patent within (A) **[*CONFIDENTIAL*]** following the notice of alleged infringement or declaratory judgment or (B) **[*CONFIDENTIAL*]** before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, KKC shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and MEI shall have the right, at its own expense, to be represented in any such action by counsel of its own choice and MEI and its counsel will reasonably cooperate with KKC and its counsel in strategizing, preparing and prosecuting any such action or proceeding.

(ii) KKC shall have the first right, as between KKC and MEI, but not the obligation, to bring an appropriate suit or take other action against any Person engaged in, or to defend against, a Product Infringement in the Field of any KKC Patent, at its own expense and by counsel of its own choice. MEI shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and MEI and its counsel will reasonably cooperate with KKC and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If KKC fails to bring an action or proceeding with respect to such Product Infringement of any KKC Patent within **[*CONFIDENTIAL*]** following the notice of alleged infringement or declaratory judgment or **[*CONFIDENTIAL*]** before the time limit, if any, set forth in the

appropriate laws and regulations for the filing of such actions, whichever comes first, MEI shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and KKC shall have the right, at its own expense, to be represented in any such action by counsel of its own choice and KKC and its counsel will reasonably cooperate with MEI and its counsel in strategizing, preparing and prosecuting any such action or proceeding.

(iii) Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to Product Infringement of any MEI Patent, KKC Patent or Joint Patent shall be used first to reimburse the Parties' documented out-of-pocket (i.e., paid to Third Parties) legal expenses relating to the action or proceeding, and any remaining damages relating to Product Infringement of a MEI Patent or Joint Patent (including lost sales or lost profits) shall be allocated as follows: **[*CONFIDENTIAL*]**.

(c) Cooperation. In the event a Party brings an action in accordance with this Section 9.4 (Infringement by Third Parties), the other Party shall reasonably cooperate, including, if required to bring such action, being named as a party to such action; provided, that if a Party is required by Applicable Laws to be named as a party, then the other Party shall bear such Party's costs in connection with being so named.

9.5 Third Party Intellectual Property Rights.

(a) Each Party shall promptly notify the other in writing of any allegation by a Third Party that the Packaging, Commercialization, Manufacture, Development, or use of the Compound or Product infringes or may infringe the intellectual property rights of a Third Party (an "**Infringement Claim**").

(b) In the case of any Infringement Claim in any Territory, the Parties shall, subject to Section 9.5(c) (Third Party Intellectual Property Rights), promptly, and within **[*CONFIDENTIAL*]** after written notice from either Party to the other thereof, discuss which Party shall control the response to such Infringement Claim, and if the Parties do not mutually agree upon which Party shall control, the Party with respect to which the Infringement Claim was brought shall control the defense and response to such Infringement Claim and, if both Parties are named, then **[*CONFIDENTIAL*]** shall have the right to control the defense and response to such Infringement Claim. For clarity, if Section 9.5(c) (Third Party Intellectual Property Rights) applies to any such Infringement Claim, then Section 9.5(c) (Third Party Intellectual Property Rights) shall control the process related to responding to such Infringement Claim in lieu of this Section 9.5(b) (Third Party Intellectual Property Rights). With respect to any Infringement Claim, each Party shall bear **[*CONFIDENTIAL*]** of the damages or recovery obtained by the Third Party asserting such Infringement Claim, by settlement or otherwise; provided, that, the Party with respect to which the Infringement Claim was brought had performed the allegedly infringing Packaging, Development, Manufacture or Commercialization of a Compound or Product in accordance with this Agreement; in all other cases, the Party with respect to which the Infringement Claim was brought shall bear **[*CONFIDENTIAL*]** of such damages or recovery. The Out-of-Pocket Costs in defending, and providing requested assistance in the defense of, such Infringement Claim shall be **[*CONFIDENTIAL*]**; unless the Party with respect to which the Infringement Claim was brought had not performed the allegedly

infringing Packaging, Development, Manufacture or Commercialization of a Compound or Product in accordance with this Agreement, in which case all Out-of-Pocket Costs of both Parties in defending, and providing requested assistance in the defense of, such Infringement Claim shall be paid by **[*CONFIDENTIAL*]**. Notwithstanding the foregoing, the Parties' rights and obligations under this Section 9.5 (Third Party Intellectual Property Rights), including payment obligations, will be subject to the terms of Article 13 (Indemnification; Liability).

(c) Notwithstanding Section 9.5(b) (Third Party Intellectual Property Rights), with respect to Infringement Claims pertaining to **[*CONFIDENTIAL*]** and the specific subject matter described in this Section 9.5(c) (Third Party Intellectual Property Rights), if:

(i) the (A) Development, use, or Commercialization of the dosage form, as of the Effective Date, of the Product in **[*CONFIDENTIAL*]**, or (B) Manufacture of the Compound or the dosage form, as of the Effective Date, of the Product in the Territory for Development or Commercialization infringes an issued Valid Claim (as defined in Section 1.186(a) (Valid Claim) but not 1.186(b) (Valid Claim) above) of a Third Party's Patent ("**Third Party Patent**"), then:

(1) MEI shall use Commercially Reasonable Efforts to either (y) procure the right to continue the activities described in subclauses (A) or (B) of Section 9.5(c)(i) (Third Party Intellectual Property Rights), as applicable, free of any liability from such Infringement Claim (e.g., through obtaining a license to practice such Third Party Patent or through invalidating such Third Party Patent), or (z) replace or modify Product or Compound, or the Development, use, Commercialization, or Manufacture thereof, as applicable, with a non-infringing substitute, and MEI shall be responsible for **[*CONFIDENTIAL*]** of any payments due in connection with implementing the foregoing subclauses (y) or (z) (including, to the extent applicable, payments due in connection with such Third Party Patents for sales or activities **[*CONFIDENTIAL*]**); and

(2) if MEI is unable to implement one of the options set forth in subclauses (y) or (z) of Section 9.5(c)(i)(1) (Third Party Intellectual Property Rights), then, solely with respect to **[*CONFIDENTIAL*]**, KKC shall have a right, but not an obligation, to implement one of such options, at KKC's expense; provided, that if KKC elects to obtain a license to such Third Party Patent(s), then KKC's royalty payment for such license shall be **[*CONFIDENTIAL*]**.

(ii) the use of the Product in **[*CONFIDENTIAL*]**, infringes an issued Valid Claim (as defined in Section 1.186(a) (Valid Claim) but not 1.186(b) (Valid Claim) above) of a Third Party's Patent in **[*CONFIDENTIAL*]** (also, a "Third Party Patent"), then:

(1) MEI shall have the first right to either (y) procure the right to continue the use of such combination for such indication free of any liability from such Infringement Claim (e.g., through obtaining a license to practice such Third Party Patent or through

invalidating such Third Party Patent), or (z) replace or modify such Product or such **[*CONFIDENTIAL*]**, or the use thereof, as applicable, with a non-infringing substitute, the details of which shall be notified to KKC in writing prior to undertaking any such action. MEI shall keep KKC informed of the progress of such action;

(2) if MEI does not desire to implement one of the options set forth in subclauses (y) or (z) of Section 9.5(c)(ii)(1) (Third Party Intellectual Property Rights), then, solely with respect to **[*CONFIDENTIAL*]**, KKC shall have a right, but not an obligation, to undertake one of such options, the details of which shall be notified to MEI in writing prior to undertaking any such action. KKC shall keep MEI informed of the progress of such action; and

(3) In either approach (MEI or KKC undertaking such options set forth in subclauses (y) or (z) of Section 9.5(c)(ii)(1) (Third Party Intellectual Property Rights)), no license to a Third Party Patent may be entered under this Section 9.5(c)(ii) (Third Party Intellectual Property Rights) without the other Party's prior consent, which consent shall not be unreasonably withheld, conditioned or delayed. Any expenses or payments incurred in implementing one of such options (including payments due to a Third Party in connection with sales or activities, subject to a reasonable allocation of any upfront or general payments to the Territory in the case of a broader license taken by MEI) shall be:

I. with respect to **[*CONFIDENTIAL*]**,

II. with respect to **[*CONFIDENTIAL*]**; provided that, (1) if KKC obtains a license to such Third Party Patent(s), then KKC shall have the right to receive from MEI **[*CONFIDENTIAL*]** of any upfront or general payments and to reduce its quarterly royalty payments to MEI by **[*CONFIDENTIAL*]** of any royalty payments to such a Third Party, subject to KKC's royalty payments to MEI not being reduced to less than **[*CONFIDENTIAL*]** of the amounts that would have otherwise been due to MEI for such Calendar Quarter; or (2) if MEI obtains such license from Third Party, then (A) KKC shall reimburse **[*CONFIDENTIAL*]** of the reasonable allocation of any upfront or general payments and **[*CONFIDENTIAL*]** of any royalty payments to such Third Party, subject to KKC's royalty payment not exceeding **[*CONFIDENTIAL*]** of the amounts that would have otherwise been due to MEI for such Calendar Quarter, and (B) payments associated with **[*CONFIDENTIAL*]** shall be appropriate and proportional to other amounts due under any such agreement, and

III. In either approach (MEI or KKC undertaking such options set forth in subclauses (y) or (z) of Section 9.5(c)(ii)(1) (Third Party Intellectual Property Rights)), if the procured right to continue the use of such combination for such indication free of any liability from such Infringement Claim or replacement or modification is not secured with terms acceptable to both Parties, then neither Party is obligated to **[*CONFIDENTIAL*]**.

(d) Each Party expressly agrees and acknowledges that (A) the rights granted to such Party under this Agreement, as and to the extent applicable, shall in all cases be subject to

the terms and conditions of any applicable license agreement related to any Third Party Patent, and (B) it shall comply with the terms and conditions of any such agreements (and shall take no action or omit to take any action, that may cause a breach of either of any such agreements). In furtherance of the foregoing, a copy of any such agreements shall be provided by the executing Party to the other Party.

