# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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			FORM 10-Q		
$\boxtimes$	QUARTERLY	REPORT PURSUANT T	TO SECTION 13 OR 15(d) OF T	- THE SECURITIES EXCHANGE ACT OF 1934	ļ
		For	r the quarterly period ended Septembe	er 30, 2016	
			OR		
	TRANSITION	REPORT PURSUANT T	TO SECTION 13 OR 15(d) OF T	THE SECURITIES EXCHANGE ACT OF 1934	1
			or the transition period from to		
			Commission File Number: 000-50		
			Commission The Number, 600-30	101	
			MEI Pharma, I		
			5 El Camino Real, Suite 101, San Dieg (Address of principal executive offices) (Zip	o, CA 92130	
			(858) 792-6300 (Registrant's telephone number, including are	ra code)	
prec		for such shorter period that the re-		on 13 or 15(d) of the Securities Exchange Act of 1934 during s), and (2) has been subject to such filing requirements for the	
subr	mitted and posted pur	whether the registrant has submitt resuant to Rule 405 of Regulation to submit and post such files). Yes	S-T (§232.405 of this chapter) during the	orate Web site, if any, every Interactive Data File required to the preceding 12 months (or for such shorter period that the	be
			ccelerated filer, an accelerated filer, a nor ler reporting company" in Rule 12b-2 of	n-accelerated filer, or a smaller reporting company. See define the Exchange Act.	itior
Larg	ge accelerated filer			Non-accelerated filer	
Acc	elerated filer	$\boxtimes$		Smaller reporting entity	
Indi	cate by check mark v	whether the registrant is a shell co	ompany (as defined in Rule 12b-2 of the	Exchange Act). Yes □ No ⊠	

As of November 8, 2016, the number of shares outstanding of the issuer's common stock, \$0.00000002 par value, was 36,772,428.

# MEI PHARMA, INC.

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# PART I FINANCIAL INFORMATION

Item 1: **Financial Statements** 

# MEI PHARMA, INC. BALANCE SHEETS (In thousands, except share and per share data)

	2(	nber 30, 016 udited)	J	June 30, 2016
ASSETS	(	,		
Current assets:				
Cash and cash equivalents	\$	13,789	\$	10,837
Short term investments		45,112	_	35,081
Total cash, cash equivalents and short-term investments		58,901		45,918
Prepaid expenses and other current assets		1,741		831
Total current assets		60,642		46,749
Intangible assets, net		357		366
Property and equipment, net		46		49
Total assets	\$	61,045	\$	47,164
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	749	\$	1,079
Accrued liabilities		2,428		4,433
Deferred revenues, current portion		14,043		_
Total current liabilities	<u></u>	17,220		5,512
Deferred revenues, less current portion		1,494		_
Total liabilities		18,714		5,512
Commitments and contingencies (Note 4)				
Stockholders' equity:				
Preferred stock, \$0.01 par value; 100,000 shares authorized; none outstanding		_		_
Common stock, \$0.00000002 par value; 113,000,000 shares authorized; 36,772,428 and 34,155,997 shares issued and outstanding at September 30, 2016 and June 30, 2016, respectively		_		_
Additional paid-in-capital	2	23,602		218,653
Accumulated deficit	(1	81,271)	(	177,001)
Total stockholders' equity		42,331		41,652
Total liabilities and stockholders' equity	\$	61,045	\$	47,164

 $See\ accompanying\ notes\ to\ the\ unaudited\ financial\ statements.$ 

# MEI PHARMA, INC. STATEMENTS OF OPERATIONS

(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		d	
		2016		2015
Revenues:				
Research and development revenue	\$	1,096	\$	
Total revenues		1,096		_
Operating expenses:			·	
Cost of research and development revenue		(1,094)		_
Research and development		(1,646)		(2,816)
General and administrative		(2,680)		(1,830)
Total operating expenses		(5,420)		(4,646)
Loss from operations		(4,324)		(4,646)
Other income (expense):				
Interest and dividend income		55		27
Income tax expense		(1)		(1)
Net loss	\$	(4,270)	\$	(4,620)
Net loss per share, basic and diluted	\$	(0.12)	\$	(0.13)
Weighted average shares outstanding—basic and diluted	35	5,747,367	34	,334,257

See accompanying notes to the unaudited financial statements.

# MEI PHARMA, INC. STATEMENTS OF CASH FLOWS

(In thousands) (Unaudited)

	Three Mon Septem	ber 30,
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (4,270)	\$ (4,620)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	737	770
Depreciation and amortization	14	15
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(910)	(94)
Accounts payable	(330)	(610)
Accrued liabilities	(2,005)	(1,222)
Deferred revenue	15,537	
Net cash provided by (used in) operating activities	8,773	(5,761)
Cash flows from investing activities:		
Purchases of property and equipment	(2)	_
Purchases of short-term investments	(20,054)	(20,125)
Proceeds from maturity of short-term investments	10,023	25,040
Net cash (used in) provided by investing activities	(10,033)	4,915
Cash flows from financing activities:		
Net proceeds from issuance of common stock	4,212	
Net cash provided by financing activities	4,212	_
Net increase (decrease) in cash and cash equivalents	2,952	(846)
Cash and cash equivalents at beginning of the period	10,837	18,722
Cash and cash equivalents at end of the period	\$ 13,789	\$ 17,876

 $See\ accompanying\ notes\ to\ the\ unaudited\ financial\ statements.$ 

# MEI PHARMA, INC. NOTES TO FINANCIAL STATEMENTS

(Unaudited)

#### Note 1. The Company

MEI Pharma, Inc., or "the Company", is an oncology company focused on the clinical development of novel therapies for cancer. The Company's common stock is listed on the Nasdaq Capital Market under the symbol "MEIP".

The Company's business purpose is the development of drugs for the treatment of cancer. The Company's portfolio of drug candidates includes Pracinostat, an oral histone deacetylase ("HDAC") inhibitor being developed in combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia ("AML") who are 3 75 years of age or unfit for intensive chemotherapy, and high-risk myelodysplastic syndrome ("MDS"). In August 2016, the Company entered into an exclusive worldwide license, development and commercialization agreement with Helsinn Healthcare SA, a Swiss pharmaceutical corporation ("Helsinn") for Pracinostat in AML, MDS, and other potential indications ("Helsinn License Agreement"). The Company's clinical development portfolio also includes ME-401, an oral inhibitor of phosphatidylinositide 3-kinase ("PI3K") delta currently in a Phase Ib study in patients with recurrent chronic lymphocytic leukemia ("CLL") or follicular non-Hodgkin's lymphoma ("fNHL"), and ME-344, a mitochondrial inhibitor currently in an investigator-sponsored study in combination with bevacizumab for the treatment of human epidermal growth factor receptor 2 ("HER2")-negative breast cancer. The Company owns exclusive worldwide rights to ME-401 and ME-344.

#### **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. The Company has 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, 2016, included in the Company's Annual Report on Form 10-K ("2016 Annual Report") filed with the Securities and Exchange Commission ("SEC") on September 9, 2016. 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. The Company uses estimates that affect the reported amounts (including assets, liabilities, revenues and expenses) and related disclosures. Actual results could materially differ from those estimates. During the quarter ended September 30, 2016, the Company recorded an adjustment of \$1.0 million to reduce accrued expenses related to clinical trials that were at or near completion for Pracinostat and ME-344 to reflect revised amounts expected to be invoiced upon final billing from third party vendors.

