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

FORM 10-Q

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

For the quarterly period ended December 31, 2018

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.)**

3611 Valley Centre Drive, Suite 500, San Diego, CA 92130
(Address of principal executive offices) (Zip Code)

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

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 definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Non-accelerated filer	☐
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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of February 5, 2019, the number of shares outstanding of the issuer’s common stock, $0.00000002 par value, was 71,149,142.

MEI PHARMA, INC.

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PART I FINANCIAL INFORMATION

Item 1: Condensed Financial Statements — Unaudited

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

	December 31, 2018 (unaudited)	June 30, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,748	$ 13,309
Short term investments	84,667	89,434
Total cash, cash equivalents and short-term investments	93,415	102,743
Prepaid expenses and other current assets	2,418	1,586
Total current assets	95,833	104,329
Intangible assets, net	279	296
Property and equipment, net	193	32
Total assets	$ 96,305	$ 104,657
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,158	$ 3,643
Accrued liabilities	4,766	3,454
Deferred revenue	3,980	788
Total current liabilities	10,904	7,885
Deferred revenue, long-term	5,161	—
Warrant liability	26,770	46,313
Total liabilities	42,835	54,198
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 100 shares authorized; none outstanding	—	—
Common stock, $0.00000002 par value; 226,000 shares authorized; 71,131 and 70,406 shares issued and outstanding at December 31, 2018 and June 30, 2018, respectively	—	—
Additional paid-in-capital	270,387	264,858
Accumulated deficit	(216,917)	(214,399)
Total stockholders' equity	53,470	50,459
Total liabilities and stockholders' equity	$ 96,305	$ 104,657

See accompanying notes to financial statements.

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2018	2017	2018	2017
Revenue	$ 2,048	$ 358	$ 2,536	$ 641
Operating expenses:				
Cost of revenue	1,009	728	1,998	1,346
Research and development	9,066	3,444	15,197	9,508
General and administrative	3,821	2,358	7,222	4,846
Total operating expenses	13,896	6,530	24,417	15,700
Loss from operations	(11,848)	(6,172)	(21,881)	(15,059)
Other income (expense):				
Change in fair value of warrant liability	23,437	—	18,475	—
Interest and dividend income	436	93	890	193
Income tax expense	—	—	(1)	(1)
Net income (loss)	$ 12,025	$ (6,079)	$ (2,517)	$(14,867)
Net income (loss):				
Basic	$ 12,025	$ (6,079)	$ (2,517)	$(14,867)
Diluted	$(11,412)	$ (6,079)	$(25,954)	$(14,867)
Net income (loss) per share:				
Basic	$ 0.17	$ (0.16)	$ (0.04)	$ (0.40)
Diluted	$ (0.15)	$ (0.16)	$ (0.36)	$ (0.40)
Shares used in computing net income (loss) per share:				
Basic	71,124	37,414	71,005	37,390
Diluted	73,951	37,414	72,418	37,390

See accompanying notes to financial statements.

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

	Six Months Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (2,517)	$(14,867)
Adjustments to reconcile loss to net cash used in operating activities:		
Change in fair value of warrant liability	(18,475)	—
Share-based compensation	3,600	1,698
Depreciation and amortization	28	27
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(833)	986
Accounts payable	(1,485)	504
Accrued liabilities	1,312	445
Deferred revenue	8,353	(106)
Net cash used in operating activities	(10,017)	(11,313)
Cash flows from investing activities:		
Purchases of property and equipment	(172)	—
Purchases of short-term investments	(19,770)	(15,038)
Proceeds from maturity of short-term investments	24,537	25,043
Net cash provided by investing activities	4,595	10,005
Cash flows from financing activities:		
Proceeds from exercise of stock options	67	189
Proceeds from exercise of warrants	1,118	—
Payment of RSU tax withholdings in exchange for common shares surrendered by RSU holders	(324)	—
Net cash provided by financing activities	861	189
Net decrease in cash and cash equivalents	(4,561)	(1,119)
Cash and cash equivalents at beginning of the period	13,309	8,458
Cash and cash equivalents at end of the period	$ 8,748	$ 7,339

See accompanying notes to financial statements.

MEI PHARMA, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

Note 1. The Company

We are a 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 one candidate in an ongoing Phase 3 global registration trial and another candidate in an on-going 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 and commercialization, or strategic partnerships, as appropriate. Our drug candidate pipeline includes:

- 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 OXPHOS complex; and
- Pracinostat, an oral histone deacetylase ("HDAC") inhibitor.

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the accompanying financial statements do not include all of the information and notes required by U.S. GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. Certain amounts have been reclassified to conform to current period presentation. We have evaluated subsequent events through the date the financial statements were issued.

The accompanying unaudited financial statements should be read in conjunction with the audited financial statements and notes thereto as of and for the fiscal year ended June 30, 2018, included in our Annual Report on Form 10-K ("2018 Annual Report") filed with the Securities and Exchange Commission ("SEC") on August 30, 2018. Interim results are not necessarily indicative of results for a full year.

Use of Estimates

The preparation of financial statements in conformity with 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.

Revenue Recognition

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. To date, we have not recognized any material cumulative catch-up adjustments from changes in our estimate of the transaction price.

We develop estimates of the stand-alone selling price for each distinct performance obligation and allocate the overall transaction price to each accounting unit based on a relative stand-alone selling price approach. 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 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 obligations, we use judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. 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. To date, we have not recognized any material cumulative catch-up adjustments from changes in our estimate of the measure of progress.

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 royalty revenue from license agreements.

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2018	2017	2018	2017
KHK License Agreement	$ 1,361	$ —	$ 1,361	$ —
Helsinn License Agreement	687	358	1,175	641
	$ 2,048	$ 358	$ 2,536	$ 641

Revenue for the three and six months ended December 31, 2018 included revenue related to the KHK License Agreement (Note 3). Based on the characteristics of the KHK License Agreement, delivery of the license is a distinct performance obligation, and we recognized related revenue of $879,000 during the three months ended December 31, 2018 when the license was transferred to the licensee and the licensee could use and benefit from the license. The license agreement included other distinct performance obligations that will be satisfied over time, and accordingly we recognized $482,000 related to our progress toward satisfying those obligations.

Revenue for the three and six months ended December 31, 2018 and 2017 included revenue related to the Helsinn License Agreement (Note 3). Based on the characteristics of the Helsinn License Agreement, control of the deliverables occurs over time and therefore we recognize revenue based on the extent of progress towards completion of the performance obligations.

As of December 31, 2018, we had $9.1 million of deferred revenue associated with our remaining performance obligations under the KHK and Helsinn license agreements. We expect to recognize approximately $4.0 million of deferred revenue in the next 12 months, and an additional $5.1 million thereafter.

Contract Balances

The following table presents changes in contract assets and contract liabilities during the six months ended December 31, 2018 (in thousands):

	As of July 1, 2018	Net Change	As of December 31, 2018
Receivables	$ 82	$ 45	$ 127
Contract Assets	$ 312	$ 91	$ 403
Contract Liabilities	$ 788	$8,353	$ 9,141

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 Condensed 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 Condensed Balance Sheet relate to the KHK License Agreement and the Helsinn License Agreement.

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 Condensed 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.

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 December 31, 2018 and June 30, 2018, 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 carry-forwards that can be utilized in the future to offset 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 December 31, 2018 or June 30, 2018.

There have been no material changes in our unrecognized tax benefits since June 30, 2018, and, as such, the disclosures included in our 2018 Annual Report continue to be relevant for the six month period ended December 31, 2018.

Recent Accounting Pronouncements

Adopted Accounting Standards

In May 2014, the FASB issued Accounting Standards Update No. 2014-09 (Topic 606) "Revenue from Contracts with Customers." The FASB subsequently issued a number of narrow-scope technical improvements to Topic 606 before it became effective. The guidance in Topic 606 provides companies with a single model for accounting for revenue arising from contracts with customers and supersedes prior revenue recognition guidance under ASC Topic 605, "Revenue Recognition" (Topic 605). On July 1, 2018, we adopted Topic 606 using the modified retrospective method applied to those contracts which were not completed as of the adoption date. We did not record any adjustment to opening retained earnings as of July 1, 2018 as the adoption of Topic 606 did not have an impact on our financial statements. Refer to *Revenue Recognition* for further details of accounting for revenue with customers.

Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02 *Leases*, which introduces the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous guidance. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record an ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. The new standard is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years with early adoption permitted. We expect to adopt this standard on July 1, 2019. We are evaluating the impact that the adoption of this standard will have on our financial statements.

Note 2. 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):

	December 31, 2018			June 30, 2018		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets:						
Cash and cash equivalents	$ 8,748	$ —	$ —	$ 13,309	$ —	$ —
U.S. government treasury bills	84,667	—	—	89,434	—	—
Total	$ 93,415	$ —	$ —	$ 102,743	$ —	$ —
Liabilities:						
Warrant liability	$ —	$ —	$(26,770)	$ —	$ —	$(46,313)
Total	$ —	$ —	$(26,770)	$ —	$ —	$(46,313)

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 Condensed 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 Condensed 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 Condensed Statement of Operations for the three and six months ended December 31, 2018.

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

	December 31, 2018	June 30, 2018
Risk-free interest rate	2.5%	2.7%
Expected life (years)	4.4	4.8
Expected volatility	80.9%	77.3%
Dividend yield	0.0%	0.0%
Black-Scholes Fair Value	$ 1.67	$ 2.81

The following table sets forth a summary of changes in the estimated fair value of our Level 3 warrant liability for the six months ended December 31, 2018 (in thousands):

	Fair Value of Warrants Using Significant Unobservable Inputs (Level 3)
Balance at July 1, 2018	$ 46,313
Reclassification of derivative liability to equity upon exercise of warrants	(1,068)
Change in estimated fair value of liability classified warrants	(18,475)
Balance at December 31, 2018	$ 26,770

Note 3. License Agreements

KHK License Agreement

In October 2018, we entered into a license agreement with Kyowa Hakko Kirin Co., Ltd., a Japanese life sciences company (“KHK”) for ME-401 (‘the KHK License Agreement’). Under the terms of the KHK License Agreement, KHK was granted the exclusive right to develop and commercialize ME-401 in Japan. We also granted KHK the right to purchase supply of ME-401 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 are also eligible to receive up to $87.5 million in additional development and commercialization milestones, as well as royalties on net sales of ME-401 in Japan extending into the mid-teens. The KHK License Agreement expires at the end of the royalty term, that is, upon the last to occur of (a) expiration of our patents in Japan, (b) expiration of regulatory exclusivity for ME-401 in Japan or (c) 10 years from the first commercial sale of ME-401 in Japan.

We assessed the KHK License Agreement in accordance with ASC 606 and determined that our performance obligations comprise the license, research and development obligations, and our obligation to provide clinical trial materials to KHK.

We determined that the transaction price amounts to the upfront payment of $10.0 million. Future milestone payments are fully contingent 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 likelihood of achieving future milestones at the end of each reporting period.

We determined that control of the license was transferred to KHK during the three months ended December 31, 2018. Revenue allocated to the research and development obligations is recognized based on the proportional performance of these research and development activities, which we expect to recognize through fiscal year 2022. Revenue allocated to providing clinical trial materials is recognized upon delivery.

Helsinn License Agreement

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 in acute myeloid leukemia ("AML"), myelosdisplastic 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. In addition, we are eligible to receive up to $444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of pracinostat, which, in the U.S., are tiered and begin in the mid-teens.

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 six months ended December 31, 2018, 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 entered into a license agreement with Presage Biosciences, Inc. ("Presage"). Under the terms of such license agreement (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 $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 are party to a license agreement with CyDex Pharmaceuticals, Inc. ("CyDex"). Under 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 4. BeiGene Collaboration

In October 2018, we entered into a clinical collaboration with BeiGene, Ltd. ("BeiGene") to evaluate the safety and efficacy of ME-401 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 ME-401 in combination with zanubrutinib in patients with B-cell malignancies. Study costs are being shared equally by the parties, and we agreed to supply ME-401 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 ME-401 and BeiGene retained full commercial rights for zanubrutinib.

Note 5. Net Income (Loss) Per Share

Basic and diluted net income (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 three and six months ended December 31, 2018 and 2017. Diluted net income (loss) per share is computed based on the sum of the weighted average number of common shares and potentially dilutive common shares outstanding during the period.

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2018	2017	2018	2017
Net income (loss) — basic	$ 12,025	$(6,079)	$ (2,517)	$(14,867)
Change in fair value of warrant liability	(23,437)	—	(23,437)	—
Net income (loss) — diluted	$(11,412)	$(6,079)	$(25,954)	$(14,867)

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2018	2017	2018	2017
Weighted average shares outstanding	71,124	37,014	71,005	36,990
Effect of vested restricted stock units	—	400	—	400
Weighted average shares used in calculating basic net loss per share	71,124	37,414	71,005	37,390
Effect of potentially dilutive common shares from equity awards and liability-classified warrants	2,827	—	1,413	—
Weighted average shares used in calculating diluted net loss per share	73,951	37,414	72,418	37,390
Potentially dilutive shares excluded from calculation due to anti-dilutive effect	8,160	8,644	16,125	8,912

Note 6. 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.

We have leased approximately 13,700 square feet of office space, located at 3611 Valley Centre Drive, San Diego, California 92130. The monthly rental rate is approximately $46,000 over the remaining lease term, plus a pro rata share of certain building expenses. In September 2018, we entered into a lease agreement for approximately 7,000 additional square feet of office space at the same location, at a rental rate of approximately $21,000 per month, plus a pro rata share of certain building expenses. Each lease term expires in May 2020. The location houses our executive and administrative offices. The remaining contractual obligations for the two leases are $0.8 million and $0.4 million, respectively.

Presage License Agreement

As discussed in Note 3, 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 December 31, 2018, 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. As of December 31, 2018, we have not accrued any amounts for potential future payments.

CyDex License Agreement

As discussed in Note 3, 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 December 31, 2018, we have not accrued any amounts for potential future payments.

Note 7. Short-Term Investments

As of December 31, 2018 and June 30, 2018, our short-term investments consisted of $84.7 million and $89.4 million, respectively, in U.S. government securities. The short-term investments held as of December 31, 2018 and June 30, 2018 had maturity dates of less than one year, are considered to be “held to maturity” and are carried at amortized cost. Due to the short-term maturities of these instruments, the amortized cost approximates the related fair values. As of December 31, 2018 and June 30, 2018, the gross holding gains and losses were immaterial.

Note 8. Stockholders' Equity

Equity Transactions

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, 2018 at $46.3 million and as of December 31, 2018 at $26.8 million; the changes in fair value were recorded in our Condensed Statement of Operations. During the six months ended December 31, 2018, warrants were exercised for 440,043 shares of common stock, and we received proceeds of $1.1 million. As of December 31, 2018, there were outstanding warrants to purchase 16,061,602 shares of our common stock.

Shelf Registration Statement

We have a shelf registration statement that permits us to sell, from time to time, up to $150.0 million of common stock, preferred stock and warrants. 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. As of December 31, 2018, we have not sold any shares under the ATM Sales Agreement, and there is $150.0 million aggregate value of securities available under the shelf registration statement.

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.

Our 2008 Stock Omnibus Equity Compensation Plan (the "2008 Equity Plan") provides for the grant of options and/or other share-based or share-denominated awards to our non-employee directors, officers, employees and advisors. The 2008 Equity Plan was initially adopted in 2008 and was amended and restated in 2011, 2013, 2014, 2015, 2016 and 2018. There are 19,089,794 shares of common stock authorized for issuance under the 2008 Equity Plan. As of December 31, 2018, there were 9,980,127 shares available for future grant under the 2008 Equity Plan.

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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2018	2017	2018	2017
Research and development	$ 554	$ 257	$ 1,184	$ 541
General and administrative	1,109	445	2,416	1,157
Total share-based compensation	$ 1,663	$ 702	$ 3,600	$ 1,698

Stock Options

Stock option activity for the six months ended December 31, 2018 was as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2018	6,281,615	$ 3.08		
Granted	2,299,250	4.18		
Exercised	(39,378)	1.70		
Forfeited / Cancelled	(162,474)	3.15		
Expired	(233,854)	7.43		
Outstanding at December 31, 2018	8,145,159	3.27	7.8	$ 3,180,109
Vested and exercisable at December 31, 2018	3,596,853	$ 3.01	6.1	$ 2,349,658

The fair value of each stock option granted during the six months ended December 31, 2018 is estimated on the grant date under the fair value method using a Black-Scholes valuation model. Stock options granted to employees during the six months ended December 31, 2018 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 during the six months ended December 31, 2018 vest ratably each month for a period of 12 months from the date of grant and expire ten years from the date of grant. The estimated fair values of the stock options, including the effect of estimated forfeitures, are expensed over the service period.

The following weighted-average assumptions were used to determine the fair value of options granted during the period:

	Six Months Ended December 31,	
	2018	2017
Risk-free interest rate	2.8%	2.1%
Expected life (years)	6.0	6.0
Expected volatility	85.7%	97.1%
Dividend yield	0.0%	0.0%
Weighted-average grant date fair value	$ 3.05	$2.19

	Three Months Ended December 31,	
	2018	2017
Research and development	$ 554	$ 257
General and administrative	1,109	445
Total share-based compensation	$1,663	$ 702

As of December 31, 2018, there was $7.4 million of unrecognized compensation expense related to the unvested portion of stock options. Such compensation expense is expected to be recognized over a weighted-average period of 1.8 years.

Restricted Stock Units

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.

Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding the future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, without limitation, those described in "Risk Factors" in our 2018 Annual Report, and elsewhere in this report, including, among other things:

- our inability to obtain required additional financing or financing available to us on acceptable terms, or at all, which may cause us to delay, scale-back or eliminate plans related to development of our drug candidates;
- parties with which we have entered into collaboration, license, development and/or commercialization agreements may not satisfy their obligations under the agreements which could impact future revenues;
- our payment obligations under the Presage License Agreement and the S*Bio Purchase Agreement, which may reduce our cash available for other development efforts, and other obligations and risks related to the Presage License Agreement and the S*Bio Purchase Agreement;
- clinical studies by their nature typically have a high level of risk and may not produce successful results;
- 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;
- our inability to maintain or enter into, and the risks resulting from our dependence upon, contractual arrangements necessary for the clinical development, manufacture, commercialization, marketing, sales and distribution of our product candidates;
- costs and delays in our clinical development programs and/or receipt of FDA or other required foreign and domestic governmental or regulatory approvals, or the failure to obtain such approvals, for our product candidates;
- the FDA's interpretation and our interpretation of data from preclinical and clinical studies may differ significantly;
- our failure to successfully commercialize our product candidates;
- pricing regulations, third-party reimbursement practices and healthcare reform initiatives;
- the failure of any products to gain market acceptance;
- our reliance on third parties to conduct our clinical trials and manufacture our products;
- our inability to control the costs of manufacturing our products;
- our reliance on acquisitions or licenses from third parties to expand our pipeline of drug candidates;
- competition and 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;
- costs stemming from our defense against third party intellectual property infringement claims;
- general economic conditions;
- our ability to attract and retain key employees;
- technological changes;
- cybersecurity;
- government regulation generally;
- changes in industry practice; and
- one-time events.

These risks are not exhaustive. Other sections of this report and our other filings with the SEC include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. 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.

You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Past performance may not be an indicator of future results. The following discussion is qualified in its entirety by, and should be read in conjunction with, the more detailed information set forth in the financial statements and the notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto included in our 2018 Annual Report, as filed with the SEC. Operating results are not necessarily indicative of results that may occur in future periods.