(e) The Parties acknowledge and agree that a defense action commenced under Section 9.5(a) (Third Party Intellectual Property Rights) may lead to **[*CONFIDENTIAL*]** negotiating an agreement under Section 9.5(c) (Third Party Intellectual Property Rights).

(f) Upon the request of the Party controlling the response to the Infringement Claim, the other Party shall reasonably cooperate with the controlling Party in the reasonable defense of such Infringement Claim, including by providing full access to documents, information and witnesses as reasonably requested by the Party controlling the response to the Infringement Claim. The other Party will have the right to consult with the controlling Party concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation.

9.6 Consent for Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any action or proceeding under this Article 9 (Intellectual Property Rights) that would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement, or rights otherwise with respect to Product, without the prior written consent of such other Party, which shall not be unreasonably withheld. Notwithstanding the above, KKC shall not enter into any settlement of any such claim without the prior written consent of MEI if such settlement would require MEI to be subject to an injunction or to make any monetary payment to KKC or any Third Party, or admit any wrongful conduct by MEI or its Affiliates, or would limit or restrict the claims of or admit any invalidity and/or unenforceability of any of the Patents Controlled by MEI.

9.7 Patent Extensions. The Parties shall jointly agree regarding, and each shall reasonably cooperate with the other in obtaining, patent term restoration, supplemental protection certificates or their equivalents, and Patent Term Extensions with respect to the Products where applicable. The Party responsible for controlling the preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of Patents under Section 9.2 (Patent Prosecution and Maintenance) shall file applications for such extensions at its own cost and the other Party shall provide such responsible Party any necessary documents and information for filing and prosecuting the Patent Term Extension application at such other Party's own cost.

9.8 Trademarks.

(a) MEI Trademarks. The Parties shall Develop, Package and Commercialize the Products in the Field in the U.S. under MEI Trademarks in accordance with the U.S. Commercialization Plan; provided, that MEI may not include in any such trademarks any corporate names or any reference to any products of KKC or any of its Affiliates or Sublicensees without the prior written consent of KKC. During the applicable Term, (i) MEI grants to KKC an exclusive, royalty-free license to use MEI Trademarks and MEI's name and logo (to the extent

necessary) solely for the purpose of conducting co-promotion activities in the Field in the U.S. in accordance with the terms of this Agreement and the Co-Promotion Agreement, provided that KKC shall comply with MEI's internal rules which are submitted to KKC in advance, and KKC shall provide MEI with any materials in which the MEI Trademarks and MEI's name and logo is used in advance for MEI's review and approval, and (ii) KKC grants to MEI a non-exclusive, royalty-free license to use the KKC name and logo (to the extent necessary) solely for the purpose of Developing, Packaging, and/or Commercializing the Products in the Field in the U.S. in accordance with the terms of this Agreement, provided that MEI shall comply with KKC's internal rules which are submitted to MEI in advance and, upon the request of KKC, MEI shall provide KKC with any sample in which the KKC name and logo is used.

(b) KKC Trademarks. KKC shall have the right to Develop, Package and Commercialize the Products in the Field in Japan and the RoW under trademarks of its choice that it registers in accordance with the JP Commercialization Plan and RoW Commercialization Plan, respectively ("**KKC Trademarks**"); provided, that KKC may not include in any such trademarks any corporate names or any reference to any products of MEI or any of its Affiliates, Direct Licensees, or Sublicensees without the prior written consent of MEI. MEI shall cooperate with KKC, at KKC's reasonable request and expense, in KKC's registration of the KKC Trademarks. In addition, KKC shall have an option to select MEI Trademarks for use with the Product and MEI shall grant KKC an exclusive (even as to MEI), royalty-free, fully-paid, license, with the right to grant sublicenses through multiple tiers, to use such trademarks in connection with Developing, Packaging or Commercializing Products in Japan and the RoW during the applicable Term. In connection with the foregoing, upon KKC's reasonable request from time-to-time, MEI shall provide KKC a list of MEI Trademarks (and not including the "MEI" corporate mark or other marks that are not exclusively used in connection with Products) including registration number, class and product/service. If KKC decides to be licensed MEI Trademarks to Develop, Package and Commercialize the Product in the Field in Japan and the RoW, KKC shall provide a notice to MEI it wishes to be licensed such MEI Trademarks. MEI shall use Commercially Reasonable Efforts to have MEI Trademarks and its local transliterations registered, filed, maintained and renewed in Japan and the RoW at MEI's cost upon KKC's request, and shall keep KKC reasonably informed of the completion of such registration process and provide KKC with updated list of registration numbers for such MEI Trademarks in Japan and the RoW (e.g., with respect to Japan, KATAKANA character trademark). In addition, notwithstanding anything to the contrary herein, MEI will have the right to use the KKC Trademark to the extent necessary to perform its obligations under this Agreement.

(c) In the event that either MEI or KKC becomes aware of any infringement or threatened infringement by a Third Party of any MEI Trademark or KKC Trademark ("**Trademark Infringement**"), it will promptly notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement, or declaratory judgment or equivalent action, by such Third Party.

(i) MEI shall have the right, as between KKC and MEI, but not the obligation, to bring an appropriate suit or take other action against any Person engaged in, or to defend against, a Trademark Infringement in the Field of any MEI Trademarks, at its own expense and by counsel of its own choice. KKC shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and KKC and its counsel will reasonably cooperate

with MEI and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If MEI fails to bring an action or proceeding with respect to such Trademark Infringement of any MEI Trademark in Japan or the RoW, the Parties shall discuss possible action against the Trademark Infringement.

(ii) KKC shall have the right, as between KKC and MEI, but not the obligation, to bring an appropriate suit or take other action against any Person engaged in, or to defend against, a Trademark Infringement in the Field of any KKC Trademarks, at its own expense and by counsel of its own choice. MEI shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and MEI and its counsel will reasonably cooperate with KKC and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If KKC fails to bring an action or proceeding with respect to such Trademark Infringement of any KKC Trademark in Japan or the RoW, the Parties shall discuss possible action against the Trademark Infringement.

ARTICLE 10
CONFIDENTIALITY; PUBLICATION

10.1 Duty of Confidence. Subject to the other provisions of this Article 10 (Confidentiality; Publication):

(a) all Confidential Information disclosed by or on behalf of a Party (the "**Disclosing Party**") or its Affiliates under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party (the "**Receiving Party**") and its Affiliates using at least the same standard of care as the Receiving Party uses to protect its own proprietary or Confidential Information (but in no event less than reasonable care for the industry); and

(b) the Receiving Party may only use any such Confidential Information for the purposes of performing its obligations or exercising its rights under this Agreement, including, for clarity, inclusion in Regulatory Materials.

10.2 Exceptions. The foregoing obligations as to particular Confidential Information of a Disclosing Party shall not apply to the extent that the Receiving Party can demonstrate by competent written evidence that such Confidential Information:

(a) is known by the Receiving Party at the time of its receipt, and not through a prior disclosure by the Disclosing Party, as shown by contemporaneous written documents of the Receiving Party;

(b) is in the public domain by use and/or publication before its receipt from the Disclosing Party, or thereafter enters the public domain through no fault of, or breach of this Agreement by, the Receiving Party or any individuals to whom the Receiving Party disclosed such Confidential Information as permitted by this Agreement;

(c) is subsequently disclosed to the Receiving Party on a non-confidential basis by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or

(d) is developed by the Receiving Party independently and without use of or access to any Confidential Information disclosed to it by or on behalf of the Disclosing Party, as shown by contemporaneous written documents of the Receiving Party.

10.3 Authorized Disclosures. Notwithstanding the obligations set forth in Section 10.1 (Duty of Confidence), the Receiving Party may disclose Confidential Information of the Disclosing Party and the terms of this Agreement to the extent such disclosure is reasonably necessary in the following instances:

(a) enforcing the Receiving Party's rights under this Agreement or performing the Receiving Party's obligations under this Agreement;

(b) prosecuting or defending litigation as permitted by this Agreement;

(c) preparing and submitting Regulatory Materials;

(d) to the Receiving Party's employees, directors, officers, Affiliates, actual or potential Sublicensees (or actual or potential Direct Licensees with respect to MEI), commercial partners, independent contractors, consultants, advisors, agents, attorneys, independent accountants or financial advisors who, in each case, have a need to know such Confidential Information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided, in each case, that any such Person agrees to be bound by terms of confidentiality and non-use (or, in the case of the Receiving Party's attorneys and independent accountants, such Person is obligated by applicable professional or ethical obligations) at least as restrictive as those set forth in this Article 10 (Confidentiality; Publication);

(e) to actual or potential investors, investment bankers, lenders, other financing sources or acquirors (and attorneys and independent accountants thereof) in connection with potential investment, acquisition, collaboration, merger, public offering, due diligence or similar investigations by such Third Parties or in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by written terms of confidentiality and non-use (or, in the case of the Receiving Party's attorneys and independent accountants, such Third Party is obligated by applicable professional or ethical obligations) that are no less stringent than those contained in this Agreement (except to the extent that a shorter confidentiality period is customary in the industry); and

(f) such disclosure is required by court order, judicial or administrative process or Applicable Law, provided that in such event the Receiving Party shall promptly inform the Disclosing Party of such required disclosure and provide the Disclosing Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed as required by court order, judicial or administrative process or Applicable Law shall remain otherwise subject to the confidentiality and non-use provisions of this Article 10 (Confidentiality; Publication), and the Receiving Party shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information.

Each Party shall be responsible for any breach of this Agreement by any Person to which Confidential Information of the other Party has been disclosed by or on behalf of such Party under this Agreement.