# Revenue Recognition

The Company may generate revenues from licensing technology rights and from the conduct of research and development activities as part of the Helsinn License Agreement. The Company recognizes revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the Company's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured.

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. The Company considers a variety of factors in determining the appropriate method of accounting under its license agreements, including whether the various elements can be separated and accounted for individually as separate units of accounting. Deliverables under an arrangement will be separate units of accounting, provided (i) a delivered item has value to the customer on a standalone basis; and (ii) the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the Company's control.

#### Multiple Element Arrangements

The Company accounts for revenue arrangements with multiple elements by separating and allocating consideration according to the relative selling price of each deliverable. If an element can be separated, an amount is allocated based upon the relative selling price of each element. The Company determines the relative selling price of a separate deliverable using the price it charges other customers when it sells that element separately. If the element is not sold separately and third party pricing evidence is not available, the Company will use its best estimate of selling price.

#### License Fee Revenue

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

#### Research and Development Revenue

Research and development revenue represents ratable recognition of fees allocated to research and development activities in accordance with the Helsinn License Agreement. The Company defers recognition of research and development revenue until the performance of the related research and development activities has occurred.

#### Cost of Research and Development Revenue

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

#### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*. The standard provides companies with a single model for accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. In August 2015, the FASB issued ASU 2015-14, *Deferral of the Effective Date*, which defers the required adoption date of ASU 2014-09 by one year. As a result of the deferred effective date, ASU 2014-09 will be effective for the Company in its first quarter of fiscal 2019. Early adoption is permitted but not before the original effective date of the new standard of the first quarter of fiscal 2018. The following ASUs were subsequently issued by the FASB to clarify the implementation guidance in some areas and add practical expedients: In March 2016, ASU 2016-08, *Revenue from Contracts with Customers, Principal versus Agent Considerations*; in April 2016, ASU 2016-10, *Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing*; in May 2016, ASU 2016-11, *Revenue from Contracts with Customers and Derivatives and Hedging—Rescission of SEC Guidance*; and ASU 2016-12, *Revenue from Contracts with Customers—Narrow Scope Improvements and Practical Expedients*. The Company is in the process of evaluating the transition method that will be elected and the impact of adoption on its financial statements.

In August 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-15, *Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern* ("ASU 2014-15"). The standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. Certain disclosures will be required if conditions give rise to substantial doubt about an entity's ability to continue as a going concern. ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. Subsequent to adoption, the Company will apply the guidance in ASU 2014-15 to assess its ability to continue as a going concern.

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 are evaluating the impact that the adoption of this standard will have on our financial statements.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. We are evaluating the impact that the adoption of this standard will have on our financial statements.

In June 2016, the FASB issued No. 2016-13, Financial Instruments —Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. Topic 326 amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current U.S. GAAP and, instead, requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner similar to current U.S. GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. ASU 2016-13 affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. This update is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company is currently evaluating the impact the adoption of this standard will have on its financial statements.

# Note 2. Helsinn License Agreement

In August 2016, the Company entered into the Helsinn License Agreement. Under the terms of the agreement, Helsinn is 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, the Company received a \$15.0 million upfront payment in August 2016, and will receive a \$5.0 million payment upon the earlier of (i) dosing of the first patient in the upcoming Phase III study of Pracinostat in newly diagnosed AML patients who are  $\geq 75$  years of age or unfit to receive induction therapy or (ii) March 1, 2017. The Company will also receive reimbursement related to agreements entered into by MEI in anticipation of the upcoming Phase III study of Pracinostat by Helsinn as well as a Phase II study for Pracinostat in combination with azacitidine for the treatment of high and very high risk MDS, which will be conducted by MEI. The current expected external cost of the Phase II study will be shared equally by Helsinn and the Company. Enrollment in the Phase II study is anticipated to commence in the first half of calendar year 2017. The Company will be eligible to receive up to \$444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of Pracinostat.

The Company has determined that the exclusive license, development and commercialization agreement represents a multiple-element arrangement for purposes of revenue recognition. Revenue related to the license will be recognized upon completion of the technology and data transfer, which is expected to be completed during the second quarter of fiscal year 2017. Revenue related to research and development elements of the arrangement will be recognized ratably over the period of each research and development activity. Revenue associated with third-party costs will be recognized on a gross basis as such costs are incurred.

Contemporaneously with the Helsinn License Agreement, the Company entered into a Common Stock Purchase Agreement (the "Helsinn Equity Agreement"), dated as of August 5, 2016, with Helsinn Investment Fund SA (the "Purchaser"). Pursuant to the terms of the Equity Agreement, the Purchaser agreed to purchase and the Company agreed to issue a number of shares of the Company's common stock determined by dividing \$5,000,000 by the volume weighted-average price for shares of the Company's common stock for the ten trading day period beginning on August 1, 2016 and ending on August 12, 2016 (the "VWAP"), rounded to the nearest whole share. The VWAP was \$1.911 per share. Accordingly, on August 16, 2016, the Company issued 2,616,431 shares of common stock. The difference between the VWAP price of \$1.911 per share and the closing price of the Company's common stock on August 5, 2016 of \$1.61 of \$788,000 has been allocated to the revenue elements.

#### Note 3. Net Loss Per Share

Basic and diluted net loss per share are computed using the weighted-average number of shares of common stock outstanding during the period, less any shares subject to repurchase or forfeiture. There were no shares of common stock subject to repurchase or forfeiture for the three months ended September 30, 2016 and 2015.

Because the Company is in a net loss position, it has excluded stock options, unvested RSUs and warrants from the calculation of diluted net loss per share because these securities are antidilutive for all periods presented. As of September 30, 2016 and 2015, the number of securities excluded from the computation of diluted net loss per share totaled 8,389,808 and 6,543,678, respectively.

# Note 4. Commitments and Contingencies

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

As of September 30, 2016, the Company leases approximately 8,800 square feet of office space for the Company's executive and administrative offices. The monthly rental rate is approximately \$29,000 during the remaining term of the lease, plus a pro-rata share of certain building expenses. The lease expires in June 2017. Total future minimum payments under the lease are \$257,000 through June 30, 2017.

#### Asset Purchase Agreement

In August 2012, the Company entered into a definitive asset purchase agreement with S\*Bio Pte Ltd ("S\*Bio"), pursuant to which the Company agreed to acquire certain assets comprised of intellectual property and technology including rights to Pracinostat, in exchange for \$500,000 of common stock. In August 2012, the Company completed the asset purchase and issued 195,756 shares of common stock to S\*Bio. The Company has also agreed to make certain milestone payments to S\*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S\*Bio. Milestone payments will be made to S\*Bio up to an aggregate amount of \$75.2 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. The first milestone payment of \$200,000 payable in cash, plus \$500,000 payable in cash or in shares of the Company's common stock, will be due upon the first dosing of a patient in a Phase III clinical trial or other pivotal trial, for any indication. Subsequent milestone payments will be due upon certain regulatory approvals and sales-based events. As of September 30, 2016, the Company has accrued \$700,000 for potential future payments.

#### CyDex License Agreement

In September 2012, the Company entered into a license agreement with CyDex Pharmaceuticals, Inc. ("CyDex"). Under the license agreement, CyDex granted to the Company an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with the Company's isoflavone-based drug compounds. The Company agreed to pay to CyDex a non-refundable license issuance fee, future milestone payments, and royalties at a low, single-digit percentage on future sales of the Company's approved drugs utilizing Captisol. Contemporaneously with the license agreement, the Company and CyDex entered into a commercial supply agreement pursuant to which the Company agreed to purchase 100% of its requirements for Captisol from CyDex. The Company may terminate both the license agreement and the supply agreement for convenience at any time upon 90 days' prior written notice. As of September 30, 2016, the Company has not accrued any amounts for potential future payments.