Overview and Recent Developments

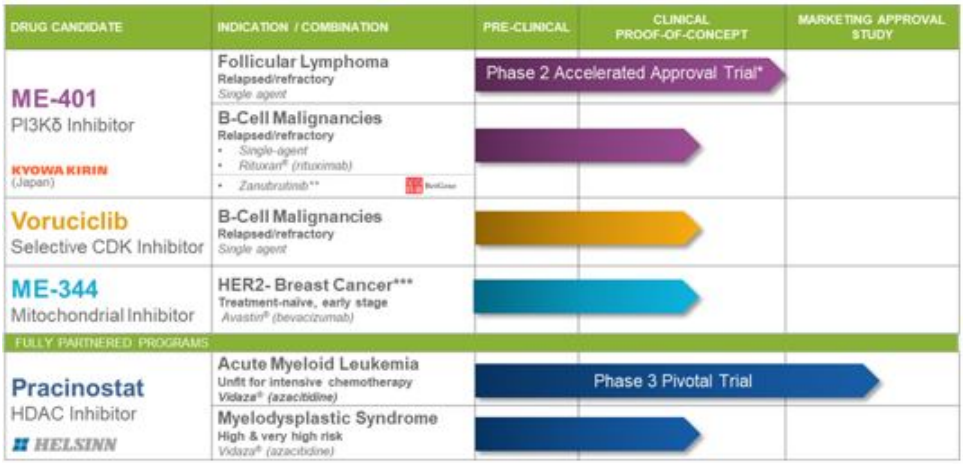
We are a pharmaceutical company focused on leveraging our extensive development and oncology expertise to identify and advance new therapies intended to meaningfully improve the treatment of cancer. Our portfolio of drug candidates contains four clinical-stage candidates, including one candidate in an ongoing Phase 3 global registration trial and another candidate 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

Cancer is often a highly adaptable disease capable of evading the body’s defenses and resisting treatment, allowing it to grow and spread. Despite new treatments that strive to leverage actionable insights into cancer biology, even the most cutting-edge therapies can struggle to balance potency with safety. As a result, the oncology community strives to improve on existing therapies and search for new and better options to optimize benefits for patients. This approach includes medicines that not only act alone, but also work well in combination with other therapies to deliver the best possible outcomes.

We currently have four clinical-stage development programs, each of which is in active development, with diverse approaches to inhibiting cancer, including epigenetics, cell signaling and cancer metabolism:

- 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 OXPHOS complex; and
- Pracinostat, an oral histone deacetylase (“HDAC”) inhibitor.



* *Phase 2 study intended to support an accelerated approval marketing application with the FDA*
** *Study arm to be initiated under clinical collaboration with BeiGene, Ltd.*
*** *Investigator-initiated study*

ME-401: PI3K Delta Inhibitor Entering Phase 2 Study to Support Accelerated Approval in Relapsed or Refractory Follicular Lymphoma

We own exclusive worldwide rights to ME-401, a selective oral inhibitor of PI3K delta. In the fourth quarter of calendar year 2018, we started patient recruitment in a Phase 2 clinical trial evaluating ME-401 as a single-agent for the treatment of adults with relapsed or refractory follicular lymphoma (“FL”). We intend to submit the results of this trial to the FDA for accelerated approval of the marketing application under 21 CFR Part 314, Subpart H.

We believe ME-401 holds best-in-class potential as a PI3K delta inhibitor based on clinical data observed to date. Clinical data from an ongoing Phase 1b, open-label, dose-escalation study has demonstrated an 82% objective response rate in patients with relapsed/refractory indolent B-cell malignances (FL, chronic lymphocytic leukemia (“CLL”), small lymphocytic lymphoma (“SLL”) and marginal zone lymphoma (“MZL”). ME-401 was generally well-tolerated in the Phase 1b trial and no dose-limiting toxicities were identified at any dose level.

The clinical data generated to date, along with important differentiating pharmaceutical properties of ME-401, support its potential as a single-agent therapy and the potential to be used in combination with existing or emerging therapies to treat multiple difficult-to-treat oncology indications.

ME-401 Scientific Overview: Cell Cycle Signaling

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 PI3K delta isoform is believed to be important for survival of certain B-cell leukemias and lymphomas.

PI3K delta Inhibitors and B-Cell Malignancies

As a class of therapies, PI3K delta inhibitors may have application across a range of B-cell malignancies and compare favorably to other therapeutic approaches.

PI3K delta inhibitors as a group demonstrate promise in the treatment of B-cell malignancies. However, the FDA and the European Medicines Agency ("EMA") approved oral PI3K delta inhibitor idealelisib (marketed as Zydelig ®), the FDA approved intravenous PI3K alpha/delta inhibitor copanlisib (marketed as Aliqopa ®), the FDA approved oral PI3K delta inhibitor duvelisib (marketed as COPIKTRA®) as well as other candidates in development, are challenged by treatment associated toxicities which may reduce their overall clinical utility. We believe this provides an opportunity for the development of a next generation candidate with superior pharmaceutical properties that can better maximize the biological potential of PI3K delta inhibition without being limited by toxicities that reduce clinical utility.

Through our extensive pre-clinical and ongoing clinical work, we have demonstrated that ME-401 has important pharmaceutical properties, including prolonged target binding, preferential cellular accumulation, significant distribution throughout the body tissues, and a 28-hour half-life suitable for once daily oral administration. We believe these positive attributes support the promising clinical results observed to date and the continued clinical advancement of ME-401 as an attractive drug candidate with single-agent activity and the potential to be used in combination with existing or emerging therapies to treat multiple difficult-to-treat oncology indications.

Clinical Program

ME-401 is in two ongoing studies: a Phase 2 study evaluating patients with relapsed/refractory FL that we intend to submit to the FDA to support accelerated approval of a marketing application under 21 CFR Part 314, Subpart H, and a multi-arm Phase 1b study evaluating patients with FL and other B-cell malignancies.

Phase 1b Multi-arm Study

Patients in the Phase 1b study receive ME-401 as a single agent dosed on a continuous daily schedule (CS) or intermittent schedule (IS) and in combination with rituximab (dosed on the IS only) to explore treatment options for patients with B-cell malignancies. The CS dosing regimen consists of 60 mg administered once daily and the IS dosing regimen consists of 60 mg given continuously, once-daily, for the first 2 cycles followed by 60 mg given on days 1-7 of each subsequent cycle. A cycle is 28 days.

In December 2018, at the American Society of Hematology ("ASH") Annual Meeting, we reported updated Phase 1b data indicating that ME-401 administered both as a single-agent and in combination with rituximab continues to be associated with high response rates: ME-401 demonstrated an 82% objective response rate among 50 evaluable patients with FL, CLL, SLL and MZL, as well as a response rate of 76% in the group of 38 patients with FL. Response rates were maintained by the large majority of patients on IS (72%). For those patients that did show evidence of disease progression on IS, disease control could be reestablished in the majority of patients when returned to CS dosing (70%). A median duration of response has not yet been reached; the lead patient has a duration of response of approximately 20 months and the median follow-up is 9.3 months.

ME-401 has been generally well-tolerated. In addition, a lower incidence of Grade 3 immune-related adverse events (irAEs) has been observed in patients administered ME-401 with IS dosing (11%) versus patients administered CS dosing (34%). No opportunistic infections or non-infectious pneumonitis were reported. There have been no Grade 4-5 adverse events. Laboratory abnormalities in the Phase 1b trial were infrequent.

The Phase 1b study is continuing to enroll patients in the study arm evaluating ME-401 (60 mg) in combination with rituximab (marketed as Rituxan®) in patients with various B-cell malignancies. Additionally, in October 2018, we entered into a clinical collaboration with BeiGene, Ltd. In connection with the BeiGene collaboration, we amended the ongoing Phase 1b trial to evaluate the safety and efficacy of ME-401 in combination with BeiGene's zanubrutinib, an investigational inhibitor of BTK, for the treatment of patients with B-cell malignancies. The cost of the combination study will be equally shared. Each company will supply its own compound. We retain all commercial rights to ME-401 and BeiGene retains all commercial rights to zanubrutinib.

Phase 2 Accelerated Approval Study

In July 2018, the Company discussed with the FDA a ME-401 monotherapy accelerated approval strategy in patients with relapsed or refractory follicular lymphoma. The FDA communicated support for the Company's proposed randomized Phase 2 trial. Accelerated approval of ME-401 will be subject to FDA review of the improvement provided by ME-401 over other therapies available at the time of the regulatory action.

Informed by our communications with the FDA, we have started recruiting patients in a global randomized Phase 2 study evaluating the efficacy, safety, and tolerability of ME-401 in patients with FL after failure of at least two prior systemic therapies including chemotherapy and an anti-CD20 antibody. The study will evaluate both the CS and IS dosing regimens; in one arm, ME-401 will be administered once daily continuously and in the other arm, ME-401 will be administered once daily for two cycles (i.e., eight weeks) followed by an intermittent schedule whereby ME-401 will be administered once daily for the first seven days of a 28-day cycle followed by 21 days of placebo. Approximately 150 patients will be randomized in the study and the primary efficacy endpoint will be the rate of objective response to therapy.

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 currently being evaluated in a Phase 1b dose ranging study in patients with 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 efficacy in an aggressive subset of DLBCL pre-clinical models. (Scientific Reports. (2017) 7:18007. DOI:10.1038/s41598-017-18368-w).

CDK9 is also a transcriptional regulator of 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

In January 2018, we announced the FDA cleared the voruciclib Investigational New Drug Application ("IND") for hematologic malignancies. In August 2018 we dosed our first patient in a dose ranging Phase 1b clinical trial of voruciclib. The study is intended to evaluate voruciclib as a single agent in patients with relapsed and/or refractory B-cell malignancies or acute myeloid leukemia ("AML") after failure of prior standard therapies to determine the safety, preliminary efficacy and maximum tolerated dose. We also plan to evaluate voruciclib in combination with venetoclax to assess synergies and the opportunity for combination treatments across multiple indications.

Voruciclib was previously evaluated in more than 70 patients 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 is currently in an ongoing investigator-initiated, multi-center, randomized study in combination with the vascular endothelial growth factor ("VEGF") inhibitor bevacizumab (marketed as Avastin ®) in a total of 40 patients with 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 study, 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. While anti-angiogenics reduce the rate of glycolysis in tumors as a mechanism to block growth, tumor metabolism often shifts to mitochondrial metabolism to continue 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.

We are investigating this approach in an ongoing, multicenter, investigator-initiated, randomized, open-label, clinical trial, which is evaluating ME-344 in a total of up to 40 patients with HER2-negative breast cancer in combination with the VEGF inhibitor bevacizumab (marketed as Avastin®). Patients are randomized one-to-one to either ME-344 in combination with bevacizumab or saline in combination with bevacizumab. The interim data review was predefined to take place after 20 patients were randomized. The primary efficacy endpoint is inhibition of cell proliferation as measured by Ki-67 reductions.

Interim data presented from the study at the ASCO Annual Meeting in June 2018 demonstrate evidence of inhibition of tumor proliferation. Mean absolute (relative) Ki-67 decreases were 5.13 (29%) and 1.2 (9%) in the active versus control arms (P=0.06). Patients with standardized uptake values via PET scan ^{3} 10% experienced an absolute average Ki-67 decrease of 16.6 vs. 2.3 in the active versus control arms (P=0.19). Treatment was generally well tolerated; two Grade 3 adverse events (high blood pressure) were reported, one in each arm, and deemed related to bevacizumab. These interim data are consistent with pre-clinical results indicating ME-344's potential to reverse resistance to anti-angiogenic therapy, thereby warranting the continuation of the ongoing study.

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 study. 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 three peripheral neuropathy.

In June 2016, pre-clinical data from a collaboration with the Spanish National Cancer Research Centre in Madrid showing 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, were published in *Cell Reports*. These data demonstrate that the anti-cancer effects when combining ME-344 with a VEGF inhibitor are due to an inhibition of both mitochondrial and glycolytic metabolism and provided a basis for commencement of the ongoing investigator-initiated study of ME-344 in combination with the VEGF inhibitor bevacizumab (marketed as Avastin ®) in HER2 negative breast cancer patients.

Pracinostat: HDAC Inhibitor Candidate in a Phase 3 Global Registration Clinical Trial

Pracinostat is an oral HDAC inhibitor being evaluated in a pivotal Phase 3 global registration clinical trial for the treatment of adults with newly diagnosed AML who are unfit to receive intensive chemotherapy. Pracinostat is also being evaluated in a Phase 2 study in patients with high or very high-risk myelodysplastic syndrome ("MDS"). 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 in AML, MDS and other potential indications (the "Helsinn License Agreement"). Under the agreement, Helsinn is primarily responsible for funding global development and commercialization costs for pracinostat. We are responsible for conducting the Phase 2 MDS study, the cost of which is being shared equally with Helsinn.

Breakthrough Therapy Designation for pracinostat was granted by the FDA in 2016, and in January 2018 the EMA granted Orphan Drug Designation to pracinostat for the treatment of AML. The designations in the US and European Union are supported by data from a Phase 2 study of pracinostat plus azacitidine in elderly patients with newly diagnosed AML who are not candidates for induction chemotherapy. The study showed a median overall survival of 19.1 months and a complete remission ("CR") rate of 42% (21 of 50 patients). These data compare favorably to an international Phase 3 study of azacitidine (AZA-001; Dombret et al. Blood. 2015 May 18), which showed a median overall survival of 10.4 months with azacitidine alone and a CR rate of 19.5% in a similar patient population. The combination of pracinostat and azacitidine was generally well tolerated, with no unexpected toxicities. The most common grade 3/4 treatment-emergent adverse events included febrile neutropenia, thrombocytopenia, anemia and fatigue.

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 single agents and in combination for the treatment of various hematologic diseases and solid tumors.

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

Clinical Program

The ongoing pivotal Phase 3 registration study, which is being run by Helsinn and was initiated in June 2017, is a randomized, double-blind, placebo-controlled study that will enroll worldwide approximately 500 adults with newly diagnosed AML who are unfit to receive intensive chemotherapy. Patients are randomized 1:1 to receive pracinostat or placebo with azacitidine as background therapy. The primary endpoint of the study is overall survival. Secondary endpoints include morphologic CR rate, event-free survival and duration of CR.

Additionally, pracinostat is being investigated in a Phase 2 dose optimization study 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, as stated by the American Cancer Society, of 1.6 years and 0.8 years, respectively. The ongoing Phase 2 open-label study is evaluating a 45 mg dose of pracinostat in combination with the standard dose of azacitidine. The study is designed to improve tolerability and retain patients in the study longer than in an earlier Phase 2 study evaluating a 60 mg dose. A prolonged treatment may result in a systemic exposure to pracinostat sufficient to achieve the desired treatment effect; data from the earlier Phase 2 study suggested that insufficient exposure to treatment may have limited overall efficacy of the combination.

A pre-planned interim analysis of the Phase 2 MDS study 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 study expanded open-label enrollment to 60 patients. A subsequent interim analysis presented at the 2018 ASH meeting has demonstrated a discontinuation rate due to adverse events in the first 3 months of 4%, substantially lower than the rate of 26% reported in the Company's prior Phase 2 study. The Phase 2 study has completed enrollment and patients will be followed for one year to evaluate safety and efficacy. The primary endpoints of the study are 1) safety and tolerability and 2) overall response rate, defined as 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. If the Phase 2 open-label study is successful, Helsinn intends to initiate a global registration study. All future development and commercialization costs after the completion of the Phase 2 study are the responsibility of Helsinn.

Pracinostat has been previously investigated in more than 300 patients in multiple Phase 1 and Phase 2 clinical trials and found to be generally well tolerated with manageable side effects often associated with drugs of this class, including fatigue, myelosuppression and gastrointestinal toxicity.

Results of Operations

Three Months Ended December 31, 2018 and 2017

We had a loss from operations of $11.8 million for the three months ended December 31, 2018 compared to a loss from operations of $6.2 million for the three months ended December 31, 2017.

Revenue: We recognized revenue of $2.0 million for the three months ended December 31, 2018 compared to $0.3 million for the three months ended December 31, 2017. Revenue increased primarily due to our license agreement with KHK and resulted from the transfer of the license, the partial satisfaction of our research and development obligations and the providing of clinical trial materials. Revenue also includes recognition of fees allocated to performance obligations in accordance with the Helsinn License Agreement.

Cost of Revenue: We recognized cost of revenue of $1.0 million for the three months ended December 31, 2018 compared to $0.7 million for the three months ended December 31, 2017. 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 to support our research and development revenue. 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.

***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.

	Three Months Ended December 31,	
Research and development expenses	**2018**	**2017**
ME-401	$ 5,324	$ 1,688
Voruciclib	990	200
ME-344	60	120
Pracinostat	—	7
Other	2,692	1,429
Total research and development expenses	$ 9,066	$ 3,444

Research and development expenses consist primarily of clinical trial costs (including payments to clinical research organizations), 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 $9.1 million for the three months ended December 31, 2018 compared to $3.4 million for the three months ended December 31, 2017. Costs related to ME-401 were higher for the three months ended December 31, 2018 due to increased clinical trial costs as a result of starting the Phase 2 study and drug manufacturing costs. Costs related to voruciclib were higher for the three months ended December 31, 2018 due to increased clinical trial costs. Other research and development costs increased for the three months ended December 31, 2018 due to higher levels of salaries and share-based compensation associated with increased headcount to support our clinical activities.

***General and Administrative*:** General and administrative expenses increased by $1.4 million to $3.8 million for the three months ended December 31, 2018 compared to $2.4 million for the three months ended December 31, 2017. The increase is primarily due to $1.1 million in increased salaries and share-based compensation associated with increased headcount to support our activities and $0.3 million in increased professional services expenses during the three months ended December 31, 2018.

Other income or expense: We recorded a non-cash gain of $23.4 million during the three months ended December 31, 2018 due to a change in the fair value of our warrant liability for warrants issued in May 2018 as part of our 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 $0.4 million for the three months ended December 31, 2018 compared to $0.1 million for the three months ended December 31, 2017. The increase was due to higher investment balances and higher yields during the three months ended December 31, 2018 compared to the three months ended December 31, 2017.

Six Months Ended December 31, 2018 and 2017

We had a loss from operations of $21.9 million for the six months ended December 31, 2018 compared to a loss from operations of $15.1 million for the six months ended December 31, 2017.

Revenue: We recognized revenue of $2.5 million for the six months ended December 31, 2018 compared to $0.6 million for the six months ended December 31, 2017. Revenue increased primarily due to our license agreement with KHK and resulted from the transfer of the license, the partial satisfaction of our research and development obligations and the providing of clinical trial materials. Revenue also includes recognition of fees allocated to performance obligations in accordance with the Helsinn License Agreement.

Cost of Revenue: We recognized cost of revenue of $2.0 million for the six months ended December 31, 2018 compared to $1.3 million for the six months ended December 31, 2017. 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 to support our research and development revenue. 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.

***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.

Research and development expenses	Six Months Ended December 31, 2018	2017
ME-401	$ 7,829	$ 3,144
Voruciclib	2,001	3,155
ME-344	265	297
Pracinostat	—	22
Other	5,102	2,890
Total research and development expenses	$ 15,197	$ 9,508

Research and development expenses consist primarily of clinical trial costs (including payments to clinical research organizations), 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 $15.2 million for the six months ended December 31, 2018 compared to $9.5 million for the six months ended December 31, 2017. Costs related to ME-401 were higher for the six months ended December 31, 2018 due to increased clinical trial costs as a result of starting the Phase 2 study and drug manufacturing costs. Costs related to voruciclib decreased for the six months ended December 31, 2018 compared with the six months ended December 31, 2017, related to a license fee payment of $2.9 million made in the prior period, partially offset by increased clinical trial costs. Other research and development costs increased for the six months ended December 31, 2018 due to higher levels of salaries and share-based compensation associated with increased headcount to support our clinical activities.