10.4 Publication.

(a) Subject to the International Committee of Medical Journal Editors Uniform Requirements for Manuscripts Submitted to Biomedical Journals and applicable legal requirements, the JDC or JCC, as applicable, will determine the overall strategy for publishing and presenting results of studies pertaining to the Compound and Products and the JDC or JCC, as applicable, shall approve all publications in the Territory prior to publication.

(b) Neither Party shall publicly present or publish (i) results of studies carried out under this Agreement or (ii) information that otherwise pertains to the Product (each such presentation or publication a "**Publication**") without the opportunity for prior review by the other Party, except to the extent otherwise required by Applicable Laws. The JDC will establish a process for both Parties to submit and jointly review publications for consideration by the JDC. Notwithstanding the foregoing, MEI shall not have the right to publish or present KKC's Confidential Information without KKC's prior written consent, and KKC shall not have the right to publish or present MEI's Confidential Information without MEI's prior written consent. Each Party agrees to acknowledge the contributions of the other Party, and the employees of the other Party, in all publications as scientifically appropriate.

10.5 Privileged Communications. In furtherance of this Agreement, it is expected that the Parties may, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential in accordance with this Article 10 (Confidentiality and Publications), that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between MEI and KKC, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of the MEI Patents, KKC Patents and Joint Patents. In the event of any litigation (or potential litigation) with a Third Party related to this Agreement or the subject matter hereof, the Parties shall, upon either Party's request, enter into a reasonable and customary joint defense or common interest agreement. In any event, each Party shall consult in a timely manner with the other Party before engaging in any conduct (e.g., producing information or documents) in connection with litigation or other proceedings that could conceivably implicate privileges maintained by the other Party. Notwithstanding anything contained in this Section 10.5 (Privileged Communications), nothing in this Agreement shall prejudice a Party's ability to take discovery of the other Party in disputes between them relating to this Agreement and no information otherwise admissible or discoverable by a Party shall become inadmissible or immune from discovery solely by this Section 10.5 (Privileged Communications).

10.6 Publicity/Use of Names. Subject to the remainder of this Section 10.6 (Publicity/Use of Names), no disclosure of the existence, or the terms, of this Agreement may be

made by either Party or its Affiliates, and neither Party shall use the name, corporate trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Law. Notwithstanding the above, (i) each Party and its Affiliates may disclose on its website and in its promotional materials that the other Party is a development partner of such Party for the Products and may use the other Party's name and logo in conjunction with such disclosure and (ii) KKC shall ensure that MEI is appropriately identified as the licensor of the Product in the Territory as and to the extent appropriate for the industry.

(a) In the event KKC proposes to file with the U.S. Securities and Exchange Commission or the securities regulators of any state or other jurisdiction under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other applicable securities law a registration statement or any other disclosure document which describes or refers to this Agreement, including filing a copy of this Agreement itself, KKC shall notify MEI of such intention and shall provide MEI with a copy of relevant portions of the proposed filing not less than **[*CONFIDENTIAL*]** prior to such filing (unless exigent circumstances do not permit such review period and then KKC will provide relevant portions of the proposed filing as reasonably in advance as is possible), and shall use Commercially Reasonable Efforts to obtain confidential treatment of any information concerning MEI that MEI requests be kept confidential, consistent with KKC's disclosure obligations under applicable securities laws. MEI may, at its discretion, file with the U.S. Securities and Exchange Commission or the securities regulators of any state or other jurisdiction under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other applicable securities law a registration statement or any other disclosure document which describes or refers to this Agreement, including filing a copy of this Agreement itself. MEI shall provide KKC with a copy of relevant portions of the proposed filing not less than **[*CONFIDENTIAL*]** prior to such filing (unless exigent circumstances do not permit such review period and then MEI will provide relevant portions of the proposed filing as reasonably in advance as is possible), and shall use Commercially Reasonable Efforts to obtain confidential treatment of any information concerning KKC that KKC reasonably requests be kept confidential, consistent with MEI's disclosure obligations under applicable securities laws. For clarity, in no event shall MEI be obligated to delay or withhold such a filing in order to comply with the foregoing sentence if such compliance would result in MEI being in violation of any Applicable Law.

(b) The Parties agree to issue the joint press release attached here as Schedule 10.6 contemporaneously with the execution of this Agreement. If either Party desires to issue a subsequent press release or make a public announcement concerning the material terms of this Agreement or the Development or Commercialization of the Product under this Agreement, such as the achievement of Regulatory Approvals of the Product, such Party shall provide the other Party with the proposed text of such announcement for prior review and, except to the extent such press release or public announcement is permitted by subsection (a) or (b) above, approval by such other Party.

(c) The Parties agree that after a public disclosure has been made or a press release or other public announcement has been issued in compliance with subsection (a), (b) or (c) hereof, each Party may make subsequent public disclosures or issue press releases or other public

announcements disclosing the same content without having to obtain the other Party's prior consent and approval.

ARTICLE 11
TERM AND TERMINATION

11.1 Term. Unless earlier terminated as permitted by this Agreement, the term of this Agreement will commence upon the Effective Date and continue in full force and effect, on a country-by-country and Product-by-Product basis, until the Expiration Date for such Product and such country (the "**Term**").

(a) With respect to the U.S., if this Agreement naturally expires, then MEI shall have **[*CONFIDENTIAL*]**, fully paid-up, royalty-free and perpetual license to Develop, Package, Manufacture and Commercialize the Product in or for the U.S.; provided, that MEI shall pay (for so long as MEI continues to sell such Product) to KKC (i) **[*CONFIDENTIAL*]** of Net Sales of such Product in the U.S. in the first year following expiration of this Agreement, (ii) **[*CONFIDENTIAL*]** of Net Sales of such Product in the U.S. **[*CONFIDENTIAL*]**, and (iii) **[*CONFIDENTIAL*]** of Net Sales of such Product in the U.S. **[*CONFIDENTIAL*]**. For clarity, MEI's payment obligation described in this Section 11.1(a) (Term) shall **[*CONFIDENTIAL*]** after the expiration of this Agreement.

(b) With respect to Japan or a given country in the RoW, if this Agreement naturally expires, then KKC shall have **[*CONFIDENTIAL*]**, fully paid-up, royalty-free and perpetual license to Develop, Package, Manufacture and Commercialize the Product in such country; provided, that, in consideration for KKC's ongoing use of MEI Trademarks, and the global safety database for Products (other than in connection with a Generic Product, which use with a Generic Product is prohibited), KKC shall pay **[*CONFIDENTIAL*]** of Net Sales in such country except Japan for KKC's use of the global safety database for Products. For clarity, MEI shall be responsible for maintenance of any MEI Trademark, in all cases subject to the terms and conditions of a trademark use agreement to be negotiated in good faith by the Parties upon one Party's request to the other therefor. Pending execution of such a trademark use agreement, with respect to Japan, Sections 5.3(d) (JP – Royalty Payments), 5.3(e) (JP – Royalty Adjustments), and Article 8 (General Payment Provisions), and with respect to the RoW, 6.3(c) (RoW – Royalty Payments) 6.3(d) (RoW – Royalty Adjustments), and Article 8 (General Payment Provisions) shall apply mutatis mutandis with respect to the payments due under this Section 11.1(b) (Term). Further, for clarity, MEI shall be responsible for maintenance of the global safety database for Products; provided that prior to the Expiration Date for a Product in the U.S., Out-of-Pocket Costs identifiable to establishing, updating and maintaining a global safety database for such Product shall be deemed to be a U.S. Development Cost, and after the Expiration Date for such Product in the U.S., MEI shall maintain such global safety database at its cost and expense, for so long as KKC continues to sell such Product and to pay the foregoing payment specified in subclause (ii) of Section 11.1(b) (Term).

11.2 Termination.

(a) Termination by KKC for Convenience. At any time, KKC may terminate this Agreement in its entirety at its sole discretion and for any reason or no reason, by providing written notice of termination to MEI, which notice includes an effective date of termination **[*CONFIDENTIAL*]** after the date of the notice if the notice is given. During such **[*CONFIDENTIAL*]**, the Parties shall transition those activities being performed by KKC under this Agreement as soon as reasonably practicable, pursuant to a transition services agreement to be agreed upon by the Parties in good faith, and KKC shall otherwise continue to perform all of its obligations and shall continue to be responsible for all costs incurred under this Agreement to be borne by KKC according to this Agreement during such **[*CONFIDENTIAL*]**.

(b) Termination for Cause. If either Party believes that the other is in material breach of this Agreement, then the non-breaching Party may deliver notice of such breach to the other Party. The allegedly breaching Party shall have **[*CONFIDENTIAL*]** (**[*CONFIDENTIAL*]** in the case of a payment-related breach) to cure such breach from the receipt of the notice. If MEI (as the allegedly breaching Party) fails to cure that breach within the applicable period set forth above, then KKC may, at its election, terminate this Agreement either in whole or in part under a Partial Termination solely with respect to a Territory (i.e., the U.S., Japan, or RoW, but not individual countries within the RoW) in which such breach occurred on written notice of termination specifying KKC's election to terminate the Agreement in whole or with respect to the applicable Territory that is the Terminated Jurisdiction. If KKC (as the allegedly breaching Party) fails to cure a breach within the applicable period set forth above, then MEI may, at its election, terminate this Agreement either in whole or with respect to a Terminated Jurisdiction on written notice of termination specifying MEI's election to terminate the Agreement in whole or with respect to a Terminated Jurisdiction. Any right to terminate this Agreement under this Section 11.2(b) (Termination for Cause) shall be stayed for up to a period of **[*CONFIDENTIAL*]** and the applicable cure period tolled in the event that, during such cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Section 14.12 (Dispute Resolution) with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Section 14.12 (Dispute Resolution) but in any event no longer than **[*CONFIDENTIAL*]** from the date that the Party alleged to have been in material breach initiates dispute resolution proceeding under Section 14.12 (Dispute Resolution). If a Party is determined to be in material breach of this Agreement, the other Party may terminate this Agreement if the breaching Party fails to cure the breach within **[*CONFIDENTIAL*]** (**[*CONFIDENTIAL*]** in the case of a payment-related breach) after the conclusion of the dispute resolution procedure (and such termination shall then be effective upon written notification from the notifying Party to the breaching Party).