#### **Note 5. Short-Term Investments**

As of September 30, 2016 and June 30, 2016, the Company's short-term investments consisted of \$45.1 million and \$35.1 million, respectively, in U.S. government securities. The short-term investments held as of September 30, 2016 and June 30, 2016 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 September 30, 2016 and June 30, 2016, the gross holding gains and losses were immaterial.

#### Note 6. Stockholders' Equity

#### **Equity Transactions**

Shelf Registration Statement

In April 2014, the Company filed a shelf registration statement on Form S-3 with the SEC ("shelf registration statement"). The shelf registration statement was declared effective by the SEC in April 2014. The shelf registration statement permits the Company to sell, from time to time, up to \$150.0 million of common stock, preferred stock and warrants. As of September 30, 2016, there is \$104.0 million aggregate value of securities available under the shelf registration statement. Pursuant to SEC regulations, if the market value of the Company's public float is below \$75.0 million, the Company cannot sell securities from the shelf registration statement which represent more than one-third of the market value of the Company's non-affiliated public float during any 12-month period. The market value of the Company's non-affiliated public float was less than \$75.0 million as of September 30, 2016. Accordingly, until the Company's non-affiliated public float exceeds \$75.0 million, the Company may not sell shares with a market value greater than one-third of its non-affiliated public float during any 12-month period under the shelf registration statement.

# Helsinn Equity Investment

The Company entered into a Common Stock Purchase Agreement (the "Helsinn Equity Agreement"), dated as of August 5, 2016, with Helsinn Investment Fund SA (the "Purchaser"). Pursuant to the terms of the Equity Agreement, the Purchaser agreed to purchase and the Company agreed to issue a number of shares of the Company's common stock determined by dividing \$5,000,000 by the volume weighted-average price for shares of the Company's common stock for the ten trading day period beginning on August 1, 2016 and ending on August 12, 2016 (the "VWAP"), rounded to the nearest whole share. The VWAP was \$1.911 per share. Accordingly, on August 16, 2016, the Company issued 2,616,431 shares of common stock. The transaction was exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended.

#### Warrants

As of September 30, 2016, there were outstanding warrants to purchase 315,484 shares of the Company's common stock at an exercise price of \$7.14 per share, which expire in May 2017, issued in conjunction with the Company's May 2012 rights offering; outstanding Series A warrants and warrants issued to the Company's placement agent for its May 2011 private placement to purchase up to 215,721 shares of common stock at an exercise price of \$6.00 per share, which expire in November 2016; and warrants to purchase 3,230,202 shares of the Company's common stock at an exercise price of \$3.12 per share, which expire in December 2017, issued in conjunction with its December 2012 private placement.

#### Note 7. Share-based Compensation

The Company uses equity-based compensation programs to provide long-term performance incentives for its employees. These incentives consist primarily of stock options and restricted stock units ("RSUs").

MEI Pharma's 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 the Company's 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 and 2015. Effective December 3, 2015, the Company's stockholders voted to further amend and restate the 2008 Equity Plan to increase the number of shares of common stock authorized for issuance under the plan to 6,686,000 shares, among other changes. As of September 30, 2016, there were 1,566,845 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	Three Months Ended September 30,		
	2016	2015		
Research and development	\$ 239	\$ 208		
General and administrative	498	562		
Total share-based compensation	\$ 737	\$ 770		

#### Stock Options

Stock option activity for the three months ended September 30, 2016 was as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2016	2,827,172	\$ 4.29		
Granted	1,494,672	1.37		
Forfeited / Cancelled	(33,333)	1.36		
Expired	(23,124)	11.38		
Outstanding at September 30, 2016	4,265,387	\$ 3.25	7.2	\$ 826,177
Vested and exercisable at September 30, 2016	1,563,068	\$ 5.04	4.7	\$ 96,916

The fair value of each stock option granted during the three months ended September 30, 2016 is estimated on the grant date under the fair value method using a Black-Scholes valuation model. Stock options granted to employees during the three months ended September 30, 2016 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 three months ended September 30, 2016 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 RSU equity awards are measured using the grant date fair value of the Company's common stock. The estimated fair values of the stock options and RSUs, 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:

	Three Months	Three Months Ended September 30,		
	2016	2015		
Risk-free interest rate	1.2%	1.8	%	
Expected life (years)	5.9	5.7		
Expected volatility	108.2%	117.49	%	
Dividend yield	0.0%	0.0	%	
Weighted-average grant date fair value	\$ 1.12	\$ 1.38		

As of September 30, 2016, there was \$2.4 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 1.6 years.

Restricted Stock Units

In March 2013, the Compensation Committee of the Board of Directors granted 400,000 RSUs to the Company's Chief Executive Officer, Dr. Daniel P. Gold. Each RSU represents the contingent right to receive one share of the Company's common stock. One-third of the RSUs vested on August 30, 2014, one-third vested on August 30, 2015, and the remaining one-third vested on August 30, 2016. The shares underlying the RSUs will be delivered to Dr. Gold on the earliest to occur of (i) March 29, 2018, (ii) Dr. Gold's death, disability or separation from service from the Company for any reason, or (iii) a change in control involving the Company. The fair value of the RSUs on the date of grant was \$3.5 million. The grant date fair value per unit was \$8.63.

In June 2016, the Company granted 364,726 RSUs to employees. Each RSU represents the contingent right to receive one share of the Company's common stock. The RSUs were subject to performance criteria that were met in August 2016. The RSUs will vest in August 2018. The fair value of the RSUs was measured at \$1.61 per unit on the date the performance criteria were met. Under the terms of the 2008 Plan, each of these RSUs is calculated as 1.25 shares of common stock for purposes of determining the number of shares available for future grant. There were 363,014 unvested RSUs outstanding as of September 30, 2016

As of September 30, 2016, unrecognized compensation expense related to the unvested portion of the Company's RSUs was approximately \$0.5 million and is expected to be recognized over approximately 1.8 years.

#### 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 2016 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;
- Helsinn or other 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;
- we are in early stage clinical studies for our product candidates on which our development plans are based; 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 U.S. Food and Drug Administration ("FDA") or other required 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;
- · the failure of any products to gain market acceptance;
- 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;
- · technological changes;
- 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. 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 2016 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 an oncology company focused on the clinical development of novel therapies for cancer. Our common stock is listed on the Nasdaq Capital Market under the symbol "MEIP".

Our business purpose is the development of drugs for the treatment of cancer. Our portfolio of clinical drug candidates includes Pracinostat, an oral HDAC inhibitor that is being developed in combination with azacitidine for the treatment of patients with newly diagnosed AML who are <sup>3</sup>75 years of age or unfit for intensive chemotherapy, and high-risk MDS. In August 2016, we entered into an exclusive worldwide license, development and commercialization agreement with Helsinn for Pracinostat in AML, MDS and other potential indications. Our clinical development portfolio also includes ME-401, an oral inhibitor of PI3K delta being developed for B-cell malignancies, and ME-344, a mitochondrial inhibitor that has shown evidence of clinical activity in refractory solid tumors. We own exclusive worldwide rights to ME-401 and ME-344.