***General and Administrative*:** General and administrative expenses increased by $2.4 million to $7.2 million for the six months ended December 31, 2018 compared to $4.8 million for the six months ended December 31, 2017. The increase is primarily due to $1.7 million in increased salaries and share-based compensation associated with increased headcount to support our activities and $0.4 million in increased professional services expenses during the six months ended December 31, 2018.

Other income or expense: We recorded a non-cash gain of $18.5 million during the six months ended December 31, 2018 due to a change in the fair value of our warrant liability for warrants issued in May 2018 as part of our 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 $0.9 million for the six months ended December 31, 2018 compared to $0.2 million for the six months ended December 31, 2017. The increase was due to higher investment balances and higher yields during the six months ended December 31, 2018 compared to the six months ended December 31, 2017.

Liquidity and Capital Resources

We have accumulated losses of $216.9 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of December 31, 2018, we had $93.4 million in cash, cash equivalents and short-term investments, which we believe will be sufficient to fund our operations through at least fiscal year 2020. 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. To date, we have obtained cash and funded our operations primarily through equity financings and license payments. 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.

Sources and Uses of Our Cash

Net cash used in operating activities for the six months ended December 31, 2018 was $10.0 million, reflecting $20.0 million used in operating activities, offset by the $10.0 million upfront payment from KHK. This compares to $11.3 million used in operating activities for the six months ended December 31, 2017. The increase in cash used in operating activities reflects increased costs in our clinical development programs, including start-up costs related to the ME-401 Phase 2 study.

Net cash provided by investing activities for the six months ended December 31, 2018 was $4.6 million compared to net cash provided by investing activities of $10.0 million in the six months ended December 31, 2017. Cash provided by investing activities represents maturities of investments in short-term U.S. government securities in excess of purchases. Cash used in investing activities represents purchases of investments in short-term U.S. government securities in excess of maturities.

Net cash provided by financing activities for the six months ended December 31, 2018 was $0.9 million compared to $0.2 million for the six months ended December 31, 2017. Cash provided during the six months ended December 31, 2018 primarily represents proceeds received from the exercise of warrants and stock options.

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 13,700 square feet of office space, located at 3611 Valley Centre Drive, San Diego, California 92130. The monthly rental rate is approximately $46,000 over the remaining lease term, plus a pro rata share of certain building expenses. In September 2018, we entered into a lease agreement for approximately 7,000 additional square feet of office space at the same location, at a rental rate of approximately $21,000 per month, plus a pro rata share of certain building expenses. The location houses our executive and administrative office. Each lease term expires in May 2020. The remaining contractual obligations for the two leases are $0.8 million and $0.4 million, respectively.

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 December 31, 2018, 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 December 31, 2018, 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, nontransferable 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 December 31, 2018, we have not accrued any amounts for potential future payments.

Critical Accounting Policies and Management Estimates

We describe our significant accounting policies in Note 1, The Company and Summary of Significant Accounting Policies, of the notes to financial statements included in our 2018 Annual Report. We discuss our critical accounting estimates in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, in our 2018 Annual Report. There have been no changes in our significant accounting policies or critical accounting estimates since June 30, 2018.

Recent Accounting Pronouncements

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

Item 3: Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market interest rates relates primarily to the investment 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 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 4: Controls and Procedures

At the end of the period covered by this Quarterly Report on Form 10-Q, 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 concluded that our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1: Legal Proceedings

None.

Item 1A: Risk Factors

There have been no material changes in our risk factors from those included in our 2018 Annual Report.

Item 2: Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3: Defaults upon Senior Securities

None.

Item 4: Mine Safety Disclosures

Not applicable.

Item 5: Other Information

None.

Item 6: Exhibits

Exhibit Index

Exhibits	
3.1	Amended and Restated Certificate of Incorporation
10.1	License, Development and Commercialization Agreement, dated as of October 31, 2018, by and between the Company and Kyowa Hakko Kirin Co., Ltd.*
10.2	Amended and Restated 2008 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))
31.1	Rule 13a-14(a) or Rule 15d-14(a) Certification of Principal Executive Officer
31.2	Rule 13a-14(a) or Rule 15d-14(a) Certification of Principal Financial Officer
32.1	Certification of Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C 1350).
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

* Portions of this exhibit have been redacted pursuant to a confidential treatment request submitted to the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Quarterly Report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEI Pharma, Inc.

/s/ Daniel P. Gold
Daniel P. Gold
President and Chief Executive Officer

Date: February 7, 2019

Delaware
The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE RESTATED CERTIFICATE OF "MEI PHARMA, INC.", FILED IN THIS OFFICE ON THE TWENTY-NINTH DAY OF NOVEMBER, A.D. 2018, AT 4:15 O`CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

Jeffrey W. Bullock, Secretary of State

3323531 8100
SR# 20187877521

Authentication: 204011179
Date: 12-03-18

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:15 PM 11/29/2018
FILED 04:15 PM 11/29/2018
SR 20187877521 - File Number 3323531

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
MEI PHARMA, INC.

I. The name of the corporation (hereinafter referred to as the "Corporation") is MEI Pharma, Inc. The date of filing of the Corporation's original certificate of incorporation with the Secretary of State of the State of Delaware was December 1, 2000. The Corporation's original name, which was included in the original certificate of incorporation, was Marshall Edwards, Inc. The Corporation's name was changed to MEI Pharma, Inc., pursuant to the Certificate of Ownership and Merger filed with the Secretary of State of the State of Delaware on June 28, 2012 and effective on July 2, 2012.

II. Pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware (the "DGCL"), this Amended and Restated Certificate of Incorporation restates and integrates and further amends the Certificate of Incorporation of the Corporation, as heretofore amended or supplemented.

III. This Amended and Restated Certificate of Incorporation was duly adopted in accordance with the provisions of Section 245 of the DGCL, the Board of Directors of the Corporation having duly adopted resolutions setting forth and declaring advisable the Amended and Restated Certificate of Incorporation, including said amendments, and thereafter, pursuant to resolution of the Board of Directors, a special meeting of the stockholders of the Corporation was duly called and held upon notice in accordance with Section 222 of the DGCL at which the number of shares as required by Section 242 of the DGCL approved such amendments.

IV. The Amended and Restated Certificate of Incorporation of the Corporation shall read as follows:

FIRST: The name of the Corporation is MEI Pharma, Inc.

SECOND: The address of the Corporation's registered office in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The total number of shares of all classes of stock which the Corporation shall have authority to issue is 226,100,000, consisting of (1) 100,000 shares of preferred stock, par value US$.01 per share (the "Preferred Stock") and (2) 226,000,000 shares of common stock, par value US$.00000002 per share (the "Common Stock").

The Board of Directors of the Corporation is expressly authorized, by resolution or resolutions, to provide, out of the unissued shares of the Preferred Stock, for series of the Preferred Stock. Before any shares of any such series are issued, the Board of Directors shall fix, and is expressly empowered to fix, by resolution or resolutions, the following provisions of the shares thereof:

(a) the designation of such series, the number of shares to constitute such series and the stated value thereof, if different from the par value thereof;

(b) whether the shares of such series shall have voting rights, in addition to any voting rights provided by law, and, if so, the terms of such voting rights (which may be special voting rights) and the preference or relation which such voting rights shall bear to the voting rights of any other class or any other series of this class;

(c) the annual dividend rate (or method of determining such rate), if any, payable on such series, the conditions and dates upon which such dividends shall be payable, the preference or relation which such dividends shall bear to the dividends payable on any other class or any other series of this class;

(d) whether dividends on the shares of such series shall be cumulative, and, in the case of shares of a series having cumulative dividend rights, the date or dates (or method of determining the date or dates) from which dividends on the shares of such series shall be cumulative;

(e) whether the shares of such series shall be subject to redemption by the Corporation and, if so, the times, prices and other conditions of such redemption;

(f) the amount or amounts payable upon shares of such series upon, and the rights of the holders of such series in, the voluntary or involuntary liquidation, dissolution or winding up of the Corporation;

(g) whether the shares of such series shall be subject to the operation of a retirement or sinking fund and, if so, the extent to and manner in which any such retirement or sinking fund shall be applied to the purchase or redemption of the shares of such series for retirement or other corporate purposes and the terms and provisions relative to the operation thereof;

(h) whether the shares of such series shall be convertible into, or exchangeable for, at the option of the holder or the Corporation or upon the happening of a specified event, shares of stock of any other class or of any other series of this class and, if so, the price or prices or the rate or rates of conversion or exchange and the method, if any, of adjusting the same;

(i) the limitations and restrictions, if any, to be effective while any shares of such series are outstanding upon the payment of dividends or the making of other distributions on, and upon the purchase, redemption or other acquisition by the Corporation of, the Common Stock, any other series of the Preferred Stock or any other class of capital stock;

(j) the conditions or restrictions, if any, upon the creation of indebtedness of the Corporation or upon the issue of any additional stock, including additional shares of such series or of any other series of the Preferred Stock or of any other class of capital stock; and

(k) any other powers, preferences or rights, or any qualifications, limitations or restrictions thereof.

Except as otherwise provided by such resolution or resolutions, all shares of the Preferred Stock shall be of equal rank. All shares of any one series of the Preferred Stock shall be identical in all respects with all other shares of such series, except that shares of any one series issued at different times may differ as to the dates from which dividends thereon shall be cumulative.

FOURTH: The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the DGCL.

FIFTH: The Board of Directors is expressly authorized to adopt, amend or repeal the By-Laws of the Corporation, subject to the reserved power of the stockholders to amend and repeal any By-Laws of the Corporation adopted by the Board of Directors.

SIXTH: Each person who at any time is or was an officer or director of the Corporation, and is or was threatened to be made a party to any threatened, pending or complete action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was an officer or director of the Corporation, or is or was serving at the request of the Corporation as an officer or director of another corporation, partnership, joint venture, trust or other enterprise, shall be indemnified against expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with any such action, suit or proceeding to the full extent permitted by Section 145 of the DGCL. The foregoing right of indemnification shall in no way be deemed exclusive of any other rights of indemnification to which such officer or director may be entitled under any statute, this Certificate of Incorporation, the By-Laws of the Corporation or any agreement, vote of stockholders or disinterested directors or otherwise.

SEVENTH: No person who is or was a director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director unless, and only to the extent that such director is liable (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL or any amendment thereto or successor provision thereto, or (iv) for any transaction from which the director derived an improper personal benefit. This article shall not eliminate or limit the liability or a director for any act or omission occurring prior to the date when this article becomes effective. No amendment to, repeal or adoption of any provision of this Certificate of Incorporation inconsistent with this article shall apply to or have any effect on the liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment, repeal, or adoption of an inconsistent provision.

EIGHTH: Any and all right, title, interest and claim in or to any dividends declared by the Corporation, whether in cash, stock or otherwise, which are unclaimed by the stockholder entitled thereto for a period of six (6) years after the close of business on the payment date, shall be and be deemed to be extinguished and abandoned, and such unclaimed dividends in the possession of the Corporation, its transfer agents or other agents or depositaries, shall at such time become the absolute property of the Corporation, free and clear of any and all claims of any persons whatsoever.

NINTH: Whenever a compromise or arrangement is proposed between the Corporation and its creditors or any class of them and/or between the Corporation and its stockholders or any class of them, any court of equitable jurisdiction within the State of Delaware may, on application in a summary way of the Corporation or of any creditor or stockholder thereof, or on the application of any receiver or receivers appointed for the Corporation under Section 291 of Title 8 of the Delaware Code or on the application of trustees in dissolution or of any receiver or receivers appointed for the Corporation under Section 279 of Title 8 of the Delaware Code, order a meeting of the creditors or class of creditors, and/or of the stockholders or class of stockholders of the Corporation, as the case may be, to be summoned in such manner as the said court directs. If a majority in number representing three-fourths in value of the creditors or class of creditors, and/or of the stockholders or class of stockholders of the Corporation, as the case may be, agree to any compromise or arrangement and to any reorganization of the Corporation as a consequence of such compromise or arrangement, the said compromise or arrangement and the said reorganization shall, if sanctioned by the court to which the said application has been made, be binding on all the creditors or class of creditors, and/or on all the stockholders or class of stockholders, of the Corporation, as the case may be, and also on the Corporation.

TENTH: Board of Directors.

(a) Number of Directors. The total number of directors which shall constitute the whole Board of Directors shall be determined in accordance with the By-laws of the Corporation, but shall not be less than two (2) nor more than nine (9).

(b) Classification of Board. (i) Subject to the rights of any holders of any series of Preferred Stock that may be issued by the Corporation pursuant to a resolution or resolutions of the Board of Directors providing for such issuance, the directors of the Corporation shall be divided into three classes with respect to the term of office, each class to contain, as near as may be possible, one-third of the whole number of the Board, with the terms of office of one class expiring each successive year. At each annual meeting of stockholders, the successors to the class of directors whose term expires at that time shall be elected by the stockholders to serve until the annual meeting of stockholders held three years next following and until their successors shall be elected and qualified.

(ii) In the event of any intervening changes in the authorized number of directors, the Board of Directors shall designate the class or classes to which the increases or decreases in directorships shall be apportioned and may designate one or more directorships as directorships of another class in order more nearly to achieve equality of number of directors among the classes; provided, however, that no such apportionment or redesignation shall shorten the term of any incumbent director.

(c) Vacancies. Subject to the limitations prescribed by law and this Restated Certificate of Incorporation, all vacancies in the office of director, including vacancies created by newly created directorships resulting from an increase in the authorized number of directors, may be filled only by a vote of a majority of the directors then holding office, although less than a quorum, or by a sole remaining director; and any director so elected shall serve for the remainder of the full term of the class of directors in which the new directorship was created or the vacancy occurred and until such director’s successor is duly elected and shall qualify or until such director’s earlier resignation or removal.

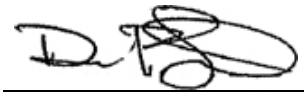
(d) Amendment to this Paragraph. In addition to any requirements of law or of any other provisions of this Restated Certificate of Incorporation, the affirmative vote of the holders of not less than eighty percent (80%) of the total number of votes eligible to be cast by the holders of all outstanding shares of capital stock entitled to vote thereon shall be required to amend, alter, rescind or repeal any provision of this Article TENTH.

(e) Written Ballot. Unless and to the extent that the By-Laws so provide, elections of directors need not be by written ballot.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, MEI Pharma, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by its President this 29th day of November, 2018.

MEI PHARMA, INC.

By: 

Daniel P. Gold
Title: President & CEO

*A request for confidential treatment has been made with respect to portions of the following document that are marked with [*CONFIDENTIAL*]. The redacted portions have been filed separately with the SEC.*

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This License, Development and Commercialization Agreement (this "**Agreement**"), dated as of October 31, 2018 (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 Hakko Kirin Co., Ltd., a Japanese corporation having an office at 1-9-2 Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan ("**KHK**"). MEI and KHK are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, MEI has developed the Compound (as defined below);

WHEREAS, KHK is interested in further developing and commercializing the Compound; and

WHEREAS, MEI wishes to grant a license to KHK under certain intellectual property rights related to the Compound to Develop and Commercialize the Compound and Product in the Territory (all as defined below), and KHK wishes to take such license, in each case in accordance with the terms and conditions set forth below; and

WHEREAS, the Parties entered into a Confidentiality Agreement on November 30, 2017 to facilitate the discussion and evaluation of a possible transaction between the Parties.

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 14.9(b) (Dispute Resolution).

1.2 "**Acquiring Party**" has the meaning set forth in Section 2.7(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 (i) 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 (ii) 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 "**Aggregate Annual Net Sales**" has the meaning set forth in Section 8.4(a) (Royalty Payments).

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

1.6 "**Alliance Managers**" has the meaning set forth in Section 3.4 (Alliance Managers).

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

1.8 "**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.

1.9 "**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.

1.10 "**Appointing Party**" has the meaning set forth in Section 3.2(e) (Appointment Not an Obligation).

1.11 "**Audit**" has the meaning set forth in Section 8.9 (Financial Records and Audit).

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

1.13 "**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 December 31, and the final Calendar Quarter will be deemed to end on the date that this Agreement expires or is terminated.

1.14 "**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.

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

1.16 "**Change of Control**" means (a) a merger or consolidation of MEI with a Third Party that results in the voting securities of MEI 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 MEI, or (c) the sale or other transfer to a Third Party of all or substantially all of MEI's and its Affiliates' assets.

1.17 "**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.

1.18 "**Clinical Quality Agreement**" has the meaning set forth in Section 6.4(a) (Quality Agreements).

1.19 "**Clinical Supply Agreement**" has the meaning set forth in Section 6.1(b) (Further Development Supply).

1.20 "**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.

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

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

1.23 "**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.

1.24 "**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. For the avoidance of doubt, Commercialization does not include Development, Packaging, and Manufacturing.

1.25 "**Commercialization Plan**" has the meaning set forth in Section 7.2 (Commercialization Plan).

1.26 "**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.

1.27 "**Commercial Quality Agreement**" has the meaning set forth in Section 6.4(b) (Quality Agreements).

1.28 "**Commercial Supply Agreement**" has the meaning set forth in Section 6.3 (Commercial Supply).

1.29 "**Competitive Program**" has the meaning set forth in Section 2.7(b) (Non-Compete).

1.30 "**Compound**" means the small molecule referred to by MEI as ME-401 having the structure set forth on Schedule 1.30 and **[*CONFIDENTIAL*]**.

1.31 "**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 terms of this Agreement are the Confidential Information of both Parties.

1.32 "**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 right, 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.

1.33 "**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.

1.34 "**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.

1.35 "**Development Plan**" has the meaning set forth in Section 4.2 (Development Plan).

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

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

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

1.39 "**Excluded Claim**" has the meaning set forth in Section 14.9(g) (Dispute Resolution).

1.40 "**Executive Officers**" has the meaning set forth in Section 3.3 (JSC Decision Making).

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

1.42 "**First Commercial Sale**" means the first shipment of the Product by or on behalf of KHK or its Affiliate or its Sublicensee to a Third Party in the Territory for end use or consumption of the Product after Regulatory Approval of the Product in the Territory 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.

1.43 "**FL**" has the meaning set forth in Section 4.3(a) (Development Diligence).

1.44 "**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.

1.45 "**GDPR**" has the meaning set forth in Section 5.9 (Personally-Identifiable Data / GDPR Compliance).

1.46 "**Generic Product**" means any pharmaceutical product that is distributed by a Third Party (that is not licensed or otherwise permitted by KHK or its Affiliates or its Sublicensees) in the Territory (i) 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 (a) 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), (b) in the EU pursuant to Article 10 of Directive 2001/83/EC as amended, or (c) in the Territory all equivalents of such provisions in (a) and (b), and (ii) which product (a) contains the same active pharmaceutical ingredient(s) as the Product, (b) is approved based in significant part upon clinical data generated and used for obtaining Regulatory Approval of the Product and (c) is approved for at least one of the same Indication(s) as the Product in the Territory.

1.47 "**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.

1.48 "**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.

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

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

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

1.52 "**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.

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

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

1.55 "**JPY**" means the Japanese Yen (i.e., the currency in the Territory).

1.56 "**JSC**" has the meaning set forth in Section 3.1 (Joint Steering Committee).