(c) Termination for Patent Challenge. Except to the extent the following is unenforceable under the laws of a particular jurisdiction, MEI may terminate this Agreement immediately upon written notice to KKC if KKC or its Affiliates or Sublicensees, individually or in association with any other Person, commences a legal action challenging the validity or enforceability of any MEI Patent.

(d) Termination for Bankruptcy. This Agreement may be terminated at any time during the Term by either Party upon the other Party's filing or institution of bankruptcy,

reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within **[*CONFIDENTIAL*]** after the filing thereof.

(e) Automatic Termination for Nonpayment. If KKC fails to pay MEI the upfront payment in accordance with, and as set forth in Section 8.1 (Upfront Payment), this Agreement will automatically and immediately terminate.

(f) Termination for Force Majeure. At any time after the third anniversary of the Effective Date, if an event of force majeure (in accordance with Section 14.9 (Force Majeure)) prevents, prohibits, or otherwise inhibits a Party from performing its obligations hereunder for a **[*CONFIDENTIAL*]** or more, the other Party shall have the right to terminate this Agreement in part under a Partial Termination solely with respect to the country(ies) in which such Party's performance of its obligations is prevented, prohibited or otherwise inhibited, upon written notice to such Party. For clarity, nothing in this Section 11.2(f) (Termination for Force Majeure) shall be deemed to modify or otherwise create, with respect to the entire RoW, any rights or obligations in a given country in the RoW.

(g) Termination Related to GDPR Agreement. If KKC's ability to meet the obligations and assurances as set out under (i) the Existing Data Agreement prior to the execution of the GDPR Agreement (to the extent applicable), or (ii) the GDPR Agreement after the execution of the GDPR Agreement, in each case, cannot be restored by reasonable and appropriate means following KKC's notice of such inability as required by the Existing Data Agreement in Section 7(f) of that agreement, and as will be required under the GDPR Agreement, then MEI shall have the right to terminate (1) this Agreement in part under a Partial Termination solely with respect to Japan prior to the execution of the GDPR Agreement, and (2) this Agreement in its entirety after the execution of the GDPR Agreement, in each case, upon written notice to KKC.

11.3 Effect of Termination. Upon termination of this Agreement by KKC pursuant to Sections 11.2(a) (Termination by KKC for Convenience) or 11.2(f) (Termination for Force Majeure), or termination of this Agreement by MEI pursuant to Sections 11.2(b) (Termination for Cause), 11.2(c) (Termination for Patent Challenge), 11.2(d) (Termination for Bankruptcy), 11.2(e) (Automatic Termination for Nonpayment), 11.2(f) (Termination for Force Majeure), or 11.2(g) (Termination Related to GDPR Agreement), the following consequences shall apply (in the case of a Partial Termination, solely for that corresponding Terminated Jurisdiction) and shall be effective as of the effective date of such termination:

(a) KKC's license under Section 3.1 (Licenses to KKC), shall become **[*CONFIDENTIAL*]** upon receipt of a notice of termination and shall terminate upon the effective date of termination except to the extent necessary to perform any surviving obligations as expressly provided in this Agreement (provided, however, that in the event of a Partial Termination, only those licenses for the corresponding Terminated Jurisdiction shall terminate);

(b) KKC hereby assigns to MEI the KKC Technology relating solely to the Compound or Product (and, in the event of a Partial Termination, used solely in the corresponding

Terminated Jurisdiction); provided that, to the extent such assignment is prohibited by Applicable Law, or certain KKC Technology does not relate solely to the Compound or Product, subject to MEI's payment of reasonable royalties as set forth below, KKC hereby grants to MEI, **[*CONFIDENTIAL*]**, royalty-bearing, worldwide (or, in the event of a Partial Termination, limited to the corresponding Terminated Jurisdiction), perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under all such KKC Technology that is not assigned to MEI, to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize the Compound and Products. KKC shall execute such documents as MEI reasonably requests in order to further memorialize the foregoing assignment (or license). The Parties shall agree in good faith to **[*CONFIDENTIAL*]**, provided further that, if the Parties are unable to agree on **[*CONFIDENTIAL*]** within **[*CONFIDENTIAL*]** of beginning discussions with respect thereto, then either Party may refer such matter for arbitration in accordance with Section 14.12 (Dispute Resolution). For clarity, at any time, MEI shall have the right to **[*CONFIDENTIAL*]**.

(c) KKC shall return to MEI or destroy, at MEI's election, all Confidential Information (or, in case of a Partial Termination, Confidential Information relating solely to the corresponding Terminated Jurisdiction) of MEI, including all copies thereof and all materials, substances and compositions delivered or provided by MEI to KKC, provided that KKC shall have the right to retain **[*CONFIDENTIAL*]** copy thereof, which may be retained by KKC solely for legal archiving purposes;

(d) KKC shall, where permitted under Applicable Law, as promptly as reasonably practical, assign to MEI all Regulatory Materials and Regulatory Approvals for any Compound and Product in the Territory (and, in the event of a Partial Termination, in the corresponding Terminated Jurisdiction only) and provide MEI with all correspondence with Regulatory Authorities related to such Regulatory Materials and Regulatory Approval;

(e) KKC shall disclose to MEI all KKC Know-How, KKC's Sole Inventions and all Joint Inventions to the extent not already known to MEI, which may be necessary or reasonably useful for MEI to continue to Develop, Package, Manufacture and Commercialize Compounds and Products in the Field in the Territory (and, in the event of a Partial Termination, in the corresponding Terminated Jurisdiction only). In addition, KKC shall, at MEI's request, provide reasonable technical assistance and transfer all KKC Know-How, KKC's Sole Inventions and Joint Inventions necessary to Package or Manufacture Compounds and Products to MEI or its designee;

(f) KKC shall, to the extent that MEI does not provide written notice that it does not want to receive the benefit thereof in part or in whole, transfer sponsorship and control to MEI of all Clinical Trials of the Product being conducted as of the effective date of termination in the Territory (and, in the event of a Partial Termination, in the corresponding Terminated Jurisdiction only), provided, that, if MEI does not desire to take over control of any given ongoing

Clinical Trial(s), then KKC shall be responsible for winding-down such trials as soon as possible in accordance with Applicable Law and industry standards.

(g) KKC shall, and shall cause its Affiliates and its and their Sublicensees to, as promptly as reasonably practicable, provide a copy to MEI of all agreements related to the Development, Packaging, Manufacture, use or Commercialization of the Compound or Product ("**Product Agreements**") in the Territory (or, in the case of a Partial Termination, Product Agreements relating solely to the corresponding Terminated Jurisdiction), including all Sublicenses, and, to the extent requested by MEI in writing, assign to MEI any Product Agreement, unless, with respect to any such Product Agreement, such Product Agreement expressly prohibits such assignment, in which case KKC (or such Affiliate or Sublicensee, as applicable) shall co-operate with MEI and use Commercially Reasonable Efforts to secure the consent of the applicable Third Party to such assignment, at KKC's expense, and if any such consent cannot be obtained with respect to a Product Agreement, KKC shall, and shall cause its Affiliates and its and their Sublicensees to, to the extent requested by MEI in writing, facilitate discussions between MEI and such Third Parties to assist MEI in entering into a direct agreement with such Third Parties;

(h) KKC shall transfer to MEI all units of Compound and Product in its possession which are intended for sale, Development or use in the Territory (and, in the event of a Partial Termination, in the corresponding Terminated Jurisdiction only) at no cost; and

(i) KKC shall, if applicable, and hereby does, effective on such termination, assign to MEI [***CONFIDENTIAL***] (and, in the event of a Partial Termination, in the corresponding Terminated Jurisdiction only) in connection with its Development, Packaging, or Commercialization of Products [***CONFIDENTIAL***], including all goodwill therein, and KKC shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment.

11.4 Effect of Termination for Cause by KKC. If KKC is entitled to terminate this Agreement under Section 11.2(b) (Termination for Cause) as a result of an uncured material breach by MEI, KKC may elect to terminate or continue this Agreement. If KKC elects to continue this Agreement, the rights and licenses granted by MEI to KKC under this Agreement shall continue, subject to KKC's related obligation under this Agreement. If KKC elects to terminate this Agreement under Sections 11.2(b) (Termination for Cause) either in whole or with respect to a Terminated Jurisdiction, or 11.2(d) (Termination for Bankruptcy), the following consequences shall apply (and, in case of a Partial Termination, solely for that corresponding Terminated Jurisdiction) and shall be effective as of the effective date of such termination:

(a) MEI shall compensate KKC any costs and expenses incurred by KKC, or its Affiliates in connection with performing any of the activities contemplated under this Section 11.4 (Effect of Termination for Cause by KKC).