#### **Clinical Development Programs**

#### **HDAC Inhibitor Drug Candidate: Pracinostat**

In August 2016, we announced that the FDA granted Breakthrough Therapy Designation for Pracinostat in combination with azacitidine for the treatment of patients with newly diagnosed AML who are <sup>3</sup>75 years of age or unfit for intensive chemotherapy. In addition, agreement has been reached with the FDA on the proposed Phase III study design. According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

The Breakthrough Therapy Designation is supported by data from a Phase II 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 response (CR) rate of 42% (21 of 50 patients). These data compare favorably to a recent international Phase III 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.

In August 2016, we entered into an exclusive license, development and commercialization agreement with Helsinn, a Swiss pharmaceutical corporation, for Pracinostat in AML, MDS and other potential indications ("Helsinn License Agreement"). Under the terms of the agreement, Helsinn is 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 will receive near-term payments of \$20.0 million, including a \$15.0 million upfront payment which was received in August 2016, and a \$5.0 million payment upon the earlier to occur of (i) dosing of the first patient in the upcoming Phase III study of Pracinostat in newly diagnosed AML patients unfit to receive induction therapy, or (ii) March 1, 2017. In addition, we will be eligible to receive up to \$444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of Pracinostat.

As part of the Helsinn License Agreement, we will work with Helsinn to determine an optimal dosing regimen of Pracinostat in combination with azacitidine for the treatment of high and very high risk MDS. The cost of this study would be shared by Helsinn and us and enrollment is anticipated to commence in the first half of calendar year 2017.

# PI3-Kinase Delta Drug Candidate: ME-401

In September 2013, we acquired exclusive worldwide rights to ME-401 from Pathway Therapeutics, Inc. for an undisclosed upfront cash payment with no future milestone or royalty obligations. Data from pre-clinical studies show ME-401 to be a potent and selective oral inhibitor of PI3K delta, a molecular target that plays a critical role in the proliferation and survival of certain hematologic cancer cells. PI3K delta is a class of drugs that has shown promise in the treatment of B-cell malignancies, but with particular toxicities. We believe this provides an opportunity for a next-generation oral drug that can produce therapeutic responses at a safe, effective dose. ME-401 has a distinct chemical structure from certain other PI3K delta inhibitors, including idelalisib (marketed as Zydelig®). Data presented at the ASH Annual Meeting in December 2012 demonstrated that ME-401 has superior pre-clinical activity compared to idelalisib.

Results from a first-in-human, single ascending dose clinical study of ME-401 in healthy volunteers were presented at the American Association for Cancer Research Annual Meeting in April 2016. The data demonstrated on-target activity at very low plasma concentrations. In addition, the results from the study suggest that ME-401 has the potential for a superior pharmacokinetic and pharmacodynamic profile and an improved therapeutic window compared to idelalisib, with a half-life that supports once-daily dosing. In March 2016, the FDA approved our Investigational New Drug application for ME-401 in B-cell malignancies. A Phase Ib dose-escalation study of ME-401 in patients with recurrent CLL or fNHL opened for enrollment in September 2016. The goal of the study is to demonstrate an improved therapeutic window with repeated dosing in cancer patients. Interim data is expected in the second quarter of calendar year 2017.

#### Mitochondrial Inhibitor Drug Candidate: ME-344

ME-344 is our isoflavone-derived mitochondrial inhibitor drug candidate. In preclinical studies, ME-344 has been shown to cause cell death in multiple human tumor cell lines, including ovarian cancer stem cells, by interfering with mitochondrial energy generation.

Results from our first-in-human, single-agent Phase I 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 3 peripheral neuropathy.

In May 2015, we announced new 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 vascular endothelial growth factor ("VEGF"). These new 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. An investigator-sponsored study of ME-344 in combination with the VEGF inhibitor bevacizumab (marketed as Avastin®) in HER2-negative breast cancer opened for enrollment in August 2016.

#### **Results of Operations**

# Three Months Ended September 30, 2016 and 2015

We incurred losses of \$4.3 million and \$4.6 million for the three months ended September 30, 2016 and 2015, respectively.

**Revenues:** We recognized research and development revenue of \$1.1 million for the three months ended September 30, 2016 compared to no revenue for the three months ended September 30, 2015. The research and development revenue resulted from the recognition of fees allocated to research and development activities in accordance with the Helsinn License Agreement which was signed in August 2016.

Cost of Research and Development Revenue: We recognized cost of research and development revenue of \$1.1 million for the three months ended September 30, 2016 compared to no cost of research and development revenue for the three months ended September 30, 2015. The cost of research and development revenue includes internal compensation and related personnel expenses to support our research and development revenue and external costs paid to third-party contractors to perform research, conduct clinical trials and develop and manufacture drug materials.

Research and Development: Research and development expenses consist primarily of clinical trial costs (including payments to contract research organizations), pre-clinical study costs, costs to manufacture our drug candidates for non-clinical and clinical studies and salaries and other personnel costs. Research and development expenses decreased by \$1.2 million to \$1.6 million for the three months ended September 30, 2016 compared to \$2.8 million for the three months ended September 30, 2015. The decrease was primarily due to a decrease in clinical trial costs associated with Pracinostat and with ME-344, including a reduction of clinical trial costs of \$1.0 million due to revisions in estimates of amounts that are owed to contract research organizations for clinical trials for Pracinostat and ME-344 that are at or near completion. Expenses related to Pracinostat decreased pursuant to our license agreement with Helsinn, under which Helsinn will be primarily responsible for funding the development and commercialization of Pracinostat and, subject to certain exceptions, will be solely responsible for all costs related thereto.

*General and Administrative*: General and administrative expenses increased by \$0.9 million to \$2.7 million for the three months ended September 30, 2016 compared to \$1.8 million for the three months ended September 30, 2015. The increase is due to higher levels of professional services expenses associated with the Helsinn License Agreement during the three months ended September 30, 2016 compared to the three months ended September 30, 2015.

*Other income or expense:* We received interest and dividend income of \$55,000 for the three months ended September 30, 2016 compared to \$27,000 for the three months ended September 30, 2015. The increase was due to higher yields during the three months ended September 30, 2016 compared to the three months ended September 30, 2015.

#### **Liquidity and Capital Resources**

We have accumulated losses of \$181.3 million since inception and expect to incur operating losses and generate negative cash flows from operations for the foreseeable future. As of September 30, 2016, we had \$58.9 million in cash, cash equivalents and short-term investments, which we believe will be sufficient to fund our operations through at least the next twelve months. 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. 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 provided by operations for the three months ended September 30, 2016 was \$8.8 million compared to \$5.8 million used in operations for the three months ended September 30, 2015, primarily due to the \$15.0 upfront payment received as part of the Helsinn License Agreement.

Net cash used in investing activities for the three months ended September 30, 2016 was \$10.0 million compared to net cash provided by investing activities of \$4.9 million in the three months ended September 30, 2015. 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 three months ended September 30, 2016 was \$4.2 million, representing the equity investment by Helsinn in a transaction related to the Helsinn License Agreement. There was no cash provided by financing activities during the three months ended September 30, 2015.

#### **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.

As of September 30, 2016, we lease approximately 8,800 square feet of office space at a monthly rental rate of approximately \$29,000 per month during the term of the lease, through June 2017.