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

1.58 "**KHK Data**" has the meaning set forth in Section 9.1(a) (Data).

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

1.60 "**KHK Know-How**" means any and all Know-How, whether or not patentable, to the extent Controlled by, or on behalf of, KHK or its Affiliates following the Effective Date or at any time thereafter during the Term (other than the MEI Know-How) that is conceived or first made in the course of, or used in the course of, KHK's performance under this Agreement, and that is necessary and/or reasonably useful for the Development, Manufacture, Packaging, Commercialization or exploitation of the Compound or Product.

1.61 "**KHK Patents**" means any Patent that (i) claims a priority date **[*CONFIDENTIAL*]** the Effective Date, (ii) is Controlled by KHK (or its Affiliates) during the Term (other than the MEI Patents) and (iii) contains one or more claims Covering the Compound and/or Product (including the Development, Manufacturing, Packaging or Commercialization of

the Compound and/or Product) or the KHK Know-How; provided, that "KHK Patents" do not include any Joint Patent.

1.62 "**KHK Sole Invention**" has the meaning set forth in Section 9.1(d)(i) (License to MEI).

1.63 "**KHK Technology**" means the KHK Know-How, the KHK Patents, KHK Sole Inventions and KHK's interest in the Joint Patents.

1.64 "**KHK Trademarks**" has the meaning set forth in Section 9.8(a) (Trademarks).

1.65 "**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.

1.66 "**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.

1.67 "**Manufacturing Option**" has the meaning set forth in Section 6.5(a) (Manufacturing Option).

1.68 "**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.

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

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

1.71 "**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. 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 **[*CONFIDENTIAL*]**.

1.72 "**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 1.72; 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 **[*CONFIDENTIAL*]**

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

1.74 "**MEI Trademarks**" has the meaning set forth in Section 9.8 (Trademarks).

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

1.76 "**Net Sales**" means, with respect to any Product, the gross amounts invoiced for sales or other dispositions of such Product by or on behalf of KHK, its Affiliates and Sublicensees to Third Parties, less the following deductions to the extent included in the gross invoiced sales price for such Product or otherwise paid or incurred by KHK or its Affiliates, as applicable, 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:

(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 KHK's, its Affiliates' or its Sublicensees' existing allocation method; *provided* that any such allocation to a Product shall be: (i) done in accordance with Applicable Law, including any price reporting laws, rules and regulations and (ii) subject to clause (i), in no event no 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 KHK, its Affiliates or its Sublicensees to Third Parties hereunder compared to the number of units of all the products sold by KHK, such Affiliates and such Sublicensees 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 KHK's, its Affiliate's, or a Sublicensee's (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 KHK and its Sublicensees 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).

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

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

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

1.80 "**non-Appointing Party**" has the meaning set forth in Section 3.2(e) (Appointment Not an Obligation).

1.81 "**Package" and "Packaging**" has the meaning set forth in Section 6.2 (Packaging; Certain Other Manufacturing Activities).

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

1.83 "**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.

1.84 "**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.

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

1.86 "**Pharmacovigilance Agreement**" has the meaning set forth in Section 5.8 (Pharmacovigilance).

1.87 "**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.

1.88 "**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.

1.89 "**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.

1.90 "**Product**" means any pharmaceutical product, containing the Compound, whether or not as the sole active ingredient, and in any dosage, form or formulation ready for dispensing to or consumption by an end-user. For clarity, (i) the Compound in drug substance form (as opposed to the drug dosage form) shall constitute the Compound, but not the Product, and (ii) the term "Product" shall not be construed to include any proprietary compounds of MEI or any of its Affiliates other than the Compound.

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

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

1.93 "**Promotional Materials**" has the meaning set forth in Section 7.4 (Creation of Promotional Materials).

1.94 "**Quality Agreements**" has the meaning set forth in Section 6.4(b) (Quality Agreements).

1.95 "**Recall**" has the meaning set forth in Section 5.7 (Remedial Actions).

1.96 "**Recall Costs**" has the meaning set forth in Section 5.7 (Remedial Actions).

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

1.98 "**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.

1.99 "**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.

1.100 "**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).

1.101 "**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 Application-holder, as applicable, including orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, or pediatric exclusivity.

1.102 "**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, Package, 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.

1.103 "**Remedial Action**" has the meaning set forth in Section 5.7 (Remedial Actions).

1.104 "**Respective Territory**" means, in the case of KHK, the Territory, and in the case of MEI, all countries of the world outside the Territory.

1.105 "**Royalty Term**" has the meaning set forth in Section 8.4(b) (Royalty Term).

1.106 "**r/r**" has the meaning set forth in Section 4.3(a) (Development Diligence).

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

1.108 "**Sublicense**" means a license or sublicense to Develop, make, use, import, promote, offer for sale or sell any Compound or Product.

1.109 "**Sublicensee**" means a Third Party or Affiliate to whom KHK has granted a Sublicense in accordance with the terms of this Agreement.

1.110 "**Supply Items**" has the meaning set forth in Section 6.1 (Development Supply).

1.111 "**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 without limitation 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).

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

1.113 "**Territory**" means Japan.

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

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

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

1.117 "**Transfer Plan**" has the meaning set forth in Section 2.4(a) (Transfer of Know-How and Materials).

1.118 "**Transition Period**" has the meaning set forth in Section 6.5(b)(i) (Manufacturing Option).

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

1.120 "**Valid Claim**" means, with respect to the Territory, a claim of (a) an issued and unexpired Patent in the Territory 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 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).

1.121 "**VAT**" has the meaning set forth in Section 8.8(b) (VAT).

1.122 "**Working Group**" has the meaning set forth in Section 3.2(d) (Working Group).

ARTICLE 2
LICENSE

2.1 Licenses to KHK. Subject to the terms and conditions of this Agreement, MEI hereby grants to KHK an exclusive, royalty-bearing license, with the right to grant Sublicenses (through multiple tiers) in accordance with Section 2.2 (Sublicense Rights), under the MEI Technology to Develop, Package, have Packaged and use Compound and Product, and Commercialize Product, in the Field in the Territory.

2.2 Sublicense Rights.

(a) Subject to the terms of this Section 2.2 (Sublicense Rights), KHK may grant a Sublicense of the licenses granted in Section 2.1 (Licenses to KHK) through to Affiliates of KHK without notice to or the prior consent of MEI. Upon **[*CONFIDENTIAL*]**, KHK may grant a Sublicense to any Third Party to Develop or Commercialize a Product.

(b) Each authorized Sublicense granted hereunder, if any, whether to an Affiliate or Sublicensee, shall be in writing and shall incorporate terms and conditions sufficient to enable KHK to comply with this Agreement. KHK 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, KHK will remain directly responsible for all amounts owed to MEI under this Agreement and KHK hereby expressly waives any requirement that MEI exhaust any right, power or remedy, or proceed against a Sublicensee for any obligation or performance hereunder prior to proceeding directly against KHK.

2.3 MEI's Retained Rights. MEI retains the right under the MEI Technology to (a) exercise its rights and perform its obligations under this Agreement; and (b) research, Develop, make, have made, use, promote, distribute, sell, offer for sale, have sold, import, export and otherwise Commercialize Compounds and Products to the extent not inconsistent with the exclusive rights granted to KHK under Section 2.1 (Licenses to KHK).

2.4 Transfer of Know-How and Materials.

(a) The Parties shall agree to a plan for the transfer of certain MEI Know-How (including the data therein) existing as of the Effective Date as attached to this Agreement as Schedule 2.4 (the "**Transfer Plan**"). As soon as practical and pursuant to the Transfer Plan, MEI shall disclose and make available to KHK, and KHK shall receive, the MEI Know-How and materials listed in the Transfer Plan, according to the timeline set forth in the Transfer Plan. The Parties shall cooperate with each other in good faith to enable a smooth transfer of such MEI Know-How to KHK. For clarity, this Section 2.4(a) (Transfer of Know-How and Materials**)** does not apply to any transfer of Manufacturing-related Know-How, which shall be required of MEI

only as set forth in Section 6.5 (Manufacturing Option), other than Manufacturing-related Know-How necessary for KHK to fulfill its obligations under this Agreement as and to the extent set forth in the Transfer Plan.

(b) Upon KHK's reasonable request, MEI shall provide reasonable technical assistance, including making appropriate employees available to KHK at reasonable times, places and frequency, and upon reasonable prior notice, for the purpose of assisting KHK to understand and use the MEI Know-How in connection with KHK's Development of Products; provided, that MEI shall have no obligation under this Section 2.4 (Transfer of Know-How and Materials**)** to provide assistance in excess of **[*CONFIDENTIAL*]** and any such assistance provided by MEI in excess of such limit shall be paid for by KHK at a rate of **[*CONFIDENTIAL*]** per hour.

(c) If, during the Term, (i) MEI becomes aware of any Know-How or Patents MEI Controls that are necessary for KHK to Develop, Package, and use Compound and Product, and Commercialize Product, in the Territory, or Manufacture (following the exercise, if ever, of KHK's Manufacturing Option) Compound and Product for the Development and Commercialization in the Territory, MEI shall promptly notify KHK; and (ii) upon reasonable request by KHK, MEI shall disclose such MEI Know-How or MEI Patents and make available such Know-How or Patents to KHK with no additional cost and shall use Commercially Reasonable Efforts to provide reasonable technical assistance, subject to Section 2.4(b) (Transfer of Know-How and Materials), including making appropriate employees available at reasonably agreed times and frequency, for the purpose of assisting KHK to understand and use such Know-How in connection with KHK's Product-related activities.

(d) The Parties acknowledge and agree that none of the technology transfer assistance required by this Section 2.4 (Transfer of Know-How and Materials**)** will require either Party to provide such assistance in person.

2.5 No Implied Licenses; Negative Covenant. Except as set forth herein, 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. KHK hereby covenants not to practice, and not to permit or cause any of its Affiliate or any Third Party to practice, any MEI Technology for any purpose other than as expressly authorized in this Agreement, including exclusively Developing and Commercializing Products in accordance with the Development Plan or Commercialization Plan, as applicable.

2.6 Non-Diversion.

(a) Each Party hereby covenants and agrees that it will not, and will ensure that its Affiliates will not, and will ensure its Sublicensees (or licensees) and subcontractors do not to, either directly or indirectly, promote, market, solicit, distribute, import, sell or have sold Products in the other Party's Respective Territory, except in each case solely in the context of exercising Manufacturing rights (and thus attendant import and the like rights) in the other Party's Respective

Territory and to the extent that such Party has the express right to conduct such Manufacturing and related activities.

(b) If a Party or any of its Affiliates or Sublicensees (or licensees) receives or becomes aware of the receipt by such Person of any orders for any Product for use outside such Party's Respective Territory, such Person shall refer such orders to the other Party.

(c) In furtherance of the foregoing, in the event that Party or any of its Affiliates or Sublicensees (or licensees) violates the provisions of this Section 2.6 (Non-Diversion) such Party shall pay, or cause to be paid, to the other Party the full amount of any Net Sales of the Product outside of such Party's Respective Territory; provided, that, such payment shall not limit either Party's other remedies with respect thereto.

2.7 Non-Compete.

(a) During the Term, both Parties and, with respect to KHK, for an additional period of **[*CONFIDENTIAL*]** after the early termination of this Agreement **[*CONFIDENTIAL*]** (but, for clarity, not the natural expiration of this Agreement), shall not, and shall ensure that its Affiliates, its licensees and Sublicensees do not, directly or indirectly, conduct, have conducted, exploit, or fund any activity that involves the conduct of, any **[*CONFIDENTIAL*]** any compound or product in or for (i) the Territory with respect to MEI, or (ii) globally, including the Territory, with respect to KHK, that is intended **[*CONFIDENTIAL*]** other than the Compound and Product in accordance with this Agreement and any applicable supply agreement between the Parties. It is the desire and intent of the Parties that the restrictive covenants contained in this Section 2.7 (Non-Compete) be enforced to the fullest extent permissible under Applicable Laws and public policies applied in each jurisdiction in which enforcement is sought. KHK and MEI believe that the restrictive covenants in this Section 2.7 (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, such amendment shall apply only with respect to the operation of such provision of this Section 2.7 (Non-Compete) in the particular jurisdiction in which such declaration is made.

(b) Notwithstanding Section 2.7(a) (Non-Compete), if during the relevant time period under Section 2.7(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 2.7(a) (Non-Compete) (a "**Competitive Program**"), unless the Parties agree otherwise in writing, the Acquiring Party shall, within **[*CONFIDENTIAL*]** after the 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 to **[*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*]** as 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 to effect **[*CONFIDENTIAL*]** within such **[*CONFIDENTIAL*]** period, then, unless otherwise required by Applicable Law, such **[*CONFIDENTIAL*]** period 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 2.7(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.

ARTICLE 3
GOVERNANCE

3.1 Joint Steering Committee. Within **[*CONFIDENTIAL*]** after the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**"), 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 the Development of the Compound and Products and Commercialization Products in the Field in the Territory. 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 JSC shall:

(a) serve as a forum for discussing and supervising Development of the Compound and Products in the Field in the Territory, including reviewing and approving the Development Plans and amendments to the Development Plans, and coordinating the conduct of the Development activities, including KHK's participation in global studies;

(b) serve as a forum for discussing and supervising the Commercialization of Products in the Field in the Territory, including by reviewing the Commercialization strategy for the Territory, reviewing the Commercialization Plans and amendments and updates to the Commercialization Plans, and coordinating the conduct of the Commercialization activities; and

(c) serve as a forum, if applicable, for discussing any Development of Compound or Product in the Territory in combination with compound or product other than **[*CONFIDENTIAL*]**. For the avoidance of doubt, if any such other compound or product is

Controlled by MEI and is not a Compound or Product, it is understood that KHK is not being granted any license under MEI Patents to exploit such other compound or product used in such combination.

The JSC shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. For clarity, The JSC shall not have any right, power or authority: (i) to determine any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (ii) to modify or amend the terms and conditions of this Agreement.

3.2 JSC Membership and Meetings.

(a) 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 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).

(b) JSC Meetings. The JSC will hold its first meeting as soon as practicable but no later than **[*CONFIDENTIAL*]** of Effective Date. At this first meeting, the JSC will address the initial transfer of MEI Know-How provided for in Section 2.4 (Transfer of Know-How and Materials) and any other topics the Parties deem appropriate. 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 least **[*CONFIDENTIAL*]** per 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.

(c) 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.

(d) Working Group. In addition to the JSC, the Parties may establish under the JSC one or more working groups to focus on discussions, information sharing and day-to-day

conduct of activities concerning Development, regulatory, 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, the decision to establish any Working Group requires the mutual agreement of the Parties and is not a determination that is under the jurisdiction of the JSC; provided, that, once established, Working Groups will report to the JSC and any disagreements on a Working Group will be referred to the JSC for resolution.

(e) Appointment Not an Obligation. The appointment of members to the JSC 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 JSC. If a Party (the "**non-Appointing Party**") does not appoint members to the JSC, it shall not be a breach of this Agreement, nor shall any consideration be required to be returned, and the other Party (the "**Appointing 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.

(f) Discontinuation; Disbandment. Subject to Section 3.2(e) (Appointment Not an Obligation), once established, the JSC shall continue to exist until the first to occur of: (i) the Parties mutually agreeing to disband the JSC; and (ii) MEI providing to KHK written notice of its intention to disband the JSC. Upon the occurrence of either of the foregoing, (A) the JSC 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 JSC 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 3.3 (JSC Decision Making) over matters that are subject to the review or approval by the JSC hereunder, with any disputes to be resolved pursuant to Section 14.9 (Dispute Resolution).

3.3 JSC Decision-Making. All decisions of 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 the JSC, the representatives of the Parties cannot reach an agreement as to such matter within **[*CONFIDENTIAL*]** after such matter was brought to the JSC for resolution, such disagreement shall be referred to the Chief Executive Officer of MEI (or his or her designee) and the Chief Executive Officer of KHK (or his or her designee) (collectively, the "**Executive Officers**") for resolution, who shall use good faith efforts to resolve such matter within **[*CONFIDENTIAL*]** after it is referred to them. If the Executive Officers are unable to reach consensus on any such matter during such period, then the Chief Executive Officer of KHK shall have the right to make the final decision except with respect to: **[*CONFIDENTIAL*]**, and in each case of subclauses **[*CONFIDENTIAL*]** through **[*CONFIDENTIAL*]**, inclusive, the Chief Executive Officer of MEI shall have the right to make the final decision. Notwithstanding the foregoing, the Parties hereby agree that matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement, are outside the

jurisdiction and authority of the JSC and not subject to the decision-making process set forth in this Section 3.3 (JSC Decision-Making).

3.4 Alliance Managers. As soon as practicable after the Effective Date, each Party shall appoint a representative to act as its 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 4
DEVELOPMENT

4.1 General. Subject to the terms and conditions of this Agreement, KHK shall be responsible for the Development of the Compound and Products in the Field in the Territory, including conduct of preclinical studies and Clinical Trials that are required by Regulatory Authority in the Territory to support Regulatory Approval of the Compound and Products in the Field in the Territory.

4.2 Development Plan. KHK shall conduct all Development of the Compound and Products in the Field in the Territory in accordance with a comprehensive development plan (as amended in accordance with this Agreement, the "**Development Plan**"), including the timelines set forth therein, the initial version of which is attached to this Agreement as Schedule 4.2. Following the Effective Date, KHK shall deliver an updated Development Plan to include, among other things, the Indications for which the Product is to be Developed, critical activities to be undertaken, certain timelines, go/no go decision points and relevant decision criteria, and feedback from the PMDA (which PMDA feedback will be reflected in a promptly updated Development Plan that is provided by KHK to MEI), if applicable. The Development Plan shall be focused on efficiently obtaining Regulatory Approval for the Product in the Field in the Territory, while taking into consideration actual and potential Development, Regulatory Approval or commercial impacts on the Product outside of the Territory and/or the Field. During the Term, KHK will review the Development Plan from time to time, not less than **[*CONFIDENTIAL*]** and amend such Development Plan on an ongoing basis as necessary. Any such amendment to the Development Plan will be reviewed, discussed and approved by the JSC; *provided*, that, under no circumstances shall KHK conduct any Development activities as part of a Development Plan that would reasonably be expected to have a material adverse safety effect on the Development or Commercialization of the Compound outside of the Territory. The then-current 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 Development Plan.

4.3 Development Diligence.

(a) KHK, 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 the Territory in accordance with the Development Plan for the Indications of **[*CONFIDENTIAL*]**. The Parties acknowledge and agree that KHK's failure to undertake any Development activities for a period of **[*CONFIDENTIAL*]** shall be deemed to be a material breach of KHK's Development diligence obligations under this Section 4.3 (Development Diligence) to the extent that there are no unexpected material delays in global Clinical Trials conducted by MEI that affect KHK's Development in the Territory.

(b) MEI shall conduct (i) subject to and using Commercially Reasonable Efforts, **[*CONFIDENTIAL*]**; provided, that the Parties acknowledge and agree that MEI shall be excused from its obligations under this Section 4.3(b) (Development Diligence) if: **[*CONFIDENTIAL*]**.

4.4 Development Costs. KHK shall be solely responsible for the cost for the Development of Compounds and Products in the Field in the Territory, including all of the costs in connection with seeking Regulatory Approval of the Product in the Territory except as otherwise set forth in Section 6.1 (Development Supply) of this Agreement. In the case of KHK joining in the Territory **[*CONFIDENTIAL*]** or its designees, KHK shall **[*CONFIDENTIAL*]**. In such case, MEI shall invoice KHK from time-to-time in connection with costs and expenses incurred in connection with the foregoing, and KHK shall pay such invoices within **[*CONFIDENTIAL*]** of receipt of an invoice thereof.