(b) KKC's license under Section 3.1 (Licenses to KKC) shall terminate (provided, however, that in the event of a Partial Termination, only those licenses for the Terminated Jurisdiction shall terminate);

(c) The Receiving Party shall return to the Disclosing Party or destroy, at the Disclosing Party's election, all Confidential Information (or, in case a Partial Termination, Confidential Information relating solely to the corresponding Terminated Jurisdiction) of the Disclosing Party, including all copies thereof and all materials, substances and compositions delivered or provided by the Disclosing Party to the Receiving Party, provided that the Receiving Party shall have the right to retain one (1) copy thereof, which may be retained by the Receiving Party solely for legal archiving purposes, and provided further, that MEI shall have no obligation to return KKC's Confidential Information to the extent such Confidential Information is KKC Technology specifically related to Compound and Product, subject to Article 10 (Confidentiality; Publication);

(d) KKC shall, at KKC's election, withdraw Regulatory Approvals for any Compound and Product in the Territory (or, in the case of a Partial Termination, in the corresponding Terminated Jurisdiction only) or, with MEI's prior written consent, assign to MEI all such Regulatory Materials and Regulatory Approvals for any Compound and Product and provide MEI with copies of all correspondence with Regulatory Authorities relating to such Regulatory Materials and Regulatory Approval; and

(e) KKC shall transfer to MEI and MEI shall purchase all units of Compound and Product which are intended for sale, Development or use in the Territory (or, in the case of a Partial Termination, in the corresponding Terminated Jurisdiction only) at a price equal to KKC's or its Affiliate's fully burdened costs for such inventory with shipment costs reimbursed by MEI.

11.5 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. In addition, the provisions of Articles 1 (Definitions) (to the extent necessary to give effect to other surviving provisions), 8 (General Payment Provisions) (with respect to amounts incurred or otherwise due or accruing on or prior to expiration or termination), 10 (Confidentiality; Publication) (but not Sections 10.4 (Publication) or 10.5 (Privileged Communications)), 13 (Indemnification; Liability) (but not Section 13.6 (Insurance)), and 14 (General Provisions), and Sections 3.6 (No Implied Licenses; Negative Covenant), 7.1(a), 7.2(b) (Inspections for Improper Activities), 9.1 (Ownership), 11.3 (Effect of Termination) and 11.4 (Effect of Termination for Cause by KKC) as applicable, 11.5 (Survival), 11.6 (Termination Not Sole Remedy), and with respect to amounts incurred or otherwise due or accruing on or prior to expiration or termination, Sections 4.1(e) (U.S. – Development Costs), 4.2(c) (U.S. – Commercialization Costs), 4.4 (U.S. – Financial Terms), 5.1(c) (JP – Development Costs), 5.3 (JP – Financial Terms) (but not Section 5.3(f) (JP - Financial Adjustments)), 6.1(c) (RoW – Development Costs), and 6.3 (RoW – Financial Terms), hereof shall survive the expiration or termination of this Agreement.

11.6 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 Representations and Warranties of Each Party. Each Party represents and warrants to the other Party as of the Effective Date that:

(a) it has the full right, power and authority to enter into this Agreement, to perform its obligations hereunder, and no approval from any governmental authority is required of such Party; and

(b) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not and will not conflict with any agreement, instrument or understanding, oral or written, to which it is or becomes a party or by which it is or may become be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

12.2 Mutual Covenants.

(a) Employees, Consultants and Contractors. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants and contractors who perform any activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign Inventions in a manner consistent with the provisions of this Agreement.

(b) Debarment. Each Party represents, warrants and covenants to the other Party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to the Compound or Product. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

(c) Compliance. Each Party covenants as follows:

(i) In the performance of its obligations and the exercise of its rights under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws, including all export control, anti-corruption and anti-bribery laws and regulations, and shall not cause such other Party's Indemnitees to be in violation of any Applicable Laws or otherwise cause any reputational harm to such other Party.

(ii) Such Party and its and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to

any Government Authority or representative thereof or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including either Party (and each Party represents and warrants that as of the Effective Date, such Party, and to its knowledge, its and its Affiliates' employees and contractors, have not directly or indirectly promised, offered or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Government Authority or representative thereof or any other person in connection with the performance of such Party's obligations under this Agreement, and each Party covenants that it and its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing).

(iii) Such Party and its and its Affiliates' employees and contractors shall have complied and will comply with all Anti-Corruption Laws and industry codes dealing with government procurement, conflicts of interest, corruption or bribery.

Each Party shall have the right to suspend or terminate this Agreement, upon written notice to the other Party, in its entirety where there is a credible finding, after a reasonable investigation, that the other Party, in connection with performance of such other Party's obligations under this Agreement, has violated any Anti-Corruption Laws.

(d) No Challenge. Each Party covenants that it shall not, and shall ensure that its Affiliates and Sublicensees, individually or in association with any other Person does not, challenge the validity, patentability, or enforceability of any claims within the Joint Patents.

12.3 Representations and Warranties by MEI. MEI represents and warrants to KKC as of the Effective Date that:

(a) it has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in MEI Technology in a manner that is inconsistent with the licenses granted to KKC under Section 3.1 (Licenses to KKC);

(b) MEI has not received any notice from a Third Party that the Development of any Compound or Product conducted by MEI prior to the Effective Date has infringed any Patents of any Third Party or misappropriated any other intellectual property of any Third Party and is not aware of any imminent or likely threat from a Third Party of such infringement or misappropriation;

(c) MEI's (and its Affiliates, Sublicensees and subcontractors) compensation programs for their respective sales representatives in connection with the Commercialization of Products do not, and will not, provide financial incentives for the promotion, sales, and marketing of Products in violation of any Applicable Laws or any professional requirements;

(d) MEI has no knowledge as of the Effective Date of any Third Party that is infringing or misappropriating any of the MEI Technology in the Territory;

(e) no claim or action has been brought or, to MEI's knowledge, threatened in writing by any Third Party alleging that the MEI Patents are invalid or unenforceable, and no MEI Patent is the subject of any interference, opposition, cancellation or other protest proceeding; and

(f) the patents and patent applications listed on Schedule 1.112 constitute all existing MEI Patents as of the Effective Date.

12.4 Representations and Warranties by KKC. KKC represents and warrants to MEI as of the Effective Date that:

(a) KKC has received satisfactory responses from MEI to each specific written request for information, in connection with the execution of this Agreement, made by KKC prior to the Effective Date;

(b) KKC's (and its Affiliates, Sublicensees and subcontractors) compensation programs for their respective sales representatives in connection with the Commercialization of Products do not, and will not, provide financial incentives for the promotion, sales, and marketing of Products in violation of any Applicable Laws or any professional requirements;

(c) All Products Commercialized, Packaged or Manufactured by, or under authority of, KKC shall be:

(i) packaged, labeled, handled, stored and shipped in accordance with, and shall conform to, applicable specifications; and

(ii) packaged, labeled, handled, stored and shipped in compliance with all Applicable Laws.

12.5 Disclaimer. KKC understands that the Compound and Product are the subject of ongoing clinical research and development and that MEI cannot ensure the safety or usefulness of the Compound or Product or that the Product will receive Regulatory Approvals.

12.6 No Other Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

ARTICLE 13
INDEMNIFICATION; LIABILITY

13.1 Indemnification by MEI. MEI shall indemnify and hold KKC, its Affiliates and Sublicensees, and their respective officers, directors, agents and employees ("**KKC Indemnitees**") harmless from and against any Claims against them to the extent arising or resulting from:

(a) a Manufacturing defect in the Compound or Product supplied by or on behalf of MEI (other than by any KKC Indemnitees) or any of its Affiliates or Third Party Sublicensees to KKC for use in Japan or RoW (except in connection with a U.S. Global Study),

except to the extent any such Claim arises or results from KKC's failure or delay in taking appropriate action after having become aware of such Manufacturing defect;

(b) the gross negligence or willful misconduct of any of the MEI Indemnitees; and

(c) any material breach by MEI of this Agreement.

except in each case, to the extent such Claims result from the material breach by KKC of any covenant, representation, warranty or other agreement made by KKC in this Agreement or the negligence or willful misconduct of any KKC Indemnitee. Notwithstanding the above, MEI will have no obligation to defend or indemnify KKC or its Affiliates for any claim brought by a shareholder or a class of shareholders of KKC or its Affiliates including, securities fraud claims, shareholder direct claims, and shareholder derivative claims, except to the extent resulting from the gross negligence or willful misconduct on the part of MEI or any Affiliate.

13.2 Indemnification by KKC. KKC shall indemnify and hold MEI, its Affiliates, Direct Licensees, and Sublicensees, and their respective officers, directors, agents and employees ("**MEI Indemnitees**") harmless from and against any Claims against them to the extent arising or resulting from:

(a) a Manufacturing defect in the Compound or Product supplied by or on behalf of KKC (other than by any MEI Indemnitees) or any of its Affiliates or Third Party Sublicensees to MEI for use in the U.S. (except in connection with a U.S. Global Study), except to the extent any such Claim arises or results from MEI's failure or delay in taking appropriate action after having become aware of such Manufacturing defect;

(b) except in connection with a U.S. Global Study, the use, Development, Packaging, Commercialization, handling, storage or other disposition by or on behalf of KKC or any of its Affiliates or Sublicensees of any Compound or Product in the Field in or for Japan or the RoW, including any Product Liability Claim in Japan or the RoW, except to the extent any such Claims are subject to MEI's indemnification obligations under Section 13.1(a) (Indemnification by MEI); or

(c) the gross negligence or willful misconduct of any of the KKC Indemnitees; or

(d) the material breach by KKC of this Agreement;

except in each case, to the extent such Claims result from the material breach by MEI of any covenant, representation, warranty or other agreement made by MEI in this Agreement or the negligence or willful misconduct of any MEI Indemnitee. Notwithstanding the above, KKC will have no obligation to defend or indemnify MEI or its Affiliates for any claim brought by a shareholder or a class of shareholders of MEI or its Affiliates including, securities fraud claims, shareholder direct claims, and shareholder derivative claims, except to the extent resulting from the gross negligence or willful misconduct on the part of KKC or any Affiliate.