CyDex License Agreement

In September 2012, the Company entered into a license agreement with CyDex. Under the license agreement, CyDex granted to the Company an exclusive, nontransferable license to intellectual property rights relating to Captisol® for use with the Company's isoflavone-based drug compounds. The Company 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 the Company's approved drugs utilizing Captisol. Contemporaneously with the license agreement, the Company and CyDex entered into a commercial supply agreement pursuant to which the Company agreed to purchase 100% of its requirements for Captisol from CyDex. The Company may terminate both the license agreement and the supply agreement for convenience at any time upon 90 days' prior written notice.

S\*Bio Asset Purchase

In August 2012, we entered into a definitive asset purchase agreement with S\*Bio, pursuant to which we agreed to acquire certain assets comprised of intellectual property and technology including rights to Pracinostat, in exchange for \$500,000 of common stock. On August 22, 2012, we completed the asset purchase and issued 195,756 shares of common stock to S\*Bio. We also agreed to make certain milestone payments to S\*Bio based on the achievement of certain clinical, regulatory and net sales-based milestones, as well as to make certain contingent earnout payments to S\*Bio. Milestone payments will be made to S\*Bio up to an aggregate amount of \$75.2 million if certain U.S., E.U. and Japanese regulatory approvals are obtained and if certain net sales thresholds are met in North America, the E.U. and Japan. The first milestone payment of \$200,000 payable in cash, plus \$500,000 payable in cash or in shares of the Company's common stock, will be due upon the first dosing of a patient in a Phase III clinical trial or other pivotal trial, for any indication. Subsequent milestone payments will be due upon certain regulatory approvals and sales-based events. As of September 30, 2016, the Company has accrued \$700,000 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 2016 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 2016 Annual Report. There have been no changes in our significant accounting policies or critical accounting estimates since June 30, 2016, other than the adoption of revenue recognition policies as a result of the Helsinn License Agreement.

In August 2016, we entered into the Helsinn License Agreement. Under the terms of the agreement, Helsinn is 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 a \$15.0 million upfront payment in August 2016, and will receive a \$5.0 million payment upon the earlier of (i) dosing of the first patient in the upcoming Phase III study of Pracinostat in newly diagnosed AML patients who are ≥ 75 years of age or unfit to receive induction therapy or (ii) March 1, 2017. We will also receive reimbursement related to agreements entered into by MEI in anticipation of the upcoming Phase III study of Pracinostat by Helsinn as well as a Phase II study for Pracinostat in combination with azacitidine for the treatment of high and very high risk MDS, which will be conducted by MEI. The current expected external cost of the Phase II study will be shared equally by Helsinn and us. Enrollment in the Phase II study is anticipated to commence in the first half of calendar year 2017. We will be eligible to receive up to \$444 million in potential regulatory and sales-based milestones, along with royalty payments on the net sales of Pracinostat.

We have determined that the exclusive license, development and commercialization agreement represents a multiple-element arrangement for purposes of revenue recognition. Revenue related to the license will be recognized upon completion of the technology and data transfer, which is expected to be completed during the second quarter of fiscal year 2017. Revenue related to research and development elements of the arrangement will be recognized over the period of each research and development activity. Revenue associated with third-party costs will be recognized on a gross basis as such costs are incurred.

Contemporaneously with the Helsinn License Agreement, we entered into a Common Stock Purchase Agreement (the "Helsinn Equity Agreement"), dated as of August 5, 2016, with Helsinn Investment Fund SA (the "Purchaser"). Pursuant to the terms of the Equity Agreement, the Purchaser agreed to purchase and we agreed to issue a number of shares of our common stock determined by dividing \$5,000,000 by the volume weighted-average price for shares of our common stock for the ten trading day period beginning on August 1, 2016 and ending on August 12, 2016 (the "VWAP"), rounded to the nearest whole share. The VWAP was \$1.911 per share. Accordingly, on August 16, 2016, we issued 2,616,431 shares of common stock. The difference between the VWAP price of \$1.911 per share and the closing price of our common stock on August 5, 2016 of \$1.61 of \$788,000 has been allocated to the revenue elements.

#### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*. The standard provides companies with a single model for accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. In August 2015, the FASB issued ASU 2015-14, *Deferral of the Effective Date*, which defers the required adoption date of ASU 2014-09 by one year. As a result of the deferred effective date, ASU 2014-09 will be effective for the Company in its first quarter of fiscal 2019. Early adoption is permitted but not before the original effective date of the new standard of the first quarter of fiscal 2018. The following ASUs were subsequently issued by the FASB to clarify the implementation guidance in some areas and add practical expedients: In March 2016, ASU 2016-08, *Revenue from Contracts with Customers, Principal versus Agent Considerations*; in April 2016, ASU 2016-10, *Revenue from Contracts with Customers, Identifying Performance Obligations and Licensing*; in May 2016, ASU 2016-11, *Revenue from Contracts with Customers and Derivatives and Hedging—Rescission of SEC Guidance*; and ASU 2016-12, *Revenue from Contracts with Customers—Narrow Scope Improvements and Practical Expedients*. We are in the process of evaluating the transition method that will be elected and the impact of adoption on our financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern.* The standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and provides guidance on determining when and how to disclose going concern uncertainties in the financial statements. Certain disclosures will be required if conditions give rise to substantial doubt about an entity's ability to continue as a going concern. ASU 2014-15 applies to all entities and is effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. Subsequent to adoption, we will apply the guidance in ASU 2014-15 to assess its ability to continue as a going concern.

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 are evaluating the impact that the adoption of this standard will have on our financial statements.

In March 2016, the FASB issued ASU 2016-09 *Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard is effective for fiscal years beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. We are evaluating the impact that the adoption of this standard will have on our financial statements.

In June 2016, the FASB issued No. 2016-13, Financial Instruments —Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. Topic 326 amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current U.S. GAAP and, instead, requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner similar to current U.S. GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. ASU 2016-13 affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. This update is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. We are currently evaluating the impact the adoption of this standard will have on its financial statements.

#### 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 the Company 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 the Company's risk factors from those included in the Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2016.

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

On August 16, 2016, pursuant to the Common Stock Purchase Agreement dated as of August 5, 2016, entered into in connection with the Helsinn License Agreement, the Company issued 2,616,431 shares of common stock to Helsinn Investment Fund SA for an aggregate purchase price of \$5,000,000 in a transaction exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

# 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**

10.1	License, Development and Commercialization Agreement, dated as of August 5, 2016, by and between MEI Pharma, Inc. and Helsinn Healthcare SA *
10.2	Common Stock Purchase Agreement, dated as of August 5, 2016, by and between MEI Pharma, Inc. and Helsinn Investment Fund SA
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

<sup>\*</sup> Portions of this exhibit have been redacted pursuant to a confidential treatment request filed with 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: November 9, 2016

# LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

**DATED AS OF AUGUST 5, 2016** 

BY AND BETWEEN

MEI PHARMA, INC.

AND

HELSINN HEALTHCARE SA

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

portions have e	reen free separately with the SDC.	
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#### LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This License, Development and Commercialization Agreement (this "Agreement"), dated as of August 5, 2016 (the "Effective Date"), is made by and between MEI Pharma, Inc., a Delaware corporation having an office at 11975 El Camino Real, Suite 101, San Diego, CA 92130 ("Licensor"), and Helsinn Healthcare SA, a Swiss corporation having its registered office at Via Pian Scairolo 9, 6912 Pazzallo-Lugano, Switzerland ("Licensee"). Licensor and Licensee are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

#### RECITALS

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

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

WHEREAS, Licensor wishes to grant a license to Licensee under certain intellectual property rights related to the Compound to develop, manufacture and commercialize the Compound and Product (as defined below), and Licensee 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 Mutual Confidential Disclosure Agreement on December 16, 2015 ("Prior CDA") 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

As used in this Agreement, the following initially capitalized terms shall have the meanings set forth in this ARTICLE 1 or as otherwise defined elsewhere in this Agreement:

1.1 "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 1.1, "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.