4.5 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 (a) be appropriate for patent and regulatory purposes, (b) be in compliance with Applicable Law, (c) properly reflect all work done and results achieved in the performance of Development activities hereunder, (d) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement, and (e) be retained by each Party for **[*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 4.5 (Development Records), provided that requesting Party shall bear all the costs for such inspection.

4.6 Development Reports. Without limiting Section 4.5 (Development Records), at least **[*CONFIDENTIAL*]** prior to each meeting of the JSC and in any event not less than **[*CONFIDENTIAL*]**, during which KHK is conducting Development activities hereunder, KHK shall provide the JSC with a detailed written 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 such report shall contain sufficient detail to enable the JSC to assess KHK's compliance with its obligations set forth in Section 4.2 (Development Plan) and Section 4.3

(Development Diligence), including: (a) KHK's, or its Affiliates' or Sublicensees' activities with respect to achieving Regulatory Approvals of Products in the Territory; (b) results of Clinical Trials and other Development activities not otherwise provided under subsection (a) above; and (c) the Regulatory Approvals that KHK or any of its Affiliates reasonably expect to make, seek or attempt to obtain in the Territory.

4.7 Provision of Development Data. During the Term, with no additional costs to MEI, KHK 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 KHK in the conduct of any Clinical Trials involving the Compound and Product (including all of KHK's Regulatory Data and KHK Data) that MEI determines would be necessary or useful to Develop the Products outside of the Territory.

4.8 Compliance. KHK agrees that in performing its obligations and exercising its rights under this Agreement: (a) it shall comply with all Applicable Laws; and (b) without limiting Section 12.2(b) (Debarment), it will not employ or engage any Person who has been debarred or disqualified by any Regulatory Authority, or is the subject of debarment or disqualification proceedings by a Regulatory Authority.

4.9 Subcontractor. Without limiting Section 2.2 (Sublicense Rights) to the extent applicable, KHK shall have the right to engage subcontractors for the performance of its obligations under the Agreement; provided, however, that KHK 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 MEI's Confidential Information and invention assignment consistent with those contained herein. KHK shall remain responsible and liable for the performance any such subcontractor(s) and KHK hereby expressly waives any requirement that MEI 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 KHK.

ARTICLE 5
REGULATORY

5.1 Regulatory Responsibilities. KHK shall be responsible for all regulatory activities necessary to obtain and maintain Regulatory Approval of Products in the Field in the Territory. KHK shall keep MEI informed of regulatory developments related to the Compound and Products in the Field in the Territory both via the JSC and KHK's reports pursuant to Section 4.6. (Development Reports).

5.2 Regulatory Materials. KHK shall prepare and submit all Regulatory Materials for Products in the Field in the Territory and shall own all Regulatory Materials and Regulatory Approvals for Products in the Field in the Territory. KHK 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 the Territory. Moreover, with respect to submission of (i) Marketing Authorization Application in the Territory, KHK 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 the any Regulatory Authority in the Territory, KHK will provide MEI with drafts of such submissions and reasonable English summaries of such submissions (which summaries will include key information) not less than **[*CONFIDENTIAL*]** 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 KHK's submission date. KHK 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*]**. KHK shall also provide to MEI copies of the final submitted version of each Regulatory Material and each granted Regulatory Approval in the Territory and an English translation of such Regulatory Approval. In addition, upon reasonable request by MEI, KHK shall also provide MEI with any Regulatory Material(s) not previously provided under this Section 5.2 (Regulatory Materials). Upon request by KHK, MEI shall, subject to the reasonable availability of MEI's relevant personnel, assist KHK in seeking and obtaining Regulatory Approvals with respect to Product in the Territory, including: **[*CONFIDENTIAL*]** provided, that MEI shall have no obligation under this Section 5.2 (Regulatory Materials) (or under any other provision of this Agreement) to assist KHK with respect to regulatory matters in excess of **[*CONFIDENTIAL*]** and any such assistance provided by MEI in excess of such limit shall be paid for by KHK at a rate of **[*CONFIDENTIAL*]** per hour.

5.3 Regulatory Inspections. If a Regulatory Authority in the Territory 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 KHK in a timely manner MEI shall allow representative(s), details of which shall be discussed under the Quality Agreements, from KHK 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. KHK shall reimburse MEI for any costs MEI incurs under this Section 5.3 (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 KHK caused by such a CMO's failure to perform its obligation under this Section 5.3 (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 KHK under any other Sections of this Agreement.

5.4 Regulatory Inspections for Improper Activities. If any Regulatory Authority (a) contacts KHK or any of its Affiliates or any Sublicensee with respect to the alleged improper

Development, Packaging, Manufacture or Commercialization of any Product, (b) conducts, or gives notice of its intent to conduct, an inspection at KHK'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 of Products, or (c) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of KHK 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 in or outside of the Territory, then KHK will (i) promptly notify MEI of such contact, inspection or notice and (ii) 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 (a), (b) or (c). In addition, MEI shall have the right to attend any such meetings or inspections to the extent not prohibited by such Regulatory Authority.

5.5 Sharing of Regulatory Data and Filings; Pricing Approval Documentation.

(a) MEI; MEI Licensees. MEI shall make available (1) MEI's, its Affiliates' or its licensee's material Regulatory Data and material Regulatory Materials to KHK, in each case, solely to the extent specific to the Clinical Trials described in subclauses (ii) and (iii) of Section 4.3(b) (Development Diligence), and (2) **[*CONFIDENTIAL*]**, which will be used for a MAA submission for Product in the United States, to KHK, its Affiliates, and Sublicensees, for no additional consideration, for use solely in the Development and Commercialization of the Compound and the Products in the Field in the Territory by KHK, its Affiliates or Sublicensees, which was not previously provided to KHK under Section 2.4(a) (Transfer of Know-How and Materials) and solely for use in exercising the rights licensed to KHK hereunder. MEI shall ensure that all licensees of MEI shall be required to provide such material Regulatory Data and material Regulatory Materials to MEI for use by KHK. Without prejudice to the foregoing, MEI shall use Commercially Reasonable Efforts to make available other material Regulatory Data and material Regulatory Materials (i.e., other than such related to the Clinical Trials referenced above) of MEI or its Affiliates or its licensees to KHK, its Affiliates, and Sublicensees (by way of MEI and not directly to any such entities), for no additional consideration, for use solely in the Development, Packaging and Commercialization of the Products in the Field in the Territory.

(b) KHK.

(i) KHK shall make available KHK's, its Affiliates', and its Sublicensees' material Regulatory Data and material Regulatory Materials to MEI, its Affiliates, and licensees, for no additional consideration, for use solely in the Development and Commercialization of the Compound and the Products outside the Territory and Manufacturing of the Compound and the Products. MEI shall not provide any Regulatory Data or Regulatory Materials of KHK, its Affiliates, or Sublicensees to any of MEI's licensees who do not agree pursuant to Section 5.5(a) (MEI; MEI Licensees) to permit its Regulatory Data and Regulatory Materials related to the Clinical Trials described in subclauses (i) and (ii) of Section 4.3(b) (Development Diligence) to be shared with KHK, its Affiliates, and its Sublicensees.

(ii) Upon MEI's reasonable request, from time-to-time, KHK shall provide to MEI KHK's, its Affiliates', and its Sublicensees' materials, including correspondence and submissions, related to negotiating for, obtaining, and maintaining Pricing Approval and shall discuss the same with MEI upon MEI's request.

(c) 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.

5.6 Rights of Reference. MEI hereby grants KHK the right to use and reference all Regulatory Materials (including data contained therein) and Regulatory Approvals for the Compound and Products outside the Territory submitted by or on behalf of MEI, its Affiliates or licensees (to the extent that MEI has the right to grant such cross reference rights on behalf of its licensee(s)), which right may be used by KHK only in the Field in the Territory **[*CONFIDENTIAL*]** to KHK. MEI shall use Commercially Reasonable Efforts to cause all relevant licensees of MEI to grant such cross reference rights, with right to sublicense to KHK, provided that if MEI, its Affiliates or its licensees does not grant such cross reference rights to KHK to either or both of the Clinical Trials described in subclauses (ii) and/or (iii) of Section 4.3(b) (Development Diligence), then KHK **[*CONFIDENTIAL*]** that is the subject of such Clinical Trial(s) for which such cross reference rights are not granted (and, accordingly, **[*CONFIDENTIAL*]** which relate to such Clinical Trial(s)). KHK hereby grants MEI the right to use and reference all Regulatory Materials (including data contained therein) and Regulatory Approvals for the Compound and Products in the Territory submitted by or on behalf of KHK, its Affiliates or Sublicensees, which right may be used by MEI only outside the Territory **[*CONFIDENTIAL*]** to MEI. KHK shall cause all relevant Sublicensees of KHK to grant such cross reference rights, with right to sublicense 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. MEI shall not provide any cross-reference rights of KHK, its Affiliates, or Sublicensees to any of MEI's licensees who do not agree to permit its Regulatory Materials to be cross-referenced by KHK, its Affiliates, and its Sublicensees.

5.7 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. KHK shall have the sole discretion with respect to any matters relating to any Remedial Action with respect to any Product in the Field in the Territory, including the decision to commence such Remedial Action and the control over the conduct of such Remedial Action, provided that KHK shall notify MEI prior to making any public disclosure of

Remedial Action and shall keep MEI regularly informed regarding any such Remedial Action. KHK shall be solely responsible for the cost and expense of any such Remedial Action in the Field in the Territory. MEI shall have the sole discretion with respect to any matters relating to any Remedial Action with respect to any Product outside the Territory, including the decision to commence such Remedial Action and the control over the conduct of such Remedial Action, provided that MEI shall notify KHK prior to making any public disclosure of Remedial Action and shall keep KHK regularly informed regarding any such Remedial Action. MEI shall be solely responsible for the cost and expense of any such Remedial Action outside the Territory. Notwithstanding anything to the contrary in this Section 5.7 (Remedial Actions), 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. Without prejudice to other rights and remedies set forth in this Agreement, or any other agreement executed pursuant to this Agreement, including the Clinical Supply Agreement, the Commercial Supply Agreement, the Pharmacovigilance Agreement and the Quality Agreements, all internal and external costs (excluding any costs or damages arising from a Claims by a Third Party to which a Party is entitled to indemnification under Article 13 (Indemnification; Liability)) incurred by the Parties in connection with implementing a recall or withdrawal (a "**Recall**") with respect to the Product in the Field in the Territory ("**Recall Costs**") shall be allocated between MEI and KHK as follows: .

(a) [*CONFIDENTIAL*]

(b) [*CONFIDENTIAL*]

(c) [*CONFIDENTIAL*]

5.8 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 the Compound and Products to protect patients and promote their well-being in a written pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"), with MEI (or its designee) as the global safety database holder. Absent the execution of a Pharmacovigilance Agreement, KHK shall not ship Product to any clinical study site in the Territory. These responsibilities 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 or, solely with respect to MEI, its other licensees) to comply with Applicable Laws and regulatory requirements in their Respective 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.

5.9 Personally-Identifiable Data / GDPR Compliance. 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 KHK and its Affiliates, sublicensees, and subcontractors in accordance with all data protection and privacy laws, rules and regulations applicable to such data, and in accordance with the GDPR Joint Controller and Onward Transfer Agreement attached in Schedule 5.9 ("**GDPR Agreement**"), and contemporaneously executed with the execution of this Agreement, and other agreements that are 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.

ARTICLE 6
MANUFACTURING

6.1 Development 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, "**Supply Items**") to KHK for use in the Development of the Product in the Territory, without further consideration by KHK to MEI, other than that set forth in Article 8 (Financial Provisions) below. The Supply Items shall be made available to KHK FCA (as defined in INCOTERMS 2010) at the warehouse locations specified in Schedule 6.1. For clarity, KHK shall bear all costs related to shipping, Taxes, and acceptance testing associated with such supply. Subject to the specific costs that KHK is responsible for in accordance with this Section 6.1 (Development Supply), Supply Items supplied for Development purposes and used in accordance with the Development Plan will be provided **[*CONFIDENTIAL*]**.

(a) Initial Supply. MEI shall **[*CONFIDENTIAL*]** the Supply Items to KHK up to the amounts and in the forms set forth on Schedule 6.1 and on the timing set forth in such schedule. MEI shall make available to KHK the Supply Items up to the amounts and in the forms specified on Schedule 6.1 with appropriate documentation (i.e., appropriate certificates of analysis and/or compliance, as applicable).

(b) Further Development Supply. Within **[*CONFIDENTIAL*]** of the Effective Date, the Parties shall enter into a supply agreement which shall include customary provisions to address the forecasting, order, delivery, and other customary provisions applicable to the supply of the Supply Items for Development purpose after the supply set forth in Section 6.1(a) (Initial Supply) (the "**Clinical Supply Agreement**"). MEI shall **[*CONFIDENTIAL*]** the Supply Items to KHK with the amounts and in the forms, and on the timing set forth in Clinical Supply Agreement, which KHK agrees to accept in accordance with the Clinical Quality Agreement. MEI shall make available to KHK the Supply Items with appropriate documentation (i.e., appropriate certificates of analysis and/or compliance, as applicable in accordance with the Clinical Quality Agreement) following receipt of a written request therefor from KHK that specifies the quantities and forms desired. Following discussions with the PMDA and/or a change to the Development Plan that is approved in writing by MEI, KHK may request changes to the amounts, forms and timing of the supply of the Supply Items set forth in this Section 6.1(b) (Further Development Supply) which the Parties shall discuss in good faith under the governance of Clinical Supply Agreement, provided that MEI shall use Commercially Reasonable Efforts to

comply with such requests by KHK. Notwithstanding forgoing, in case, after completion of KHK's first **[*CONFIDENTIAL*]** in the Territory, there is an amendment to the Development Plan for the Product to be Developed in the Territory with **[*CONFIDENTIAL*]**, onward supply of **[*CONFIDENTIAL*]** for Development purposes will be provided to KHK **[*CONFIDENTIAL*]** and further manufacturing and supply, including commercial supply and which Party will be responsible for supplying such, shall be discussed in good faith between the Parties.

6.2 Packaging; Certain Other Manufacturing Activities. Subject to the remainder of this Section 6.2 (Packaging; Certain Other Manufacturing Activities), MEI shall supply the Product to KHK in its bulk capsule form unless otherwise defined and/or agreed by the Parties. KHK or its designated Third Party shall be responsible (at its sole cost and expense) for 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 patient 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 (collectively, "**Package**" or "**Packaging**"). For clarity, KHK's Packaging responsibilities apply to the Product supplied by MEI under Section 6.1 (Development Supply) and Section 6.3 (Commercial Supply). KHK 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 6.2 (Packaging; Certain Other Manufacturing Activities), KHK shall be wholly responsible for, and bear one hundred percent (100%) 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 global Clinical Trials, including the portion of any such Clinical Trials in the Territory; provided, that KHK shall be responsible for the costs associated with such Packaging for Product to be used in the Territory in accordance with Section 4.4 (Development Costs).

6.3 Commercial Supply. MEI shall Manufacture, or arrange for a Third Party to Manufacture, and **[*CONFIDENTIAL*]** all of KHK's requirements of the Product for commercial sale in the Field in the Territory in accordance with a commercial supply agreement, which shall include customary provisions to address the forecasting, order, delivery and other customary provisions applicable to the commercial supply of pharmaceuticals from a licensor to a licensee ("**Commercial Supply Agreement**"). MEI shall **[*CONFIDENTIAL*]** the Product to KHK in accordance with the conditions set forth in Commercial Supply Agreement, which KHK agrees to accept in accordance with the Commercial Quality Agreement. MEI shall make available to KHK the Product with appropriate documentation (i.e., appropriate certificates of analysis and/or compliance, as applicable in accordance with the Commercial Quality Agreement) following receipt of a written request therefor from KHK that specifies the quantities and forms desired. The Commercial Supply Agreement shall be negotiated by the Parties in good faith after

the Effective Date; provided, that the Parties acknowledge and agree that the supply price for Product intended for Commercial purposes will be **[*CONFIDENTIAL*]**.

6.4 Quality Agreements.

(a) At the same time that the Parties enter into the Clinical Supply Agreement, the Parties shall enter into a 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 clinical supply of the pharmaceuticals (the "**Clinical Quality Agreement**").

(b) At the same time that the Parties enter into the Commercial Supply Agreement, the Parties shall enter into a 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 commercial supply of pharmaceuticals (the "**Commercial Quality Agreement**"). MEI shall use Commercial Reasonable Effort, but shall not be obligated to incur any costs, to cause MEI CMOs to be a party to the Commercial Quality Agreement if required by Applicable Law. Clinical Quality Agreement and the Commercial Quality Agreement are collectively "**Quality Agreements**".

6.5 Manufacturing Option.

(a) MEI hereby grants KHK an option under MEI Technology to Manufacture and to have Manufactured the Compound and/or the Product in the Territory or outside of the Territory exclusively for Development and Commercialization in the Territory, which can be exercised by written notice from KHK to MEI (i) in the event that MEI experiences a "supply failure" with respect to supplying the Compound or Product to KHK under the Commercial Supply Agreement as "supply failure" is defined in the Commercial Supply Agreement and/or Commercial Quality Agreement; (ii) if MEI's cost of Manufacturing under the Commercial Supply Agreement increases by more than **[*CONFIDENTIAL*]** from one Calendar Year to the next for reasons other than raw material costs; or (iii) for a period of **[*CONFIDENTIAL*]** starting **[*CONFIDENTIAL*]** prior to the anticipated expiration of the Term (the "**Manufacturing Option**"); provided, that, the Manufacturing Option shall expire **[*CONFIDENTIAL*]** prior to the anticipated expiration of the Agreement.

(b) If the Manufacturing Option is exercised, then:

(i) for a transition period of not less than **[*CONFIDENTIAL*]** (but only longer if the Parties mutually agree) MEI shall continue to supply the Compound and/or the Product to KHK for Development and Commercialization (in accordance with, as applicable, this Agreement or one or more separate supply agreement(s) between the Parties) (the "**Transition Period**"). MEI shall have no obligation to supply KHK with the Compound and/or Product after the Transition Period.

(ii) during Transition Period, MEI shall make available and transfer to KHK, copies of existing embodiments of the MEI Know-How in MEI's possession that are necessary or reasonably useful in, and as of such date are being used by MEI to, Manufacture of the Compound and Products solely for KHK to Manufacturer or have Manufactured (to the extent permitted by this Agreement) the Compound and Products in accordance with the terms and conditions of this Agreement with no additional consideration during Transition Period. Subject to the proviso in the foregoing sentence, MEI shall use Commercially Reasonable Efforts to provide KHK with reasonable assistance to facilitate the practice of such Manufacturing rights by KHK, its Affiliate or its Sublicensee. In the event that KHK elects to have one or more of MEI's existing contract manufacturers to Manufacture the Product and/or Compound for the Territory, MEI shall reasonably cooperate to allow KHK to enter into a direct contract manufacturing agreement with such contract manufacturers. Any Product Manufactured by KHK pursuant to the foregoing rights shall be exclusively sold in the Territory. Any regulatory activities that are necessary for KHK to engage the foregoing Manufacture of the Product or the Compound shall be conducted by the Parties in accordance with Section 4.3 (Development Diligence).