13.3 Indemnification Procedure. If either Party is seeking indemnification under Sections 13.1 (Indemnification by MEI) or 13.2 (Indemnification by KKC) (the "**Indemnified Party**"), it shall inform the other Party (the "**Indemnifying Party**") of the claim giving rise to the obligation to indemnify pursuant to such section as soon as reasonably practicable after receiving notice of the claim. The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without such Party's written consent, which consent shall not be unreasonably withheld or delayed. If the Parties cannot agree as to the application of Section 13.1 (Indemnification by MEI) or 13.2 (Indemnification by KKC) as to any claim, pending resolution of the dispute pursuant to Section 14.12 (Dispute Resolution), the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 13.1 (Indemnification by MEI) or 13.2 (Indemnification by KKC) upon resolution of the underlying claim. For clarity, the Financial Exhibit addresses the treatment and allocation of Collaboration Losses for which the Parties will share liability, including Product Liability Claims in the U.S.

13.4 Mitigation of Loss. Each Indemnified Party will take and will procure that its Affiliates take reasonable steps and actions to mitigate any Claims (or potential losses or damages) under this Article 13 (Indemnification; Liability). Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

13.5 Special, Indirect and Other Losses. EXCEPT IN THE EVENT OF A PARTY'S BREACH OF Article 10 (CONFIDENTIALITY; PUBLICATION) OR A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOST REVENUES OR LOST PROFITS, IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that this Section 13.5 (Special, Indirect and Other Losses) shall not be construed to limit **[*CONFIDENTIAL*]**.

13.6 Insurance. Each Party, at its own expense, shall maintain Product Liability and other appropriate insurance in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

ARTICLE 14
GENERAL PROVISIONS

14.1 Non-Compete.

(a) During the Term of this Agreement (i.e., this Agreement has not been terminated in its entirety) and for an additional period of **[*CONFIDENTIAL*]** thereafter with respect to the U.S. and RoW, and, with respect to Japan, **[*CONFIDENTIAL*]** thereafter, in each case following: (i) the early termination of this Agreement [***CONFIDENTIAL***] (provided, for clarity, that no such additional period shall apply in the case of the natural expiration of this Agreement), each Party shall not, and shall ensure that its Affiliates and its Sublicensees do not, directly or indirectly, conduct, have conducted, exploit, or fund any activity that involves the conduct of, **[*CONFIDENTIAL*]** any compound or product in or for Japan that is intended **[*CONFIDENTIAL*]** other than, in each case of (1) and (2), the Compound and Product in accordance with this Agreement and any applicable supply agreement between the Parties. For clarity, the Parties agree that the scopes of restrictions with respect to subsections (1) and (2) shall be independent of each other, and accordingly that any restrictions set forth in subsection (2) with respect to the U.S. and RoW above will not, and are not intended to, result in any substantive expansion or modification to the scope of restrictions under the subsection (1) with respect to Japan. It is the desire and intent of the Parties that the restrictive covenants contained in this Section 14.1 (Non-Compete) be enforced to the fullest extent permissible under Applicable Laws and public policies applied in each jurisdiction in which enforcement is sought. KKC and MEI believe that the restrictive covenants in this Section 14.1 (Non-Compete) are valid and enforceable. However, if any restrictive covenant should for any reason become or be declared by a competent court or competition authority to be invalid or unenforceable in any jurisdiction, such restrictive covenant shall be deemed to have been amended to the extent necessary in order that such provision be valid and enforceable, provided that such amendment shall apply only with respect to the operation of such provision of this Section 14.1 (Non-Compete) in the particular jurisdiction in which such declaration is made.

(b) Notwithstanding Section 14.1(a) (Non-Compete), if during the relevant time period under Section 14.1(a) (Non-Compete), a Party (such Party, the "**Acquiring Party**") or any of its Affiliates (as applicable) merges or consolidates with, or otherwise acquires, or is acquired by, a Third Party wherein such Third Party is engaged in activities that would otherwise constitute a breach of Section 14.1(a) (Non-Compete) (a "**Competitive Program**"), unless the Parties agree otherwise in writing, the Acquiring Party shall, within **[*CONFIDENTIAL*]** after the closing date of the merger, consolidation or acquisition, notify the other Party in writing that it intends to either (i) **[*CONFIDENTIAL*]** or (ii) **[*CONFIDENTIAL*]**. If the Acquiring Party notifies the other Party that it:

(i) intends **[*CONFIDENTIAL*]**, then the Acquiring Party or its Affiliate **[*CONFIDENTIAL*]** as quickly as possible (and in any event, subject to Applicable Law, within **[*CONFIDENTIAL*]** of the date of such written notice); or

(ii) intends **[*CONFIDENTIAL*]**, then the Acquiring Party or its relevant Affiliate shall use all reasonable efforts to effect **[*CONFIDENTIAL*]** quickly as possible (and in any event within **[*CONFIDENTIAL*]** of the date of such written notice); provided, that, if the Acquiring Party or its relevant Affiliate fails to complete

[*CONFIDENTIAL*] within such **[*CONFIDENTIAL*]**, but can demonstrate to the other Party's reasonable satisfaction that it used all reasonable efforts **[*CONFIDENTIAL*]** within such **[*CONFIDENTIAL*]**, then, unless otherwise required by Applicable Law, **[*CONFIDENTIAL*]** shall be extended for such additional reasonable period thereafter as is necessary to enable such Competitive Program **[*CONFIDENTIAL*]**, not to exceed an additional **[*CONFIDENTIAL*]**; provided, further, however, that all times periods under this Section 14.1(b) (Non-Compete) shall be extended for such period as is necessary to obtain any governmental or Regulatory Approvals required to complete **[*CONFIDENTIAL*]** for so long as the Acquiring Party or its relevant Affiliate is using good faith efforts to obtain such approvals.

14.2 Personally-Identifiable Data / GDPR Compliance. The Parties will negotiate in good faith and enter into a Joint Controller and Onward Transfer Agreement **[*CONFIDENTIAL*]** of the Effective Date ("**GDPR Agreement**"). Upon the execution of such GDPR Agreement, the Existing Data Agreement will automatically terminate and be superseded and replaced by the GDPR Agreement. All Confidential Information containing personally-identifiable data or personal data (as defined in the General Data Protection Regulation (EU) 2016/679 ("**GDPR**")) shall be processed by each Party and its Affiliates, Sublicensees, and processors and sub-processors in accordance with all data protection and privacy laws, rules and regulations applicable to such data, and in accordance with the (a) the Existing Data Agreement prior to the execution of the GDPR Agreement (to the extent applicable), and (b) the GDPR Agreement after the execution of the GDPR Agreement. In addition, the Parties will execute other appropriate agreements and provide the other Party full and timely cooperation and support that is reasonably required to achieve or to ensure full GDPR compliance and/or compliance of either Party with national laws and regulations for such personally-identifiable data or personal data.

14.3 Subcontractor. Without limiting Section 3.3 (Sublicense Rights), to the extent applicable, each Party shall have the right to engage subcontractors for the performance of its obligations under this Agreement; provided, however, that such Party shall remain responsible for and be guarantor of the performance by its Affiliates and Third Party subcontractors and shall cause its Affiliates and Third Party subcontractors to comply with the provisions of this Agreement in connection with such performance, including obligations of confidentiality and non-use of the other Party's Confidential Information and invention assignment consistent with those contained herein. Each Party shall remain responsible and liable for the performance any such subcontractor(s) and such Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against an Affiliate or a Third Party subcontractor, for any obligation or performance hereunder prior to proceeding directly against it.

14.4 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York without reference to any rules of conflict of laws with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law; provided, that, the Existing Data Agreement and the GDPR Agreement shall be governed by and construed in accordance with the laws identified therein.

14.5 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that either Party may assign or otherwise transfer this Agreement

and its rights and obligations hereunder without the other Party's consent: (a) in connection with the transfer or sale of all or substantially all of the business or assets of such Party to which this Agreement relates to a Third Party, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets or otherwise; provided that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the Parties to this Agreement) and its Affiliates existing prior to the transaction shall not be included in the technology licensed hereunder; or (b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such assignee. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Section 14.5 (Assignment) shall be null and void.

14.6 Entire Agreement; Modification; JP Agreement and Prior CDA.

(a) This Agreement is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

(b) As of the Effective Date, each of the JP Agreement and Prior CDA shall be deemed to be terminated in their respective entirety (including any provisions that would otherwise survive termination), and of no further force or effect, notwithstanding anything to the contrary contained in the JP Agreement or the Prior CDA; provided that, notwithstanding anything to the contrary herein, the Existing Data Agreement shall survive the termination of the JP Agreement and continue in full force and effect until the execution of the GDPR Agreement. This Agreement will be deemed to satisfy any requirement that any amendment to the JP Agreement or the Prior CDA be in writing and executed by the Parties.

14.7 Relationship Between the Parties. The Parties' relationship with one another, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party. Neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

14.8 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

14.9 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Government Authority. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations in spite of the ongoing circumstances.

14.10 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

14.11 Notices. Any notice to be given under this Agreement must be in writing and delivered either (a) in person, (b) by air mail (postage prepaid) requiring return receipt, (c) by overnight courier, or (d) by e-mail with delivery and return receipts requested and confirmation of delivery thereafter, to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt; (ii) if air mailed, five (5) days after the date of postmark; (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries or (iv) if sent by e-mail, the date of confirmation of receipt.