- 1.2 "Applicable Law" 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.
- 1.3 "Azacitidine" means that certain compound referred to as azacitidine with the IUPAC name 4-Amino-1-β-D-ribofuranosyl-1,3,5-triazin-2(1*H*)-one, including any [\*CONFIDENTIAL\*].

# 1.4 [\*CONFIDENTIAL\*].

- 1.5 "Baseline Quarter Net Sales" means, on a country-by-country basis, the average cumulative Net Sales of the Product in such country during the [\*CONFIDENTIAL\*] consecutive [\*CONFIDENTIAL\*] that immediately precede the Calendar Quarter during which a Generic Product with respect to the Product is first commercially sold in such country. For example, if a Generic Product with respect to the Product is commercially sold in the U.S. for the first time on [\*CONFIDENTIAL\*], then the Baseline Quarter Net Sales with respect to the U.S. are the cumulative Net Sales of the Product in the U.S. during the [\*CONFIDENTIAL\*] Calendar Quarters of [\*CONFIDENTIAL\*] divided by [\*CONFIDENTIAL\*].
  - 1.6 "Business Day" means a day other than a Saturday, Sunday, or bank or other public holiday in California and/or in the Canton of Ticino.
- 1.7 "Calendar Quarter" means each three (3) month period commencing January 1, April 1, July 1 or October 1 of any year; provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.
- 1.8 "Calendar Year" means the period beginning on the 1st of January and ending on the 31st of December of the same year; provided, however, that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same year and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

- 1.9 "Change of Control" means (a) a merger or consolidation of Licensor with a Third Party that results in the voting securities of Licensor 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 Licensor, or (c) the sale or other transfer to a Third Party of all or substantially all of Licensor's and its Affiliates' assets.
- 1.10 "Clinical Trial" means a clinical trial, including any phase I trial, phase II trial, phase III trial, or phase IV trial (including any non-interventional studies, safety studies, investigator initiated clinical trial trials, and epidemiological studies), as the case may be, and as any such trial is defined by an applicable Regulatory Authority to obtain information regarding a product, including information relating to the safety, tolerability, pharmacological activity, pharmacological activity, pharmacological studies), as the case may be, and as any such trial is defined by an applicable Regulatory Authority to obtain information regarding a product, including information relating to the safety, tolerability, pharmacological activity, pharmacological studies).
- 1.11 "Collaboration Patent" means any Patent Covering (i) any Invention relating to the Compound and/or Product that is conceived, reduced to practice or otherwise developed through, based on or derived from work carried out after the Effective Date under this Agreement, including in the performance of the On-Going Agreements or in connection with the On-Going Studies or the POC Study or (ii) any improvement, addition, refinement, modification, development, discovery or invention that references, is based on or is derived from the data contained in that certain document titled [\*CONFIDENTIAL\*], which was provided by Licensee to Licensor prior to the Effective Date, or any data that replicates or recreates such data. For clarity, Collaboration Patents are a subset of Licensee Patents.
- 1.12 "Commercialize" means, with respect to (a) a Royalty Product, to promote, market, distribute, sell (and offer for sale or contract to sell), import, export, or otherwise commercially exploit or provide product support for the Royalty Product and to conduct activities, other than Development 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, and (b) the Compound, to distribute, sell (and offer for sale or contract to sell), import or export the Compound, and to conduct activities, other than Development or Manufacturing, in preparation for conducting the foregoing activities. "Commercializing" and "Commercialization" shall have correlative meanings. For the avoidance of doubt, Commercialization does not include Development and Manufacturing.
- 1.13 "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.

- **1.14 "Compound"** means (i) that certain compound referred to as pracinostat, with the IUPAC name (2*E*)-3-(2-Butyl-1-(2-(diethylamino)ethyl)-1*H*-benzo[*d*]imidazol-5-yl)-*N*-hydroxyacrylamide ("**Pracinostat"**), and (ii) [\***CONFIDENTIAL\***]; provided, that the Parties acknowledge and agree that "Compound" does not include anything that is covered or claimed by any of those Patents included in <u>Schedule 1.14</u>.
- 1.15 "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.
- 1.16 "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, 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.
- 1.17 "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 Royalty Product, as well as any and all activities pertaining to manufacturing development, formulation development, including new indications, new formulations and all other activities, including regulatory activities, related to securing and maintaining Regulatory Approval, for the Compound or a Royalty Product. "Development" shall have correlative meanings.
- 1.18 "Development Activities" means those Development activities undertaken by or on behalf of Licensee with respect to the Compound or a Royalty Product.
  - 1.19 "Dollar" or "\$" means the legal tender of the United States of America.
  - 1.20 "Executive Officer" means, with respect to each Party, an appropriate executive officer as indicated by each such Party.
  - 1.21 "FDA" means the United States Food and Drug Administration and any successor Regulatory Authority having substantially the same function.

- 1.22 "FD&C Act" means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder.
- 1.23 "First Commercial Sale" means, with respect to any country, the first shipment of the Product by or on behalf of Licensee or its Affiliate or its Sublicensee to a Third Party in such country for end use or consumption of the Product in such country after Regulatory Approval of the Product in such country or, if earlier, the invoicing of a Third Party for such shipment. Sales or transfers of reasonable quantities of the Product for Clinical Trial purposes, or for compassionate or similar use, shall not be considered a First Commercial Sale.
- 1.24 "Force Majeure" means any circumstances whatsoever which are not within the reasonable control of the Party affected thereby, potentially including an act of God, war, act of terrorism, insurrection, riot, strike or labor dispute, shortage of materials, fire, explosion, flood, government requisition or allocation, breakdown of or damage to plant, equipment or facilities, interruption or delay in transportation, fuel supplies or electrical power, embargo, boycott, order or act of civil or military authority.
- 1.25 "Generic Product" means, with respect to a country, any pharmaceutical product that is distributed by a Third Party (that is not licensed or otherwise permitted by Licensee or its Affiliates or its Sublicensees) in such country (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) [\*CONFIDENTIAL\*], (b) [\*CONFIDENTIAL\*], or (c) [\*CONFIDENTIAL\*], and (ii) which product (a) contains the same active pharmaceutical ingredient(s) as the Product, (b) [\*CONFIDENTIAL\*] and (c) [\*CONFIDENTIAL\*].
- 1.26 "Good Clinical Practices" or "GCP" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (i) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products, (ii) the Declaration of Helsinki (1964) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (iii) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (iv) the equivalent Applicable Law in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.
- 1.27 "Good Laboratory Practices" or "GLP" means the then-current standards, practices and procedures promulgated or endorsed by (a) the European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices as well as "The rules governing medicinal products in the European Union," Volume 3, Scientific

guidelines for medicinal products for human use (ex - OECD principles of GLP), (b) the FDA as defined in 21 C.F.R. Part 58, and (c) the equivalent Applicable Law in any relevant country, each as may be amended and applicable from time to time.