ARTICLE 7
COMMERCIALIZATION

7.1 General. Subject to the terms and conditions of this Agreement, KHK shall be responsible for all aspects of the Commercialization of the Products in the Field in the Territory, including, solely with respect to the Products in the Field in the Territory: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Government Authorities in the Territory 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 the Territory. As between the Parties, KHK shall be solely responsible for the costs and expenses of Commercialization of the Products in the Field in the Territory.

7.2 Commercialization Plan. KHK shall conduct all Commercialization of Products in the Field in the Territory in accordance with a comprehensive commercialization plan that is consistent with this Agreement (as amended in accordance with this Agreement, the "**Commercialization Plan**"), the initial version of which KHK will prepare and provide to the JSC for review no later than **[*CONFIDENTIAL*]** after initial submission of Marketing Authorization Application of Product in the Field in the Territory, and such plan will include a pricing strategy for the Product. From time to time, but at least once every **[*CONFIDENTIAL*]**, KHK will update the Commercialization Plan and submit such updated plan to the JSC for review and discussion. Notwithstanding anything to the contrary herein, if the terms of the Commercialization Plan contradict, or create actual or potential inconsistencies with, the terms of

this Agreement, then the terms of this Agreement shall govern and KHK shall perform relevant activities in accordance with this Agreement and not the Commercialization Plan.

7.3 Commercial Diligence. KHK, directly and/or with or through Affiliates or 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 Territory. Without limiting the foregoing, in connection with the Commercialization of Products in the Field in the Territory:

(a) KHK shall promote Products in a professional, diligent and honest manner in accordance with Applicable Law and industry standards;

(b) KHK 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;

(c) KHK shall seek a daily NHI Price equal to or greater than **[*CONFIDENTIAL*]**; and

(d) KHK shall undertake a First Commercial Sale within **[*CONFIDENTIAL*]** of the NHI Price listing for a Product in the Territory.

7.4 Creation of Promotional Materials. KHK will create and develop materials for marketing, advertising and promoting of the Products in the Field in the Territory ("**Promotional Materials**") in accordance with the Regulatory Approvals and Applicable Laws and at KHK's sole cost and expense. To the extent KHK includes any MEI corporate trademarks in the Promotional Materials for the Territory, KHK shall comply with MEI's then current guidelines for trademark usage. KHK will review all Promotional Materials and programs in connection with the Commercialization of Products prior to use thereof to ensure that all are in accordance with the Commercialization Plan, the Regulatory Approvals and Applicable Laws. KHK shall provide MEI with copies of final versions of material Promotional Materials which are prepared in connection with the First Commercial Sale of the Product and that KHK is intending to use in connection with Commercialization the Products and any change to the key message(s) contained in such Promotional Materials.

7.5 Commercialization Reports. [*CONFIDENTIAL*], commencing upon KHK's, any of its Affiliates' or any Sublicensee's first filing for Marketing Authorization Application of a Product in the Territory and thereafter, KHK shall provide to the JSC 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 JSC to assess KHK's compliance with its obligations set forth in Sections 7.2 (Commercialization Plan) and 7.3 (Commercial Diligence), including, in each case, Net Sales for such Product in the Territory.

*A request for confidential treatment has been made with respect to portions of the following document that are marked with [*CONFIDENTIAL*]. The redacted portions have been filed separately with the SEC.*

7.6 Compliance with Applicable Law. KHK 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 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.

7.7 Training. KHK shall be solely responsible for training, and all costs associated with such training, its employees and representatives engaged in activities under this Agreement. Such training shall be in accordance with Applicable Laws, including with respect to timely reporting of any adverse events with respect to the Products.

ARTICLE 8
FINANCIAL PROVISIONS

8.1 Upfront Payment. (i) Within thirty (30) days after the Effective Date or (ii) thirty (30) days following KHK's receipt from MEI of the tax forms provided to MEI under Section 8.8(d) (Tax Cooperation), whichever comes later, KHK shall pay to MEI a one-time, non-refundable and non-creditable upfront payment of ten million Dollars ($10,000,000).

8.2 Development and Regulatory Milestone Payments. Within **[*CONFIDENTIAL*]** after the first achievement of each milestone event below by or on behalf of KHK or any of its Affiliates or Sublicensees, KHK shall notify MEI of the achievement of such milestone event and pay to MEI the applicable non-refundable, non-creditable milestone payment corresponding to such milestone event as shown below.

Development or Regulatory Milestone Events	Milestone Payments (in U.S. Dollars)
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**

[*CONFIDENTIAL*].

*A request for confidential treatment has been made with respect to portions of the following document that are marked with [*CONFIDENTIAL*]. The redacted portions have been filed separately with the SEC.*

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8.3 Commercial Milestones.

(a) Within **[*CONFIDENTIAL*]** after the annual Net Sales for a Calendar Year reach any threshold indicated in the milestone events listed below, KHK 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*]**

(b) For purposes of determining whether a Net Sales milestone event has been achieved, Net Sales of all Products in the Territory shall be aggregated. For clarity, the annual Net Sales milestone payments set forth in this Section 8.3 (Commercial Milestones) shall be payable only once for all Products, upon the first achievement of the applicable milestone event.

(c) If a Milestone Event in Section 8.3 (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 KHK for such unpaid previous milestone event(s) and KHK shall pay MEI such unpaid previous milestone payment(s) within thirty (30) days of receipt of such invoice.

8.4 Royalty Payments.

(a) KHK shall pay to MEI non-refundable, non-creditable royalties on aggregate annual Net Sales of all Products in the Territory in each Calendar Year ("**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 Aggregate Annual Net Sales in such Calendar Year by the corresponding royalty rate set forth in the table below:

Aggregate Annual [*CONFIDENTIAL*] Net Sales of the Products	Royalty Rates
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**
[*CONFIDENTIAL*]	**[*CONFIDENTIAL*]**

(b) Royalty Term. Royalties under this Section 8.4 (Royalty Payments) shall be payable on a Product-by-Product basis from the First Commercial Sale of such Product in the Territory until the latest of: (i) 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 such Product (or the Compound contained therein) in the Territory; (ii) expiration of Regulatory Exclusivity for such Product in the Territory; or (iii) **[*CONFIDENTIAL*]** after the First Commercial Sale of the Product in the Territory (the "**Royalty Term**" for such Product).

(c) Royalty Reports and Payment. KHK shall calculate all Royalty Payments payable to MEI pursuant to this Section 8.4 (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 8.6 (Currency Conversion). KHK 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 (i) 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), (ii) an itemized calculation of Net Sales showing deductions from gross sales provided for in the definition of "Net Sales" during such Calendar Quarter, and (iii) a statement of the prices and the number of units of Products sold. KHK shall be responsible for the proper accounting of Net Sales by or on behalf of its Affiliates and Sublicensees.

(d) Blended Royalty. KHK acknowledges that (i) the MEI Know-How and the information included in MEI's Regulatory Materials licensed to KHK are proprietary and valuable and that without the MEI Know-How and such information, KHK would not be able to obtain and maintain Regulatory Approvals with respect to the Products, (ii) such Regulatory Approvals will allow KHK to obtain and maintain Regulatory Exclusivity with respect to the Products in the Field in the Territory, (iii) access to the MEI Know-How and the rights with respect to the MEI's Regulatory Materials will have provided KHK 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) and 8.4 (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 8.4(a) (Royalty

Payments) reflects an efficient and reasonable blended allocation of the value provided by MEI to KHK.

8.5 Royalty Adjustments. Except as otherwise set forth in this Agreement, royalties due hereunder 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 8.4(a) (Royalty Payments) shall not be reduced by more than **[*CONFIDENTIAL*]** of the amounts set forth in Section 8.4(a) (Royalty Payments) by any or all reasons of the adjustments set forth below.

(a) 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 8.4(a) (Royalty Payments) with respect to the Territory shall be adjusted in accordance with Section 9.5 (Third Party Intellectual Property Rights).

(b) Royalty Adjustment for Generic Competition. If a Generic Product receives Regulatory Approval and is sold in the Territory, then for so long as such Generic Product is being sold in the Territory the royalties payable to MEI on the sales of such Product shall be reduced by **[*CONFIDENTIAL*]**.

(c) Royalty Adjustment for Pricing. If the 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 the Territory, then the royalties payable to MEI on the sales of such Product shall be reduced by **[*CONFIDENTIAL*]**.

8.6 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 KHK'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 KHK's discretion.

8.7 Late Payments. Any amount required to be paid by KHK hereunder which is not paid on the date due shall accrue interest from the date due at the rate of the one-month London Interbank Offered Rate as quoted in the Wall Street Journal (or if it no longer exists, similarly authoritative source) plus **[*CONFIDENTIAL*]** basis points; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit MEI 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.

8.8 Taxes and Withholding.

(a) Taxes on Income. Notwithstanding anything else set forth in this Section 8.8 (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 KHK to MEI 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, KHK shall pay such VAT, and (i) if such VAT is owing as a result of any action by KHK, including any assignment or sublicense (including assignment to, or payment hereunder by, a KHK-related entity or Affiliate), or any failure on the part of KHK 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 MEI 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 KHK, KHK shall promptly reimburse MEI for the deducted amount. For the sake of clarity, any increase in payments to MEI under this Section (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, MEI will provide to KHK tax invoices showing the correct amount of VAT in respect of such payments hereunder.

(c) Withholding Tax Matters. If KHK is required to make a payment to MEI subject to a deduction of tax or withholding tax, the sum payable by KHK (in respect of which such deduction or withholding is required to be made) shall be made to MEI 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 MEI.

(d) Tax Cooperation. To the extent KHK is required to deduct and withhold taxes on any payments to MEI, KHK shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to MEI an official tax certificate or other evidence of such withholding reasonably sufficient to enable MEI to claim such payments of taxes. MEI shall provide to KHK any tax forms that may be reasonably necessary in order for KHK not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral

income tax treaty. MEI shall use reasonable efforts to provide any such tax forms to KHK at least thirty (30) days prior to the due date for any payments for which the MEI desires that KHK 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.

8.9 Financial Records and Audit. KHK 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), during the Term and for **[*CONFIDENTIAL*]** thereafter or such longer period as required by Applicable Laws. MEI shall have a right to request **[*CONFIDENTIAL*]** audit of KHK **[*CONFIDENTIAL*]** throughout the Term in order to confirm the accuracy of the foregoing (an **"Audit"**); provided, that, such **[*CONFIDENTIAL*]** limitation shall not apply in the event of any subsequent "for cause" audit. Upon the written request by MEI to Audit KHK, MEI shall have the right to engage an independent, internationally recognized accounting firm reasonably acceptable to KHK 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 MEI. KHK, 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 KHK shall be paid to MEI within **[*CONFIDENTIAL*]** of notification of the results of such Audit. Any overpayments made by KHK shall be refunded by MEI within **[*CONFIDENTIAL*]** of notification of the results of such Audit. The cost of the accountants shall be the responsibility of MEI 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 KHK for the period subject to the Audit, in which case KHK shall bear the costs of the accountants. Any information obtained during such audit shall be treated as Confidential Information. In the event that MEI has a good faith basis, which shall be shared with KHK, for believing that a Sublicensee of KHK is not accurately reporting Net Sales (and thus that KHK is not making appropriate royalty payments hereunder), then at MEI's request, KHK shall enforce its audit rights with respect to any such Sublicensee and KHK shall report back to MEI regarding the outcome of any such audit.

8.10 Financial Adjustments. In case it appears likely that the **[*CONFIDENTIAL*]**, the Parties shall discuss and negotiate in good faith regarding potential adjustments to the **[*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 9
INTELLECTUAL PROPERTY RIGHTS

9.1 Ownership.

(a) Data. All data generated in connection with any Development, regulatory, Manufacturing or Commercialization activities with respect to any Compound or Product conducted by or on behalf of KHK or its Affiliates or Sublicensees without the involvement of MEI (the "**KHK Data**") shall be the sole and exclusive property of KHK or of its Affiliates or Sublicensees, 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.

(d) License to MEI.

(i) If, during the Term, KHK, its Affiliate or its sublicensee identifies any (A) KHK Technology, or (B) through development, any improvement that is conceived in the course of KHK's or its Affiliate's or its sublicensee's performance under this Agreement that are necessary or reasonably useful for MEI to Develop, Package, Manufacture, use or Commercialize the Compound or Product ("**KHK Sole Invention**"), KHK shall promptly notify MEI and KHK shall disclose and make available such KHK Technology including any KHK Sole Inventions, to MEI and KHK hereby grants to MEI a perpetual, **[*CONFIDENTIAL*]**, royalty-free, fully-paid, license, with the right to grant sublicenses through multiple tiers, under, in and to the KHK Technology, including any KHK Sole Inventions, to Develop, make, have made, use, import, offer for sale, sell and otherwise Commercialize the Compound and Products. In addition, KHK hereby grants to MEI **[*CONFIDENTIAL*]**.

(ii) KHK shall make the KHK 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 KHK shall have no obligation under this Section 9.1(d)(ii) (License to MEI) to provide such assistance in excess of **[*CONFIDENTIAL*]** and any such assistance provided by KHK in excess of such limit shall be paid for by MEI at a rate of **[*CONFIDENTIAL*]**.

9.2 Patent Prosecution and Maintenance.

(a) MEI Patents and Joint Patents in the Territory.

(i) MEI 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 MEI Patents and Joint Patents in the Territory, at its sole cost and expense and by counsel of its own choice. MEI shall consult with KHK and keep KHK reasonably informed of the status of such Patents and shall promptly provide KHK with all material correspondence received from any patent authority in connection therewith. In addition, MEI shall promptly provide KHK with drafts of all proposed material filings and correspondence to any patent authority with respect to such Joint Patents for KHK's review and comment prior to the submission of such proposed filings and correspondence. MEI shall confer with KHK and consider in good faith KHK's comments prior to submitting such filings and correspondence, provided that KHK 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 in the Territory, MEI shall provide reasonable prior written notice to KHK of such intention to abandon (which notice shall be given no later than **[*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 KHK's written election, KHK shall have the right to assume prosecution and maintenance of such Patent at KHK's expense; provided that KHK shall not be obligated to pay royalties for such Patent under Section 8.4 (Royalty Payments) from and after the date that KHK assumes responsibility for such Patent, including responsibility for all costs incurred in connection therewith. If KHK 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) Joint Patents outside the Territory.

(i) MEI 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 Joint Patents outside the Territory, at its sole cost and expense and by counsel of its own choice.

(c) KHK Patents. KHK 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 KHK Patents, at its sole cost and expense and by counsel of its own choice. In the event that KHK desires to abandon or cease prosecution or maintenance of any KHK Patent, KHK shall provide reasonable prior written notice to MEI of such intention to abandon (which notice shall, to the extent possible, be given no later than **[*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 than **[*CONFIDENTIAL*]** after such notice from KHK, MEI shall have the right to assume prosecution and maintenance of such KHK Patent at MEI's expense. If MEI does not provide such election within **[*CONFIDENTIAL*]** after such notice from KHK, KHK may, in its sole discretion, continue prosecution and maintenance of such KHK Patent or discontinue prosecution and maintenance of such KHK 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 KHK becomes aware of any infringement or threatened infringement by a Third Party of any MEI Patent, KHK Patent or Joint Patent in the Territory, or the submission to a Party or a Regulatory Authority in the Territory of an application for a product referencing a Product, or any declaratory judgment or equivalent action challenging any MEI Patent, KHK Patent or Joint Patent in the 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, KHK Patents and Joint Patents.

(i) MEI shall have the first right, as between KHK 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. KHK shall have the right, at its own expense, to be

represented in any such action by counsel of its own choice, and KHK and its counsel will reasonably cooperate with MEI and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the Territory. If MEI fails to bring an action or proceeding with respect to such Product Infringement of any MEI Patent or Joint Patent in the Territory 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, KHK 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 KHK and its counsel in strategizing, preparing and prosecuting any such action or proceeding.

(ii) KHK shall have the first right, as between KHK 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 KHK 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 KHK and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If KHK fails to bring an action or proceeding with respect to such Product Infringement of any KHK Patent in the Territory 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, 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 KHK shall have the right, at its own expense, to be represented in any such action by counsel of its own choice and KHK 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, KHK 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 in the Territory (including lost sales or lost profits) shall belong: **[*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.

(d) Other Infringement. MEI shall have the sole right, but not the obligation, to bring and control, at its own cost and expense, any legal action in connection with any infringement of any MEI Patent or Joint Patent outside the Territory.

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 in the Territory infringes or may infringe the intellectual property rights of a Third Party. If a Third Party asserts that any of its Patents or other rights are infringed by the Manufacture, Commercialization or Development by KHK or its Affiliates of any Product in the Territory, KHK shall have the right but not the obligation to defend against any such assertions at its sole cost and expense. In the event that KHK elects not to defend against such Third Party claims within **[*CONFIDENTIAL*]** of learning of same, MEI shall have the right, but not the obligation, to defend against such an action. In any event, the other Party shall reasonably cooperate and shall provide full access to documents, information and witnesses as reasonably requested by the Party defending such action. The Party defending the action will reimburse all Third Party costs incurred in connection with such requested cooperation. 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).

(b) Notwithstanding Section 9.5(a) (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 the Territory as a **[*CONFIDENTIAL*]**, or (B) manufacture of the Compound or the dosage form, as of the Effective Date, of the Product in the Territory and in the United States for Development or Commercialization in the Territory infringes an issued Valid Claim (as defined in Section 1.120(a) (Valid Claim) but not 1.120(b) (Valid Claim) above) of a Third Party's Patent ("**Third Party Patent**"), then MEI shall use Commercially Reasonable Efforts to obtain a license to such Third Party Patent(s) and MEI shall be responsible for **[*CONFIDENTIAL*]** of any payments due in connection with sales or activities in the Territory (including any upfront or general payments). If MEI does not obtain such license, then KHK shall have a right, but not an obligation, to obtain a license to such Third Party Patent(s), provided that KHK's royalty payment for such license shall be **[*CONFIDENTIAL*]**.

(ii) the use of the Product in the Territory in **[*CONFIDENTIAL*]**, infringes an issued Valid Claim (as defined in Section 1.120(a) (Valid Claim) but not 1.120(b) (Valid Claim) above) of a Third Party's Patent in the Territory (also, a "Third Party Patent"), then MEI would have the first right to negotiate a license to any such Third Party Patent(s), details of which shall be notified to KHK in writing prior to undertaking any such action. MEI shall keep KHK informed of the progress of such action. If MEI does not desire to obtain such license directly, then KHK shall have a right, but not an obligation, to obtain such license. In either

approach (MEI or KHK obtaining such a license): (A) no license to a Third Party Patent may be entered under this Section 9.5(b)(ii) (Third Party Intellectual Property Rights) without the other Party's prior consent, which consent shall not be unreasonably withheld, conditioned or delayed, and (B) KHK will be responsible for **[*CONFIDENTIAL*]** of any payments due in connection with sales or activities in the Territory (including a reasonable allocation of any upfront or general payments to the Territory in the case of a broader license taken by MEI). For clarity, if KHK obtains such a license, KHK 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 KHK'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. In case MEI obtains such license from Third Party, KHK shall reimburse **[*CONFIDENTIAL*]** of the reasonable allocation of any upfront or general payments and **[*CONFIDENTIAL*]** of any royalty payment to such Third Party, subject to KHK's royalty payment not exceeding **[*CONFIDENTIAL*]** of the amounts that would have otherwise been due to MEI for such Calendar Quarter. In the event that MEI negotiates the license to any such Third Party Patent, payments associated with the Territory shall be appropriate and proportional to other amounts due under any such agreement. In either approach, if such license is not secured with terms acceptable to both Parties, neither Party is obligated to **[*CONFIDENTIAL*]**.