If to MEI:
MEI Pharma, Inc.
3611 Valley Centre Drive STE 500
San Diego, CA 92130
[***CONFIDENTIAL***]
[***CONFIDENTIAL***]

If to KKC:
Kyowa Kirin Co., Ltd.
1-9-2 Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan
[***CONFIDENTIAL***]
[***CONFIDENTIAL***]

14.12 Dispute Resolution.

(a) The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. Subject to Section 14.12(h) (Dispute Resolution), in the event the Parties cannot resolve such dispute, controversy or claim within a period of **[*CONFIDENTIAL*]**, then the matter shall be

referred to the Chief Executive Officer of KKC (or his or her designee) and the Chief Executive Officer of MEI (or his or her designee) (collectively, the "**Executive Officers**"), who shall use good faith efforts to resolve promptly such matter, which good faith efforts shall include at least **[*CONFIDENTIAL*]** between such Executive Officers within **[*CONFIDENTIAL*]** after the submission of such matter to them.

(b) Except as expressly set forth in Section 14.12(h) (Dispute Resolution), if, after going through the procedure above in Section 14.12(a) (Dispute Resolution), the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an Excluded Claim (defined in Section 14.12(g) (Dispute Resolution)) shall be finally resolved, at either Party's request, by binding arbitration administered by the American Arbitration Association ("**AAA**") pursuant to the arbitration rules then in effect.

(c) The arbitration shall be conducted by a panel of three (3) neutral arbitrators experienced in the pharmaceutical business, none of whom shall be a current or former employee or director, or a current stockholder, of either Party or any of their respective Affiliates or any Sublicensee. Within **[*CONFIDENTIAL*]** after initiation of arbitration, each Party shall select one (1) person to act as arbitrator and the two (2) Party-selected arbitrators shall select a third (3rd) arbitrator within **[*CONFIDENTIAL*]** of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third (3rd) arbitrator, the third (3rd) arbitrator shall be appointed by AAA. The place of arbitration shall be San Francisco, California, and all proceedings and communications shall be in English. The arbitrators shall take into account both the desirability of making discovery efficient and cost-effective and the needs of the Parties for an understanding of any legitimate issue raised in the arbitration. The award rendered by the arbitrators shall be final, binding and non-appealable (except in the event of gross error or fraud), and judgment may be entered upon it in any court of competent jurisdiction.

(d) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. The arbitrators' authority to award punitive or any other type of damages not measured by a Party's compensatory damages shall be subject to the limitation set forth in Section 13.5 (Special, Indirect and Other Losses). Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.

(e) Except to the extent necessary to confirm or enforce an award or as may be required by law, neither Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the other Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

(f) The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

(g) As used in this Section, the term "**Excluded Claim**" means a dispute, controversy or claim that concerns the construction, scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright.

(h) Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the construction, scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright, and no such claim shall be subject to arbitration pursuant to subsections (b) and (c) of this Section 14.12 (Dispute Resolution). In the event that injunctive or other equitable relief is granted by a court, no bond or other security will need to be posted.

14.13 Performance by Affiliates. Each Party may discharge any obligations and exercise any rights hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

14.14 Headings. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

14.15 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

14.16 Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", (c) the word "will" shall be construed to have the same meaning and effect as the word "shall", (d) 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 or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors and assigns, (f) 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, (g) all references herein to Articles, Sections, or Schedules shall be construed to refer to Articles, Sections, or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other

written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding electronic mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the terms "or" and "and/or" shall be interpreted in the inclusive sense commonly associated with the term "and/or".

14.17 Business Day Requirements. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day then such notice or other action or omission shall be deemed to require to be taken on the next occurring Business Day.

14.18 Offset Rights. Except as expressly permitted in this Agreement, neither Party may, at any time or for any reason, offset any payments due to the other Party or its Affiliates under this Agreement.

14.19 English Language. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

14.20 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party shall prepare such counterpart by electronically transmitting a signed copy of this Agreement (*e.g.*, by portable document format), which counterpart shall be deemed an original and fully valid and binding on the Party whose name is contained therein. Without limitation to the foregoing, each Party agrees to, as soon as reasonably practicable, execute and deliver to the other Party physical signed copies of the Agreement upon request by the other Party.

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IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

KYOWA KIRIN CO., LTD.		**MEI PHARMA, INC.**	
By:	/s/ Masashi Miyamoto	By:	/s/ Daniel P. Gold
Name:	Masashi Miyamoto, Ph.D.	Name:	Daniel P. Gold, Ph.D.
Title:	President & Chief Executive Officer	Title:	President & Chief Executive Officer
Date:	April 13, 2020	Date:	April 13, 2020

Schedule 1.35

Compound Structure

[ONE PAGE HAS BEEN REDACTED]

[*CONFIDENTIAL*]

Schedule 1.59

Financial Exhibit

Net Profit or Loss shall exclude all of the payments set forth in Sections 8.1 (Upfront Payment), 4.4(a) (U.S. –Milestone Payments), 5.3 (JP – Financial Terms), 6.3 (RoW – Financial Terms), all Development Costs and capital expenditures, and any other cost not specifically included in U.S. Commercialization Costs, including costs attributable to general corporate activities, executive management, investor relations, treasury services, business development, corporate government relations, external financial reporting and other overhead activities. For the sake of clarity, cost items included in components of Net Profit or Loss shall not be double counted and shall not be included in Development Costs.

Calculation of Net Profit or Loss

Net Profit or Loss shall be calculated for each Calendar Quarter by determining the Net Sales of Products in the U.S., adding any Other Income and subtracting the sum of the U.S. Commercialization Costs incurred with regard to Products in the U.S. during such Calendar Quarter. Notwithstanding the foregoing, on a Calendar Year-to-date basis, U.S. Commercialization Costs shall not be included in such calculation if such expenses are in excess of the amounts allocated for such Calendar Year-to-date period, in the applicable U.S. Commercialization Budget and each Party will be solely responsible for U.S. Commercialization Costs it incurs in excess of the amounts set forth in the U.S. Commercialization Budget; provided, however, that U.S. Commercialization Costs in excess of the applicable U.S. Commercialization Budget shall be included in the calculation of Net Profit or Loss (i) if the JSC approves such excess U.S. Commercialization Costs (either before or after they are incurred), which approval shall not be unreasonably withheld to the extent the U.S. Commercialization Costs in excess of the applicable U.S. Commercialization Budget were not within the reasonable control of the Party (or Party's Affiliate) incurring such expense, (ii) to the extent such excess does not exceed by more than **[*CONFIDENTIAL*]** of the total U.S. Commercialization Costs allocated to be incurred by such Party and its Affiliates in the applicable Calendar Year-to-date period in accordance with the applicable U.S. Commercialization Budget for such Calendar Year, or (iii) if such U.S. Commercialization Cost is a Product Liability-related cost which were not anticipated at the time the applicable Budget was established for a Calendar Year, in which case such Product Liability-related costs shall not be included for determining whether the Parties have exceeded the amounts budgeted to be incurred by such Parties in such Calendar Year for U.S. Commercialization Costs. Notwithstanding the foregoing, for clarity, Product Liability-related costs that are entitled to indemnification under Article 13 (Indemnification; Liability) shall be solely borne by the relevant Indemnifying Party, and shall not be shared hereunder.

General Principles.

Each Party shall provide financial statements in such reporting format as the JFC may establish for use by the Parties.

All calculations to be made pursuant to this Financial Exhibit shall be made in accordance with (i) the applicable definitions and terms set forth in this Financial Exhibit and in the Agreement in a manner consistent with the methodologies used for the applicable U.S. Commercialization Budget (first priority), (ii) the specific accounting policies as may be established by JFC (second priority) and (iii) GAAP (third priority). All undefined terms shall be construed in accordance with GAAP, but only to the extent consistent with the other express terms and definitions in this Financial Exhibit and the Agreement and specific accounting policies established by the JFC.

For the avoidance of doubt, income and withholding Taxes imposed on either of the Parties or their Affiliates hereunder will not be included in the calculation of Net Profit or Loss.

Losses from Third Party Claims; Exclusion of Costs Subject to Indemnification under Section 13.1 (Indemnification by MEI) or Section 13.2 (Indemnification by KKC)

The Parties agree that any Collaboration Losses will be charged to the Net Profit or Loss; provided, that Net Profit or Loss will not include Collaboration Losses of a Party or its Affiliate that are subject to indemnification by such Party pursuant Section 13.1 (Indemnification by MEI) or Section 13.2 (Indemnification by KKC) (and for clarity, if a Third Party makes a Third Party Claim (other than a Product Liability Claim for which the costs are shared) directly against MEI (or any of its Affiliates) or KKC (or any of its Affiliates), respectively, that would otherwise be indemnified by MEI or KKC, respectively, if such Third Party Claim had been made against the other Party (or any of its Affiliates), then costs incurred by MEI or KKC in connection with such direct Third Party Claim will not be included in the calculation of Net Profit or Loss).

Reconciliations

The JFC will coordinate to resolve any differences in or disputes regarding the calculation of Net Profit or Loss, or any component thereof and escalate any unresolved differences for resolution to the JSC.

Schedule 1.98

● KKC Patents

[***CONFIDENTIAL***]

Schedule 1.112

MEI Patents

[4 PAGES HAVE BEEN REDACTED]

[*CONFIDENTIAL*]

Schedule 3.7(c)

Manufacturing Technology Transfer Plan

The Parties shall conduct Manufacturing technology transfer of the Compound and the Products in accordance with this Manufacturing Technology Transfer Plan and Section 3.7(c) (Technology Transfer to KKC) of the Agreement. MEI will provide subject matter expertise including making appropriate employees available at reasonably agreed times and frequency, for the purpose of enabling KKC's CMO to Manufacture the Compound and the Product and supply the JP and RoW Supply Items.