- 1.28 "Good Manufacturing Practices" or "GMP" means all applicable Good Manufacturing Practices including, as applicable, (i) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601 and 610, (ii) the principles detailed in the ICH Q7 guidelines, and (iii) the equivalent Applicable Law in any relevant country, each as may be amended and applicable from time to time.
  - 1.29 "GxPs" means each of GCP, GLP and GMP as and to the extent applicable.
- 1.30 "Government Official" means: (i) any official, officer, employee, representative, or anyone acting in an official capacity on behalf of: (a) any government or any department or agency thereof; (b) any public international organization (such as the United Nations, the International Monetary Fund, the International Red Cross, or the World Health Organization), or any department, agency, or institution thereof; or (c) any government-owned or controlled company, institution, or other entity, including a government-owned hospital or university; (ii) any political party or party official; and (iii) any candidate for political office.
- 1.31 "Governmental 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.
- **1.32 "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.
- **1.33 "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.
- **1.34 "Joint Invention"** means any Invention conceived, reduced to practice or otherwise developed by one (1) or more employees or contractors of Licensee and one (1) or more employees or contractors of Licensor.
- 1.35 "Know-How" means all secret and substantial technical, scientific, regulatory and other information, results, knowledge, techniques, in whatever form and whether or not confidential, patented or patentable, including 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.

- 1.36 "Licensed Field" means all uses and indications in human and animal health.
- **1.37 "Licensee Know-How"** means any and all Know-How, whether or not patented or patentable, to the extent Controlled by, or on behalf of, Licensee or its Affiliates following the Effective Date or at any time thereafter during the Term (other than the Licensor Know-How) that is specifically related to the Development, Manufacture, Commercialization or other use of the Compound or Product.
- 1.38 "Licensee Patent" means any Patent, including any Collaboration Patent, that (i) claims a priority date after the Effective Date, (ii) is Controlled by Licensee (or its Affiliates) during the Term (other than the Licensor Patents) and (iii) contains one or more claims Covering the Compound and/or Product (including the Development, Manufacturing or Commercialization of the Compound and/or Product).
  - 1.39 "Licensee Technology" means Licensee Know-How and Licensee Patents.
- 1.40 "Licensor Know-How" means any and all Know-How, whether or not patented or patentable, to the extent Controlled by, or on behalf of, Licensor or its Affiliates as of the Effective Date or at any time during the Term that is necessary in connection with the Development, Manufacture, Commercialization or other use of the Compound or Product as contemplated herein. Licensor Know-How Controlled by Licensor as of the Effective Date is either outlined in Schedule 1.40 or will be included by Licensor in the transfer under the Technology Transfer Plan. Notwithstanding the foregoing, "Licensor Know-How" does not include any Know-How that is owned or in-licensed by a Third Party described in the definition of "Change of Control" or such Third Party's Affiliates (a) prior to the closing of such Change of Control, except to the extent that any such Know-How was Controlled by Licensor or any of its Affiliates prior to such Change of Control, or (b) after such Change of Control (other than arising from (i) Licensor's or any of its Affiliates' performance of activities hereunder or (ii) the use of any Licensor Technology or Licensee Technology).
- 1.41 "Licensor Patent" means (i) the Patents set forth on <u>Schedule 1.41</u>, including patents issuing from any patent application set forth on <u>Schedule 1.41</u> (ii) [\*CONFIDENTIAL\*], (iii) all provisional applications, substitutions, continuations, continuations-in-part, divisionals, renewals, 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, and foreign counterparts of any of the foregoing, and (iv) [\*CONFIDENTIAL\*]. For the sake of clarity, the term "Licensor Patent" shall not be construed to include any Collaboration Patent or any Patent that Covers (or otherwise claims) a Joint Invention. Notwithstanding the foregoing, "Licensor Patent" does not include [\*CONFIDENTIAL\*].

- **1.42 "Licensor Technology"** means Licensor Know-How and Licensor Patents.
- 1.43 "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, Packaging and Labeling, 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.
- **1.44 "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.
- 1.45 "Net Sales" means, with respect to a Royalty Product ([\*CONFIDENTIAL\*]), the gross amount invoiced for sales of a Royalty Product by Licensee or its Sublicensees to Third Parties (other than Third Parties that are also Affiliates or Sublicensees of Licensee), less the following deductions from such gross amounts to the extent attributable to such Royalty Product and to the extent actually incurred, allowed, accrued or specifically allocated:
  - (a) trade, cash and quantity discounts actually given;
- (b) price reductions or rebates, retroactive or otherwise, or charge backs actually granted or paid to Governmental Authorities, group purchasing organizations, Third Party payors (including managed health care organizations) or trade customers;
  - (c) amounts repaid or credited by reason of rejections, defects, return goods allowance, recalls or returns;
- (d) reasonable and customary freight, shipping insurance and other transportation charges directly related to the sale of the Royalty Product separately stated on the invoice to the Third Party;
  - (e) fees for any services provided by wholesalers and warehousing chains related to the distribution of such Royalty Product; and
- (f) sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, to the extent that such items are included in the gross invoice price of the Royalty Product and actually borne by Licensee or its Sublicensees without reimbursement from any Third Party (other than Third Parties that are also Affiliates or Sublicensees of Licensees) (but not including taxes assessed against the income derived from such sale);

all as determined in accordance with generally accepted accounting principles in the U.S. ("GAAP") on a basis consistent with Licensee's or its Sublicensee's, as applicable, annual audited financial statements.

The transfer of a Royalty Product between or among Licensee and its Affiliates or Sublicensees for resale (which resale will give rise to Net Sales), use in a Clinical Trial or use as a free marketing sample, will not be considered a sale.

Upon the sale or other disposal of a Royalty 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 Royalty Product for or use of a Royalty 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 Licensee 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).

- **1.46 "On-Going Agreements"** means certain agreements and specific work orders entered into by Licensor with Third Parties as of the Effective Date with respect to the Compound and/or the Product, as such agreements and work orders are listed in <u>Schedule 1.46</u>.
- 1.47 "On-Going Studies" means, collectively, (i) those Clinical Trials involving the Compound internally designated by Licensor as [\*CONFIDENTIAL\*] respectively, and (ii) that certain Clinical Trial [\*CONFIDENTIAL\*], with clinicaltrial.gov identifier [\*CONFIDENTIAL\*].
- 1.48 "Patents" means any and all (i) issued patents, (ii) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisionals and renewals, and all patents granted thereon, (iii) 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, (iv) inventor's certificates, (v) other forms of government-issued rights substantially similar to any of the foregoing, and (vi) United States and foreign counterparts of any of the foregoing.
- 1.49 "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.
- 1.50 "Person" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, Governmental Authority, association or other entity.
  - 1.51 "POC Study" means a Clinical Trial of the Product for the Second Indication.
- 1.52 "Pre-Marketing" means all sales and marketing and medical affairs activities undertaken prior to and in preparation for the launch of the Product. Pre-Marketing shall include

market research, key opinion leader development, advisory boards, medical education, disease-related public relations, health care economic studies, sales force training and other pre-launch activities prior to the First Commercial Sale of the Product in a given country or other regulatory jurisdiction.