(iii) 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.

(iv) The Parties acknowledge and agree that a defense action commenced under Section 9.5(a) (Third Party Intellectual Property Rights) may lead to MEI negotiating an agreement under this Section 9.5(b) (Third Party Intellectual Property Rights).

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, in the case of MEI, with respect to the Product outside the Territory, without the prior written consent of such other Party, which shall not be unreasonably withheld. Notwithstanding the above, KHK 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 KHK 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 in the Territory 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) KHK shall have the right to Develop, Package and Commercialize the Products in the Field in the Territory under trademarks of its choice that it registers ("**KHK Trademarks**"); provided, that KHK may not include in any such trademarks any corporate names or any reference to any products of MEI or any of its Affiliates or licensees without the prior written consent of MEI. In addition, KHK shall have an option to select trademark(s) registered or created by MEI ("**MEI Trademarks**") for use with the Product and MEI shall grant KHK 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 the Territory during the Term. In connection with the foregoing, upon KHK's reasonable request from time-to-time, MEI shall provide KHK 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 KHK decides to be licensed MEI Trademarks to Develop, Package and Commercialize the Product in the Field in the Territory, KHK 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 (KATAKANA character trademark) registered, filed, maintained and renewed in the Territory at MEI's cost upon KHK's request, and shall keep KHK reasonably informed of the completion of such registration process and provide KHK with updated list of registration numbers for such MEI Trademarks in the Territory. KHK acknowledges and agrees that it has no rights to the KHK Trademarks outside of the Territory and that, as between the Parties, MEI is free to use the KHK Trademarks outside of the Territory. In addition, MEI will have the right to use the KHK Trademark in the Territory to the extent necessary to perform its obligations under this Agreement.

(b) In the event that either MEI or KHK becomes aware of any infringement or threatened infringement by a Third Party of any MEI Trademark or KHK Trademark in the Territory ("**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 KHK 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. KHK shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and KHK 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 the Territory, each party shall discuss possible action against the Trademark Infringement.

(ii) KHK shall have the right, as between KHK 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 KHK Trademarks, at its own expense and by counsel of its own choice.

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 in each Party's Respective Territory.

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 (in the case of KHK), actual or potential (sub)licensees (in the case of 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. Prior to any publication or public disclosure of KHK Data related to the Compound or any Product, including any peer reviewed manuscripts disclosing the results of studies carried out under this Agreement, KHK shall provide MEI with the opportunity to review and comment on such proposed publication at least **[*CONFIDENTIAL*]** prior to its intended submission for publication or public disclosure. MEI shall review any proposed publication and shall respond in writing to KHK within **[*CONFIDENTIAL*]** after receipt of the proposed disclosure with comments, if any. KHK shall: (i) consider in good faith any comments thereto provided by MEI; (ii) remove any Confidential Information of MEI identified by MEI as part of its review; and (iii) delay such publication or public disclosure for an additional **[*CONFIDENTIAL*]** (at MEI's request and dated from the date of such request) to enable filing of Patents. For clarity, KHK has no right to publish anything related to the Compound or Product except for KHK Data. Prior to any peer-reviewed publication related to the Compound or any Product by MEI, including any peer reviewed manuscripts disclosing the results of studies carried out by MEI, MEI shall provide KHK at least **[*CONFIDENTIAL*]** with the opportunity to review and comment on such proposed publication and MEI shall consider in good faith any comments thereto provided by KHK.

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 KHK, 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, KHK 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

the 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 law. Notwithstanding the above, (a) 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 (b) KHK 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 KHK 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, KHK 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 KHK 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 KHK'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 KHK 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 KHK that KHK 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 Product-by-Product basis, until the expiration of the Royalty Term for such Product (the "**Term**"). If this Agreement naturally expires (as opposed to ending earlier due to an affirmative exercise of a Party's termination right), then KHK shall have **[*CONFIDENTIAL*]**, fully paid-up, royalty-free and perpetual license to Develop, Package, Manufacture and Commercialize the Product in the Territory; provided, that, in the event that KHK uses or has its Sublicensee(s) or designee use any trademark of the Product Controlled by MEI after the Term to Commercialize and Manufacture (if KHK's option is exercised) the Product in the Territory (other than in connection with a Generic Product, which use with a Generic Product is prohibited), KHK shall pay to MEI **[*CONFIDENTIAL*]** of Net Sales in the Territory as a trademark royalty, and MEI shall be responsible for maintenance of such 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, Sections 8.4 (Royalty Payments)-8.9 (Financial Records and Audit) (inclusive) shall apply mutatis mutandis with respect to the payments due).

11.2 Termination.

(a) Termination by KHK for Convenience. At any time, KHK may terminate this Agreement, 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 at least one hundred eighty (180) days after the date of the notice if the notice is given.

(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 the allegedly breaching Party fails to cure that breach within the applicable

period set forth above, then the Party originally delivering the notice of breach may terminate this Agreement on written notice of termination. 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 14.9 (Dispute Resolution) with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Section 14.9 (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 14.9 (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 KHK if KHK 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 KHK fails to pay MEI the upfront payment set forth in Section 8.1 (Upfront Payment), this Agreement will automatically and immediately terminate.

(f) Termination for Force Majeure. Each Party shall have the right to terminate this Agreement upon written notice to the other Party if an event of force majeure (in accordance with Section 14.6 (Force Majeure)) prevents, prohibits, or otherwise inhibits such other Party from performing its obligations hereunder for a period of six (6) months.

(g) Termination Related to GDPR Agreement. Consistent with Section 7(f) of the GDPR Agreement, if KHK's ability to meet the obligations and assurances as set out under the GDPR Agreement cannot be restored by reasonable and appropriate means following KHK's notice provided under Section 7(f) of the GDPR Agreement, then MEI shall have the right to terminate this Agreement upon written notice to KHK.

11.3 Effect of Termination. Upon termination of this Agreement by KHK pursuant to Section 11.2(a) (Termination by KHK for Convenience) or 11.2(f) (Termination for Force Majeure), or termination of this Agreement by MEI pursuant to Section 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 and shall be effective as of the effective date of such termination:

(a) KHK's license under Section 2.1 (Licenses to KHK) shall terminate;

(b) KHK hereby grants to MEI, **[*CONFIDENTIAL*]**, royalty free, fully paid, worldwide, perpetual and irrevocable license, with the right to grant sublicenses through multiple tiers, under the KHK Data and KHK Technology, to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize the Compound and Products;

(c) KHK shall return to MEI or destroy, at MEI's election, all Confidential Information of MEI, including all copies thereof and all materials, substances and compositions delivered or provided by MEI to KHK, provided that KHK shall have the right to retain **[*CONFIDENTIAL*]** copy thereof, which may be retained by KHK solely for legal archiving purposes;

(d) KHK 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 and provide MEI with all correspondence with Regulatory Authorities related to such Regulatory Materials and Regulatory Approval;

(e) KHK shall disclose to MEI all KHK Know-How 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 addition, KHK shall, at MEI's request, provide reasonable technical assistance and transfer all KHK Know-How and Joint Inventions necessary to Package or Manufacture Compounds and Products to MEI or its designee;

(f) KHK 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 (provided, that, if MEI does not desire to take over control of any given ongoing Clinical Trial(s), then KHK shall be responsible for winding-down such trials as soon as possible in accordance with Applicable Law and industry standards.

(g) KHK 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**"), 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 KHK (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 KHK's expense, and if any such consent cannot be obtained with respect to a Product Agreement, KHK shall, and shall cause its Affiliates and its and their Sublicensees to cooperate, 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) KHK shall transfer to MEI all units of Compound and Product in its possession at no cost; and

(i) KHK shall, if applicable, and hereby does, effective on such termination, assign to MEI all of KHK's and its Affiliates' right, title and interest in and to the KHK Trademarks used by KHK and its Affiliates in the Territory in connection with its Development, Packaging, or Commercialization of Products (excluding any such trademarks that include, in whole or part, any corporate name or logo of KHK or its Affiliates), including all goodwill therein, and KHK 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 KHK. If KHK is entitled to terminate this Agreement under Section 11.2(b) (Termination for Cause) as a result of an uncured material breach by MEI, KHK may elect to terminate or continue this Agreement. If KHK elects to terminate this Agreement under Sections 11.2(b) (Termination for Cause), or 11.2(d) (Termination for Bankruptcy), the following consequences shall apply and shall be effective as of the effective date of such termination. MEI shall compensate KHK any costs and expenses incurred by KHK, or its Affiliates in connection with performing any of the activities contemplated under Section 11.4 (Effect of Termination for Cause by KHK). If KHK elects to continue this Agreement, the rights and licenses granted by MEI to KHK under this Agreement shall continue, subject to KHK's related obligation hereunder:

(a) KHK's license under Section 2.1 (Licenses to KHK) shall terminate;

(b) the Receiving Party shall return to the Disclosing Party or destroy, at the Disclosing Party's election, all Confidential Information 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;

(c) KHK shall, at KHK's election, withdraw Regulatory Approvals for any Compound and Product in the Territory or, with MEI's prior written consent, assign to MEI all 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

(d) KHK shall transfer to MEI and MEI shall purchase all units of Compound and Product which are intended for sale in the Territory at a price equal to KHK'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 (Financial Provisions) (but not Section 8.10 (Financial Adjustments) and only with respect to amounts 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 2.5 (No Implied Licenses; Negative Covenant), 2.7 (Non-Compete) (to the extent applicable), 4.4 (Development Costs) (with respect to amounts incurred or otherwise due or accruing on or prior to expiration or termination), 5.4 (Regulatory Inspections for Improper Activities), 9.1(d)(i) (License to MEI), 11.3 (Effect of Termination) or 11.4 (Effect of Termination for Cause by KHK) as applicable, this 11.5 (Survival), and 11.6 (Termination Not Sole Remedy), hereof shall survive the expiration or termination of this Agreement. Notwithstanding the foregoing, with respect to the survival of **[*CONFIDENTIAL*]** solely in the event that this Agreement is terminated by KHK pursuant to Section 11.2(b) (Termination for Cause) or 11.2(d) (Termination for Bankruptcy), the Parties shall promptly negotiate in good faith **[*CONFIDENTIAL*]**; provided, that, (i) 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 14.9 (Dispute Resolution), and (ii) at any time MEI shall have the right to terminate **[*CONFIDENTIAL*]** upon written notice to KHK and to forego paying **[*CONFIDENTIAL*]**.

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 Development 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 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.

12.3 Representations and Warranties by MEI. MEI represents and warrants to KHK 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 exclusive license granted to KHK under Section 2.1 (Licenses to KHK);

(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 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;

(d) 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

(e) the patents and patent applications listed on Schedule 1.72 constitute all existing MEI Patents as of the Effective Date.

12.4 Representations and Warranties by KHK. KHK represents and warrants to MEI as of the Effective Date that:

(a) KHK has received satisfactory responses from MEI to each specific written request for information, in connection with the execution of this Agreement, made by KHK prior to the Effective Date;

(b) KHK'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 or (to the extent KHK's Manufacturing Option is exercised) Manufactured by, or under authority of, KHK 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. KHK 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 KHK, its Affiliates and Sublicensees, and their respective officers, directors, agents and employees ("**KHK Indemnitees**") harmless from and against any Claims against them to the extent arising or resulting from:

(a) the use, Development, Packaging, Manufacture, Commercialization, handling, storage or other disposition by or on behalf of MEI (other than by any KHK Indemnitees) or any of its Affiliates or Third Party licensees (excluding Sublicensees) of any Compound or Product outside the Territory, including any product liability claim outside the Territory;

(b) any product liability claim in the Territory resulting from a defect in the manufacturing of Compound or Product supplied by or on behalf of MEI for the Territory;

(c) the gross negligence or willful misconduct of any of the MEI Indemnitees; and

(d) any material breach by MEI of this Agreement.

except in each case, to the extent such Claims result from the material breach by KHK of any covenant, representation, warranty or other agreement made by KHK in this Agreement or the negligence or willful misconduct of any KHK Indemnitee. Notwithstanding the above, MEI will have no obligation to defend or indemnify KHK or its Affiliates for any claim brought by a shareholder or a class of shareholders of KHK 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 KHK. KHK shall indemnify and hold MEI, its Affiliates and (sub)licensees, 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) the use, Development, Packaging, Manufacture (only if KHK's Manufacturing Option has been exercised), Commercialization, handling, storage or other disposition by or on behalf of KHK or any of its Affiliates or Sublicensees of any Compound or Product in the Field in or for the Territory, including any product liability claim in the Territory that is not subject to MEI's indemnification obligations under Section 13.1(b) (Indemnification by MEI); or

(b) the gross negligence or willful misconduct of any of the KHK Indemnitees; or

(c) the material breach by KHK 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, KHK 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, but not limited to, 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 KHK 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 KHK) (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 KHK) as to any claim, pending resolution of the dispute pursuant to Section 14.9 (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 KHK) upon resolution of the underlying claim.

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 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 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 GDPR Agreement shall be governed by and construed in accordance with the laws identified therein.

14.2 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 14.2 (Assignment) shall be null and void.

14.3 Entire Agreement; Modification. 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.

14.4 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.

14.5 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.

14.6 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.

14.7 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.

14.8 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

Attention: CEO

If to KHK:

Kyowa Hakko Kirin Co., Ltd.

1-9-2 Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan

Attention: Director, Business Development Department

14.9 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 14.9(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 designated senior executives of the Parties for resolution. The initial designated senior executives shall be the Head of Business Development Department of KHK and Chief Operating Officer of MEI. Each Party shall be entitled to name substitute senior executives upon written notice to the other Party.

(b) Except as expressly set forth in Section 14.9(h) (Dispute Resolution), if, after going through this procedure, 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 14.9(g) (Dispute Resolution) shall be finally resolved 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 thirty (30) days 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 thirty (30) days 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 14.9 (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.

14.10 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.

14.11 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.

14.12 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.

14.13 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".

14.14 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.

14.15 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.

14.16 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.

14.17 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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*A request for confidential treatment has been made with respect to portions of the following document that are marked with [*CONFIDENTIAL*]. The redacted portions have been filed separately with the SEC.*

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

KYOWA HAKKO KIRIN CO., LTD.

By: /s/ Masashi Miyamoto, Ph.D.

Name: Masashi Miyamoto, Ph.D.

Title: President & Chief Operating Officer

Date: October 31, 2018

MEI PHARMA, INC.

By: /s/ Daniel P. Gold, Ph.D.

Name: Daniel P. Gold, Ph.D.

Title: President & Chief Executive Officer

Date: October 31, 2018

*A request for confidential treatment has been made with respect to portions of the following document that are marked with [*CONFIDENTIAL*]. The redacted portions have been filed separately with the SEC.*

LIST OF SCHEDULES

- Schedule 1.30 (Compound Structure)
- Schedule 1.72 (MEI Patents)
- Schedule 2.4 (Transfer Plan)
- Schedule 4.2 (Development Plan)
- Schedule 5.9 (Data Protection Agreement)
- Schedule 6.1 (Development Supply)
- Schedule 10.6 (Joint Press Release)

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Schedule 1.30

Compound Structure [ONE PAGE HAS BEEN REDACTED]

[*CONFIDENTIAL*]

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Schedule 1.72

MEI Patents [13 PAGES HAVE BEEN REDACTED]

[*CONFIDENTIAL*]

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Schedule 2.4

Transfer Plan

MEI, at its own cost and expense, shall disclose and make available to KHK the MEI Know-How in accordance with the following timeline. Additional transfer of MEI Know-How which are necessary for Development in the Field in the Territory, and that are not listed in this Transfer Plan will be disclosed upon reasonable request by KHK and MEI will use Commercially Reasonable Efforts to disclose and make available such MEI Know-How to KHK during the Term.

[*CONFIDENTIAL*]

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Schedule 4.2

Development Plan

Version: 0.0 (Initial)

Effective date of the Development Plan: Effective Date of the Agreement

[*CONFIDENTIAL*] [THREE PAGES HAVE BEEN REDACTED]

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Schedule 5.9

GDPR JOINT CONTROLLER AND ONWARD TRANSFER AGREEMENT

1. **Kyowa Hakko Kirin Co. Ltd. ("KHK")** and **MEI Pharma, Inc. ("MEI")** will both act as a "**joint controller**" with respect to the "**Personal Data**" (terms as defined under Art. 26 and 4 (1) EU Regulation 2016/679 ("GDPR")) and any other applicable data protection, data privacy and data security laws applicable in the jurisdictions in the EU/EEA or Switzerland (together the "**Data Protection Laws**") where either or both of the Parties are performing medical studies, and the Personal Data are provided to the Parties, or are made accessible under the terms of the License, Development and Commercialization Agreement , dated as of October 31, 2018 (the "License Agreement" (to which this Schedule 5.9 is attached)) for the studies related to MEI's proprietary compound, ME-401 (each a "Study").

2. Except as provided in the License Agreement, KHK shall not engage any processors to process any Personal Data or share the Personal Data with any other third party without the prior specific or general written authorization of MEI.

3. MEI's Privacy Representative, DPO Consultancy LLC, Reitscheweg 37, 5237 BB 's-Hertogenbosch, The Netherlands, is hereby designated as contact point for all data subjects and regulatory inquiries under this GDPR Data Joint Controller and Onward Transfer Agreement and Data Protection Laws.

4. KHK and MEI both shall always comply with Data Protection Laws as applicable to joint controllers as defined by Art. 26 GDPR and shall, in particular, fully comply with the following provisions:

   (a) keep the Personal Data confidential in accordance with the License Agreement and applicable Data Protection Laws;

   (b) take all appropriate technical and organisational measures necessary to ensure that Personal Data are protected against loss, destruction and damage, unauthorised access, use, modification, disclosure or other misuse and, at a minimum, comply with MEI's Privacy Notice available at http://www.meipharma.com/privacy-notice;

   (c) use the Personal Data obtained as a result of the License Agreement only for the purposes permitted in the License Agreement and/or by Data Protection Laws and for no other purposes;

   (d) ensure that only persons authorised by the joint controller have access to Personal Data and ensure the reliability of the persons who will be approved by the joint controller to have

access to Personal Data and who otherwise process the Personal Data;

(e) notify each other immediately (within 24 hours) on becoming aware of a breach of its obligations as a joint controller, and/or any actual, threatened, alleged or suspected data security incident involving the actual or alleged or threatened unlawful access, loss, destruction, restriction, anonymization and/or deletion of Personal Data; further, each joint controller must keep records of processing activities it provided to the other joint controller;

(f) provide reasonable and prompt assistance with requests of the other joint controller in the management of any actual, threatened, alleged or suspected, data security incident where the assistance of the joint controller is reasonably requested;

(g) provide reasonable and prompt assistance with requests of a joint controller to enable it to comply with its obligations of providing access to Personal Data, restriction, anonymization, deletion and/or rectification of Personal Data under the Data Protection Laws; and

(h) allow the other joint controller or its representatives to audit its processing operations, systems and/or facilities where reasonably required by the requesting joint controller to assess the other joint controller's compliance with this GDPR Data Joint Controller and Onward Transfer Agreement and/or, at the requesting joint controller's option, promptly and fully co-operate and respond to all requests of the requesting joint controller for information to demonstrate the other joint controller's compliance with this GDPR Data Joint Controller and Onward Transfer Agreement and Data Protection Laws. The requesting joint controller shall pay for the costs of any third party it may engage to conduct an audit, unless in the case of a data security breach at the other joint controller receiving such request.