[*CONFIDENTIAL*]

Schedule 4.1(a)

U.S. Development Plan

[*CONFIDENTIAL*] [8 PAGES HAVE BEEN REDACTED]

Schedule 4.3

Co-Promotion Terms

[*CONFIDENTIAL*] [5 PAGES HAVE BEEN REDACTED]

Schedule 5.1(a)

JP Development Plan

[*CONFIDENTIAL*] [4 PAGES HAVE BEEN REDACTED]

Schedule 10.6

Joint Press Release

MEI Pharma and Kyowa Kirin Announce Global License, Development and Commercialization Agreement for ME-401

- *MEI Pharma and Kyowa Kirin will co-develop and co-promote ME-401 in the U.S.; MEI to book U.S. sales on 50-50 profit and cost sharing*
- *Kyowa Kirin obtains exclusive commercialization rights ex-U.S.; MEI to receive escalating tiered royalty payments on ex-U.S. sales*
- *MEI to receive $100 million in an upfront cash payment and is eligible to receive up to an additional $582.5 million based on the achievement of specified development, regulatory and commerical milestones*
- *MEI to host conference call on April 15 at 8:00 a.m. ET*

SAN DIEGO, and TOKYO, April 15, 2020 – MEI Pharma, Inc. (NASDAQ: MEIP) and Kyowa Kirin Co., Ltd. (Kyowa Kirin, TSE: 4151) today jointly announced that the companies have entered into a global license, development and commercialization agreement to further develop and commercialize MEI's ME-401, an oral, once-daily, investigational drug-candidate, selective for phosphatidylinositol 3-kinase delta (PI3Kd), in clinical development for the treatment of B-cell malignancies. MEI and Kyowa Kirin will co-develop and co-promote ME-401 in the U.S., with MEI booking all revenue from U.S. sales. Kyowa Kirin has exclusive commercialization rights outside of the U.S.

ME-401 is being studied in the ongoing Phase 2 TIDAL clinical trial evaluating patients with relapsed or refractory follicular lymphoma which, subject to results, may support an accelerated approval of a marketing application with the U.S. Food and Drug Administration (FDA). An ongoing Phase 1b study is evaluating ME-401 as a monotherapy and in combination with rituximab (Rituxan®) or zanubrutinib (Brukinsa™) in patients with B-cell malignancies. Also, a Phase 1 study was initiated in 2019 evaluating ME-401 as a monotherapy in patients with indolent B-cell malignancy in Japan.

"This global partnership with Kyowa Kirin is a key step to achieving our goal of broadly developing and commercializing ME-401, optimizing the opportunity to benefit patients across multiple B-cell malignancies inside and outside the U.S., and also building value for our shareholders," said David M. Urso, J.D., chief operating officer & general counsel of MEI Pharma. "The decision to expand our alliance with Kyowa Kirin is based on the successful relationship we've built working together to date under our 2018 Japan license agreement, and the respect we have for Kyowa Kirin and their ability to jointly execute our shared vision of ME-401 in the U.S. and around the world."

“I am delighted to expand our agreement with MEI Pharma for the development and commercialization of ME-401 all over the world,” said Tomohiro Sudo, Executive Officer, Director of Strategic Product Planning Department for Kyowa Kirin. “We believe that ME-401 may be an important new treatment option for patients and further enhances our global oncology pipeline.

About the Global License, Development and Commercialization Agreement

Under the terms of the agreement, which substantially retains and consolidates the terms of the 2018 license agreement between MEI and Kyowa Kirin to develop and commercialize ME-401 in Japan, MEI will receive a $100 million upfront payment from Kyowa Kirin. MEI is also eligible to receive up to $582.5 million in additional payments from Kyowa Kirin depending on the achievement of certain U.S. and ex-U.S. development, regulatory and commercial milestones.

If approved by FDA in the U.S., MEI and Kyowa Kirin will co-promote ME-401, with MEI booking all revenue from sales. MEI and Kyowa Kirin will share U.S. profits and costs (including development costs) on a 50-50 basis.

Outside the U.S., Kyowa Kirin will have exclusive commercialization rights, lead commercialization and book all revenues from sales of ME-401. Kyowa Kirin will pay MEI escalating tiered royalties on ex-U.S. sales starting in the teens. Kyowa Kirin will be responsible for all incremental ex-U.S. clinical development costs and all ex-U.S. regulatory, CMC and commercial costs.

The companies have agreed to a development plan designed to broadly evaluate ME-401 in patients with various B-cell malignancies, including in combination with other agents.

Conference Call & Webcast Information (Conducted by MEI)

When: April, 15, 2020, 8:00 a.m. ET
Dial-in:
Conference ID:

Please join the conference call at least 10 minutes early to register. You can access the live webcast under the investor relations section of MEI’s website at: www.meipharma.com. A replay of the conference call will be archived under events and webcasts for at least 30 days after the call.

About ME-401

MEI-401 is an investigational treatment and not approved by the U.S. Food and Drug Administration (FDA) or other Health Authorities. Clinical development of ME-401 as an oral, once-daily, selective PI3Kd inhibitor for the treatment of B-cell malignancies is ongoing. The U.S. FDA recently granted ME-401 Fast Track designation.

MEI is currently conducting two ongoing studies evaluating ME-401. The first is a Phase 2 clinical trial evaluating ME-401 as a monotherapy for the treatment of adults with relapsed or refractory follicular lymphoma after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. Subject to the results, upon completion of the Phase 2 clinical trial, ME-401 is planned to be submitted with the FDA to support an accelerated approval of a marketing application under 21 CFR Part 314.500, Subpart H. The second study is a multi-arm, open-label, Phase 1b dose escalation and expansion trial evaluating ME-401 as a monotherapy and in combination with other therapies or investigational agents in patients with relapsed or refractory B-cell malignancies. Additionally, a Phase 1 study was initiated by Kyowa Kirin in 2019 evaluating ME-401 as a monotherapy in patients with indolent B-cell malignancy in Japan.

About MEI Pharma

MEI Pharma, Inc. (Nasdaq: MEIP) is a late-stage pharmaceutical company focused on developing potential new therapies for cancer. Our portfolio of drug candidates contains four clinical-stage assets, including one candidate in an ongoing global registration trial and another candidate in a Phase 2 clinical trial which may support an accelerated approval marketing application with the U.S. Food and Drug Administration. Each of our pipeline candidates leverages a different mechanism of action with the objective of developing therapeutic options that are: (1) differentiated, (2) address unmet medical needs and (3) deliver improved benefit to patients either as standalone treatments or in combination with other therapeutic options. For more information, please visit www.meipharma.com.

About Kyowa Kirin

Kyowa Kirin commits to innovative drug discovery driven by state-of-the-art technologies. The company focuses on creating new value in the four therapeutic areas: nephrology, oncology, immunology/allergy and neurology. Under the Kyowa Kirin brand, employees from 36 group companies across North America, EMEA and Asia/Oceania unite to champion the interests of patients and their caregivers by discovering solutions to address unmet medical needs. You can learn more about the business of Kyowa Kirin at www.kyowakirin.com.

Forward-Looking Statements

Under U.S. law, a new drug cannot be marketed until it has been investigated in clinical studies and approved by the FDA as being safe and effective for the intended use. Statements included in this press release that are not historical in nature are "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. You should be aware that our actual results could differ materially from those contained in the forward-looking statements, which are based on management's current expectations and are subject to a number of risks and uncertainties, including, but not limited to, our failure to successfully commercialize our product candidates; costs and delays in the development and/or FDA approval, or the failure to obtain such approval, of our product candidates; uncertainties or differences in interpretation in clinical trial results; the impact of the COVID-19 pandemic on our industry and individual companies, including on our counterparties, the supply chain, the execution of our clinical development programs, our access to financing and the allocation of government resources; our inability to maintain or enter into, and the risks resulting from our dependence upon, collaboration or contractual arrangements necessary for the development, manufacture, commercialization, marketing, sales and distribution of any products; competitive factors; our inability to protect our patents or proprietary rights and obtain necessary rights to third party patents and intellectual property to operate our business; our inability to operate our business without infringing the patents and proprietary rights of others; general economic conditions; the failure of any products to gain market acceptance; our inability to obtain any additional required financing; technological changes; government regulation; changes in industry practice; and one-time events. We do not intend to update any of these factors or to publicly announce the results of any revisions to these forward-looking statements.

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

MEI Pharma, Inc.
San Diego, CA

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File Nos. 333-238056, 333-225465, 333-186070, 333-184011, 333-174789, 333-146453, and 333-136440) and Form S-8 (File Nos. 333-229554, 333-216103, 333-213278, 333-201703, 333-179591, 333-174790, 333-169719, and 333-156985) of MEI Pharma, Inc. (the "Company") of our report dated September 9, 2020, relating to the financial statements, which appears in this Form 10-K.

/s/ BDO USA, LLP

San Diego, California
September 9, 2020

Exhibit 31.1

CERTIFICATION

I, Daniel P. Gold, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended June 30, 2020 of MEI Pharma, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its 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 the 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.

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: September 9, 2020

/s/ Daniel P. Gold

Daniel P. Gold
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Brian G. Drazba, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended June 30, 2020 of MEI Pharma, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have;

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its 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 the 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.

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: September 9, 2020

/s/ Brian G. Drazba

Brian G. Drazba
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Each of the undersigned hereby certifies, for the purposes of Section 1350 of Chapter 63 of Title 18 of the U.S. Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of MEI Pharma, Inc. ("MEI Pharma") that, to his knowledge, this Annual Report on Form 10-K of MEI Pharma, for the year ended June 30, 2020, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of MEI Pharma.

Date: September 9, 2020

/s/ Daniel P. Gold	/s/ Brian G. Drazba
Daniel P. Gold	Brian G. Drazba
Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	(Principal Financial Officer)

These certifications accompanying the report to which they relate, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of MEI Pharma under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent MEI Pharma specifically incorporates it by reference.

A signed original of this written statement required by Section 906 has been provided to MEI Pharma and will be retained by MEI Pharma and furnished to the Securities and Exchange Commission or its staff upon request.