5. On the termination of the License Agreement, howsoever arising, KHK shall return all copies of the Personal Data to MEI, or, at MEI's specific and written request, delete all copies of the Personal Data subject to applicable legal obligations on each joint controller to retain any such documents containing Personal Data (in which event the other joint controller shall restrict the access to and processing of such Personal Data to the extent necessary to meet the requirements of such legally required obligations).

6. The License Agreement between the parties shall remain valid and in full force. In case of a conflict between the License Agreement and this GDPR Data Joint Controller and Onward Transfer Agreement, this GDPR Data Joint Controller and Onward Transfer Agreement shall govern.

7. For the Personal Data that KHK will receive from MEI, or to which MEI will grant KHK access, the following provisions shall apply:

a. KHK is obligated to provide at least the same level of privacy protection for the Personal Data received from MEI as is required by the EU-US and Swiss US Privacy Shield Principles ("Privacy Shield Principles"). This obligation shall apply at all times when Personal Data is transferred from the EU, EEA and/or Switzerland to MEI, either directly or via onward transfer. A summary of the Privacy Shield Principles is attached as **APPENDIX** to this GDPR Data Joint Controller and Onward Transfer Agreement. A more detailed description is available at www.privacyshield.gov.

b. KHK may only process Personal Data for the limited and specific purposes consistent with the License Agreement and shall Process Personal Data through the performance of its obligations under the License Agreement.

c. KHK will take reasonable and appropriate technical and organizational security measures to protect the Personal Data received from MEI from loss, misuse and unauthorized access, disclosure, alteration and destruction, taking into due account the risks involved in the processing and the nature of the Personal Data. KHK will regularly monitor compliance with the safeguards in this Section 8 and the Appendix. KHK will not decrease its overall security efforts during the term of the License Agreement.

d. KHK will cooperate and take reasonable and appropriate steps to ensure that the Personal Data are processed in a manner consistent with MEI's obligations pursuant the Privacy Shield Principles. In particular, KHK will

   i. reasonably respond to all inquiries from MEI relating to the processing of Personal Data subject to this GDPR Data Joint Controller and Onward Transfer Agreement;

   ii. fully cooperate with audit procedures, whereby audit procedures may not infringe on KHK's contractual confidentiality obligations towards third parties.

e. KHK will reasonably assist MEI in responding to individuals exercising their rights under the Privacy Shield Principles and in case of complaints MEI receives under its Privacy Shield certification without directly responding to such requests by individuals, unless it has been otherwise authorised to do so. KHK will inform MEI about any legally binding request for disclosure of Personal Data received from MEI unless applicable law prohibits such information.

f. KHK will notify MEI in writing and without undue delay if it makes a determination that it can no longer meet the obligations and assurances as set out under this GDPR Data Joint Controller and Onward Transfer Agreement. When such a determination is made, KHK will assist MEI with any reasonable and appropriate steps to stop and remediate unauthorized processing of Personal Data. If KHK's ability to meet the obligations and assurances as set out under this GDPR Data Joint Controller and Onward Transfer

Agreement cannot be restored by reasonable and appropriate means, MEI shall have the right to terminate the License Agreement pursuant to Section 11.2(g) of the License Agreement.

g. If KHK processes Personal Data on behalf of MEI in a manner that is inconsistent with the Privacy Shield Principles, KHK will indemnify MEI for any damages incurred should MEI be held liable by an individual or entity, unless KHK demonstrates that it is not responsible for the event giving rise to the damages.

8. This Joint Controller and Onward Transfer 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, unless mandatory Data Protection Law applies. Section 14.9 of the License Agreement (Dispute Resolution) shall also apply to any disputes between the Parties related to this Joint Controller and Onward Transfer Agreement.

*A request for confidential treatment has been made with respect to portions of the following document that are marked with [*CONFIDENTIAL*]. The redacted portions have been filed separately with the SEC.*

IN WITNESS WHEREOF, the parties hereto have executed or caused this GDPR Data Joint Controller and Onward Transfer Agreement to be executed as of the day, month and year first below written.

MEI PHARMA, INC.

By: _____
Print Name: David M. Urso
Title: SVP Corporate Development, COO & General Counsel

Date: _____
Address: 3611 Valley Centre Drive, Suite 500
San Diego, CA 92130, USA

KYOWA HAKKO KIRIN CO. LTD.

By: _____
Print Name: Satoshi Nakanishi
Title: Director, Corporate Social Responsibility Management Department

Date: _____
Address: 1-9-2 Otemachi, Chiyoda-ku,
Tokyo 100-0004, Japan

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APPENDIX TO SCHEDULE 5.9

Summary of the Privacy Shield Principles ("Principles")

(see www.privacyshield.gov for further information:
https://www.privacyshield.gov/servlet/servlet.FileDownload?file=015t00000004qAg = and EU- U.S. Privacy Shield Framework

https://www.trade.gov/td/services/odsi/swiss-us-privacyshield-framework.pdf = Swiss-U.S. Privacy Shield Framework – together the "Framework")

Introduction:

The Principles state:

Sec 3. ACCOUNTABILITY FOR ONWARD TRANSFER

"a. To transfer personal information to a third party acting as a controller, organizations must comply with the Notice and Choice Principles. Organizations must also enter into a contract with the third-party controller that provides that such data may only be processed for limited and specified purposes consistent with the consent provided by the individual and that the recipient will provide the same level of protection as the Principles and will notify the organization if it makes a determination that it can no longer meet this obligation. The contract shall provide that when such a determination is made the third party controller ceases processing or takes other reasonable and appropriate steps to remediate."

Sec. 10 c (i):

"For transfers between controllers, the recipient controller need not be a Privacy Shield organization or have an independent recourse mechanism. The Privacy Shield organization must enter into a contract with the recipient third-party controller that provides for the same level of protection as is available under the Privacy Shield, not including the requirement that the third party controller be a Privacy Shield organization or have an independent recourse mechanism, provided it makes available an equivalent mechanism."

The following text, based on the wording of the US Department of Commerce posted at https://www.privacyshield.gov/article?id=Requirements-of-Participation, describes the obligations of KHK as the recipient (third party) controller for the Personal Data under the Framework, in particular under its cited Sections 3 (a) and 10 c (i):

1. NOTICE

a. An organization must inform individuals about:

i. the types of personal data collected and, where applicable, the entities or subsidiaries of the organization also adhering to the Principles,

ii. its commitment to subject to the Principles all personal data received from the EU in reliance on the Privacy Shield,

iii. the purposes for which it collects and uses personal information about them,

iv. how to contact the organization with any inquiries or complaints, including any relevant establishment in the EU that can respond to such inquiries or complaints,

v. the type or identity of third parties to which it discloses personal information, and the purposes for which it does so,

vi. the right of individuals to access their personal data,

vii. the choices and means the organization offers individuals for limiting the use and disclosure of their personal data,

viii. an equivalent recourse designated to address complaints and provide appropriate recourse free of charge to the individual,

ix. the requirement to disclose personal information in response to lawful requests by public authorities, including to meet national security or law enforcement requirements, and

x. its liability in cases of onward transfers to third parties.

b. This notice must be provided in clear and conspicuous language when individuals are first asked to provide personal information to the organization or as soon thereafter as is practicable, but in any event before the organization uses such information for a purpose other than that for which it was originally collected or processed by the transferring organization or discloses it for the first time to a third party.

2. CHOICE

a. An organization must offer individuals the opportunity to choose (opt out) whether their personal information is (i) to be disclosed to a third party or (ii) to be used for a purpose that is materially different from the purpose(s) for which it was originally collected or subsequently authorized by the individuals. Individuals must be provided with clear, conspicuous, and readily available mechanisms to exercise choice.

b. By derogation to the previous paragraph, it is not necessary to provide choice when disclosure is made to a third party that is acting as an agent to perform task(s) on behalf of and under the instructions of the organization. However, an organization shall always enter into a contract with the agent.

c. For sensitive information (i.e., personal information specifying medical or health conditions, racial or

ethnic origin, political opinions, religious or philosophical beliefs, trade union membership or information specifying the sex life of the individual), organizations must obtain affirmative express consent (opt in) from individuals if such information is to be (i) disclosed to a third party or (ii) used for a purpose other than those for which it was originally collected or subsequently authorized by the individuals through the exercise of opt-in choice. In addition, an organization should treat as sensitive any personal information received from a third party where the third party identifies and treats it as sensitive.

3. ACCOUNTABILITY FOR ONWARD TRANSFER

a. To transfer personal information to a third party acting as a controller, organizations must comply with the Notice and Choice Principles (Sections 1 and 2 above). Organizations must also enter into a contract with the third-party controller that provides that such data may only be processed for limited and specified purposes consistent with the consent provided by the individual and that the recipient will provide the same level of protection as the Principles and will notify the organization if it makes a determination that it can no longer meet this obligation. The contract shall provide that when such a determination is made the third party controller ceases processing or takes other reasonable and appropriate steps to remediate.

b. To transfer personal data to a third party acting as an agent, organizations must: (i) transfer such data only for limited and specified purposes; (ii) ascertain that the agent is obligated to provide at least the same level of privacy protection as is required by the Principles; (iii) take reasonable and appropriate steps to ensure that the agent effectively processes the personal information transferred in a manner consistent with the organization's obligations under the Principles; (iv) require the agent to notify the organization if it makes a determination that it can no longer meet its obligation to provide the same level of protection as is required by the Principles; (v) upon notice, including under (iv), take reasonable and appropriate steps to stop and remediate unauthorized processing; and (vi) provide a summary or a representative copy of the relevant privacy provisions of its contract with that agent to the US Department of Commerce upon request.

4. SECURITY

a. Organizations creating, maintaining, using or disseminating personal information must take reasonable and appropriate measures to protect it from loss, misuse and unauthorized access, disclosure, alteration and destruction, taking into due account the risks involved in the processing and the nature of the personal data.

5. DATA INTEGRITY AND PURPOSE LIMITATIONS

a. Consistent with the Principles, personal information must be limited to the information that is relevant for the purposes of processing. An organization may not process personal information in a way

that is incompatible with the purposes for which it has been collected or subsequently authorized by the individual. To the extent necessary for those purposes, an organization must take reasonable steps to ensure that personal data is reliable for its intended use, accurate, complete, and current. An organization must adhere to the Principles for as long as it retains such information.

b. Information may be retained in a form identifying or making identifiable the individual only for as long as it serves a purpose of processing within the meaning of 5a. This obligation does not prevent organizations from processing personal information for longer periods for the time and to the extent such processing reasonably serves the purposes of archiving in the public interest, journalism, literature and art, scientific or historical research, and statistical analysis. In these cases, such processing shall be subject to the other Principles and provisions of the Framework. Organizations should take reasonable and appropriate measures in complying with this provision.

2. Depending on the circumstances, examples of compatible processing purposes may include those that reasonably serve customer relations, compliance and legal considerations, auditing, security and fraud prevention, preserving or defending the organization's legal rights, or other purposes consistent with the expectations of a reasonable person given the context of the collection.

3. In this context, if, given the means of identification reasonably likely to be used (considering, among other things, the costs of and the amount of time required for identification and the available technology at the time of the processing) and the form in which the data is retained, an individual could reasonably be identified by the organization, or a third party if it would have access to the data, then the individual is "identifiable."

6. ACCESS

Individuals must have access to personal information about them that an organization holds and be able to correct, amend, or delete that information where it is inaccurate, or has been processed in violation of the Principles, except where the burden or expense of providing access would be disproportionate to the risks to the individual's privacy in the case in question, or where the rights of persons other than the individual would be violated.

7. RECOURSE, ENFORCEMENT AND LIABILITY

a. Effective privacy protection must include robust mechanisms for assuring compliance with the Principles, recourse for individuals who are affected by non-compliance with the Principles, and consequences for the organization when the Principles are not followed. At a minimum such mechanisms must include:

i. readily available recourse mechanisms by which each individual's complaints and disputes are investigated and expeditiously resolved;

ii. follow-up procedures for verifying that the attestations and assertions organizations make about their privacy practices are true and that privacy practices have been implemented as presented and, in particular, with regard to cases of non-compliance; and

iii. obligations to remedy problems arising out of failure to comply with the Principles by organizations announcing their adherence to them and consequences for such organizations. Sanctions must be sufficiently rigorous to ensure compliance by organizations.

b. Organizations will respond promptly to inquiries and requests by the Department for information relating to the Privacy Shield. All organizations must respond expeditiously to complaints regarding compliance with the Principles referred by EU Member State authorities through the Department. Organizations that have chosen to cooperate with DPAs, including organizations that process human resources data, must respond directly to such authorities with regard to the investigation and resolution of complaints.

c. In the context of an onward transfer, a Privacy Shield organization has responsibility for the processing of personal information it receives under the Privacy Shield and subsequently transfers to a third party acting as an agent on its behalf. The Privacy Shield organization shall remain liable under the Principles if its agent processes such personal information in a manner inconsistent with the Principles, unless the organization proves that it is not responsible for the event giving rise to the damage.

* * *

*A request for confidential treatment has been made with respect to portions of the following document that are marked with [*CONFIDENTIAL*]. The redacted portions have been filed separately with the SEC.*

Schedule 6.1

Development Supply

1. Manufacturer locations

   [*CONFIDENTIAL*]

2. Timing of initial supply

   [*CONFIDENTIAL*]

3. Amount and forms of Supply Items for initial supply

   [*CONFIDENTIAL*]

*A request for confidential treatment has been made with respect to portions of the following document that are marked with [*CONFIDENTIAL*]. The redacted portions have been filed separately with the SEC.*

Schedule 10.6

Joint Press Release

MEI Pharma and Kyowa Hakko Kirin Announce License Agreement to Develop and Commercialize ME-401 in Japan

MEI to Receive $10 Million Upfront Payment, Plus Milestones and Tiered Royalty Payments

SAN DIEGO, and TOKYO, November 5, 2018 – MEI Pharma, Inc. (NASDAQ: MEIP) and Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, "Kyowa Hakko Kirin"), today announced the execution of a license development and commercialization agreement ("License Agreement") granting Kyowa Hakko Kirin exclusive rights to develop and commercialize ME-401 in Japan. ME-401 is MEI's phosphatidylinositol 3-kinase ("PI3K") delta inhibitor being developed by MEI for the treatment of patients with B-cell malignancies. MEI is planning to initiate a Phase 2 study to evaluate patients with follicular lymphoma that is intended to support an accelerated approval marketing application with the U.S. Food and Drug Administration.

Under the terms of the License Agreement, MEI will receive a $10 million upfront payment and is eligible to receive additional development and commercialization milestones totaling up to $87.5 million. MEI is also eligible to receive tiered double-digit royalties extending into the mid-teens. The agreement grants Kyowa Hakko Kirin exclusive rights to ME-401 to develop and commercialize ME-401 in Japan. The initial indication for development and regulatory approval under the agreement is relapsed or refractory follicular lymphoma.

"Kyowa Hakko Kirin is a well-regarded leader in the development and commercialization of hematology and oncology therapies in Japan," said David M. Urso., J.D., Chief Operating Officer of MEI Pharma. "This agreement is important for MEI as an opportunity to expand the development of ME-401 as a potential best-in-class PI3K delta inhibitor outside of the U.S. and is consistent with our strategy to optimize value through partnering opportunities abroad while developing capabilities for domestic commercialization."

"I am delighted to enter into an agreement with MEI Pharma for the development and commercialization of ME-401 in Japan," said Wataru Murata, Executive Officer, Director of Corporate Strategy & Planning Department. "We believe that ME-401 will be an important drug candidate in our oncology pipeline."

Kyowa Hakko Kirin plans to initiate a Phase 1 study in Japan in 2019.

About ME-401 ME-401 is an investigational oral phosphatidylinositol 3-kinase ("PI3K") delta inhibitor; PI3K delta is often overexpressed in cancer cells and plays a key role in the proliferation and survival of hematologic cancer cells. ME-401 displays high selectivity for the PI3K delta isoform and has distinct pharmaceutical properties from other PI3K delta inhibitors. It is being clinically evaluated in patients with various B-cell malignancies. MEI is initiating a Phase 2 study to evaluate the efficacy, safety, and tolerability of ME-401 as a single agent in patients with follicular lymphoma after failure of at least two prior systemic

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therapies including chemotherapy and an anti-CD20 antibody. The Phase 2 study is intended to support an accelerated approval marketing application with the U.S. Food and Drug Administration.

About MEI Pharma, Inc.

MEI Pharma, Inc. (Nasdaq: MEIP) is a San Diego-based pharmaceutical company focused on leveraging its extensive development and oncology expertise to identify and advance new therapies for cancer. The Company's portfolio of drug candidates includes pracinostat, an oral HDAC inhibitor that is partnered with Helsinn Healthcare, SA. Pracinostat has been granted Breakthrough Therapy Designation from the U.S. Food and Drug Administration for use in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are unfit for intensive chemotherapy. Pracinostat is also being developed in combination with azacitidine for the treatment of patients with high and very high-risk myelodysplastic syndrome (MDS). MEI Pharma's clinical development pipeline also includes ME-401, a highly differentiated oral PI3K delta inhibitor currently in a Phase 1b study in patients with relapsed refractory follicular lymphoma or CLL, and voruciclib, an oral, selective CDK inhibitor shown to suppress MCL1, a known mechanism of resistance to BCL2 inhibitors. The Company is also developing ME-344, a novel mitochondrial inhibitor currently in an investigator-initiated study in combination with bevacizumab evaluating patients with HER2-negative breast cancer. Pracinostat, ME-401, ME-344 and voruciclib are investigational agents and are not approved for use in the U.S. For more information, please visit www.meipharma.com.

About Kyowa Hakko Kirin Co., Ltd.

Kyowa Hakko Kirin Co., Ltd. is a research-based life sciences company, with special strengths in biotechnologies. In the core therapeutic areas of oncology, nephrology and immunology/allergy, Kyowa Hakko Kirin leverages leading-edge biotechnologies centered on antibody technologies, to continually discover innovative new drugs and to develop and market those drugs world-wide. In this way, the company is working to realize its vision of becoming a Japan-based global specialty pharmaceutical company that contributes to the health and wellbeing of people around the world. You can learn more about the business at: www.kyowa-kirin.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; 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 31.1

CERTIFICATION

I, Daniel P. Gold, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of MEI Pharma, Inc.;

2. Based on my knowledge, this Quarterly 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 Quarterly Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly 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 Quarterly Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly 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 Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and

   (d) disclosed in this Quarterly 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:

   (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: February 7, 2019

/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 Quarterly Report on Form 10-Q of MEI Pharma, Inc.;

2. Based on my knowledge, this Quarterly 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 Quarterly Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Quarterly 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 Quarterly Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly 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 Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Quarterly Report based on such evaluation; and

   (d) disclosed in this Quarterly 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. Our 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:

   (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: February 7, 2019

/s/ Brian G. Drazba
Brian G. Drazba
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Daniel P. Gold, the Chief Executive Officer of MEI Pharma, Inc. (the "Registrant"), and Brian G. Drazba, the Chief Financial Officer of the Registrant, each hereby certifies that, to his knowledge:

1. The Registrant's Quarterly Report on Form 10-Q for the period ended December 31, 2018, (the "Form 10-Q") to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition of the Registrant at the end of the period covered by the Form 10-Q and results of operations of the registrant for the period covered by the Form 10-Q.

These certifications accompanying the Form 10-Q 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 the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Dated: February 7, 2019

/s/ Daniel P. Gold
Daniel P. Gold
Chief Executive Officer
(Principal Executive Officer)

/s/ Brian G. Drazba
Brian G. Drazba
Chief Financial Officer
(Principal Financial Officer)