- **1.53 "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).
- 1.54 "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 Licensor or any of its Affiliates other than the Compound.
- **1.55 "Product Complaint"** means any written, verbal or electronic expression of dissatisfaction regarding Product sold by or on behalf of Licensee or its Sublicensees, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.
- 1.56 "Promotional Materials" means all written, printed, video or graphic advertising, promotional, educational and communication materials (other than the Product labels and package inserts) for marketing, advertising and promoting of the Product, for use (i) by a Sales Representative or (ii) in advertisements, web sites or direct mail pieces.
- 1.57 "Qualified Sublicensee" means (a) any Affiliate of Licensee that is headquartered and incorporated in the United States, or (b) a reputable Third Party that has (i) the capability to effectively market, distribute and sell the Product in [\*CONFIDENTIAL\*] [\*CONFIDENTIAL\*] through a dedicated sales force, (ii) has a strategic focus [\*CONFIDENTIAL\*], and (iii) has been actively commercializing products [\*CONFIDENTIAL\*] in [\*CONFIDENTIAL\*] for at least the [\*CONFIDENTIAL\*] preceding the execution of a sublicense agreement with Licensee.
- **1.58 "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.
- **1.59 "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.
- 1.60 "Regulatory Data" means any and all research data, pharmacology data, chemistry, manufacturing and control 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 ("DMFs"), Chemistry, Manufacturing and Control ("CMC") data, or similar documentation).

- 1.61 "Regulatory Materials" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, Manufacture, obtain marketing authorization, market, sell or otherwise Commercialize the Product in a particular country or regulatory jurisdiction. Regulatory Materials include INDs, MAAs, presentations, responses, and applications for other Regulatory Approvals.
  - 1.62 "Royalty Product" means (i) the Product or (ii) [\*CONFIDENTIAL\*].
  - 1.63 "Royalty Term" means, on a country-by-country basis, the following:
- 1.63.1 with respect to each Tier 1 Country, the period of time beginning on the First Commercial Sale of the Product in such country and ending upon the later of (i) the date of expiration of the last to expire Licensor Patent or Collaboration Patent containing a Valid Claim Covering the Commercialization, Manufacturing or use, but where the only remaining Valid Claim Covers a method of use, only a use in an indication that is approved and included in Promotional Materials used by Licensee or its Sublicensees in the applicable jurisdiction, of the Compound or Product in such country, (ii) fifteen (15) years from First Commercial Sale of the Product in such country, or (iii) the date of expiration of data exclusivity as conferred by a competent Regulatory Authority for the Product in such country; and
- **1.63.2** with respect to each Tier 2 Country, the period of time beginning on the First Commercial Sale of the Product in such country and ending after fifteen (15) years from First Commercial Sale of the Product in such country.
- **1.64 "S\*BIO Agreement"** means the Asset Purchase Agreement between S\*BIO Pte Ltd. ("S\*BIO") and Licensor, dated as of August 7, 2012, in the form attached hereto in Schedule 1.64, as may be amended from time-to-time only in accordance with Section 10.2.14.
- 1.65 "Sales Representative" means an individual who is employed by a Party and who performs details and other promotional efforts with respect to the Product.
- **1.66 "Second Indication"** means the use of the Product in combination with Azacitidine for the treatment of intermediate and/or high risk and/or very high risk myelodysplastic syndrome (MDS).
- **1.67 "Target Indication"** means the use of the Product in combination with Azacitidine for the treatment of patients with diagnosed acute myeloid leukemia (AML) who are "unfit" for intensive chemotherapy. The Parties acknowledge and agree that "unfit" will be construed broadly to include all synonyms thereof and analogous concepts with respect thereto, including "unsuited" and "not able" to receive intensive chemotherapy.

- 1.68 "Territory" means all countries worldwide.
- 1.69 "Third Indication" means any indication other than the Target Indication or the Second Indication.
- 1.70 "Third Party" means any Person other than Licensor, Licensee or their respective Affiliates.
- 1.71 "Tier 1 Country" means any of the following countries: [\*CONFIDENTIAL\*].
- 1.72 "Tier 2 Country" means any country in the Territory other than a Tier 1 Country.
- 1.73 "United States" or "U.S." means the United States of America and its possessions and territories.
- 1.74 "Valid Claim" with respect to any country, means (i) a claim of an issued and unexpired Patent in such country which has not been revoked, held unenforceable, unpatentable or invalid by an administrative agency, court or other governmental agency of a competent jurisdiction in a final and non-appealable decision (or decision unappealed within the time allowed for appeal), and which has not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise and (ii) a claim in 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).
  - 1.75 Additional Definitions. The following terms have the meanings set forth in the corresponding Sections of this Agreement:

Term	Section	Term (D)	Section	Term	Section
"AAA"	15.1.2	"Development Plan"	4.3.1	"ICH"	1.26
"Agreement"	Preamble	"Dispute"	15.1	"Indemnified Party"	11.3.1
"Audit"	8.9	"DMFs"	1.60	"Indemnifying Party"	11.3.1
"Bankrupt Party"	14.7	"Effective Date"	Preamble	"Infringement Claim"	9.2(a)
"Breaching Party"	13.2.1	"Essential Development	4.3.2	"JSC"	3.1
"Claim"	11.1	Elements"	4.3.2	"LIBOR"	8.8
"CMC"	1.60	"External Data"	2.6	"Licensee"	Preamble
"Commercialization Data"	6.6	"External Know-How"	10.2.8	"Licensor"	Preamble
"Confidential Information"	12.1.1	"GAAP"	1.45	"Losses"	11.1
"Courts"	15.13.3			"Milestone Notification	8.2

Term Notice"	Section	<u>Term</u> Trade Dress"	Section	<u>Term</u> Transfer Plan"	Section
"Packaging and Labeling"	7.2	"Product Trademark"	6.5.1	"Upfront Payment"	8.1
"Party" or "Parties"	Preamble	"Recovery"	9.3(c)(v)	"VAT"	8.6.1
"Pracinostat"	1.14	"S*BIO"	1.64		
"Prior CDA"	Recitals	"Sublicensee"	2.3.2		
"Product	6.5.1	"Term"	13.1		
		"Technology	2.5		

## ARTICLE 2 LICENSES

#### 2.1 License Grants.

- 2.1.1 Grant to Licensee. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee during the Term an exclusive (even as to Licensor, but subject to the sentence in this Section 2.1.1 beginning with "For clarity"), payment-bearing license with the right to sublicense only in accordance with Section 2.3.2, under and with respect to the Licensor Technology, to, directly or indirectly, Develop, Manufacture and Commercialize the Compound and Product in and for the Licensed Field throughout the Territory. For clarity, but without limiting the scope of the preceding sentence, (i) Licensor shall have the right to use the Licensor Technology for the sole and limited purposes of performing its obligations under this Agreement, and (ii) Licensee and its Affiliates shall not promote, market, distribute or sell the Compound to end-users, but may sell (including related distribution, importing and exporting) or otherwise supply the Compound to Affiliates and/or Sublicensees and/or Third Party manufacturers for further Manufacturing into Product for sale to end-users.
- **2.1.2 Grant to Licensor.** Subject to the terms and conditions of this Agreement, Licensee hereby grants to Licensor during the Term a non- exclusive, royalty free license, with the right to sublicense ([\*CONFIDENTIAL\*]), under and with respect to the Licensee Technology, for the sole and limited purposes of performing its obligations under this Agreement.

## 2.2 Additional Licensing Provisions.

- **2.2.1 Negative Covenant.** Licensee covenants that it will not use or practice any of Licensor's rights to and under the Licensor Patents or other intellectual property rights licensed (or sublicensed, as applicable) to it under this ARTICLE 2, except for the purposes expressly permitted in the applicable license grant.
- 2.2.2 Freedom to Operate. In addition to the exclusive license granted under Section 2.1.1, Licensor hereby grants to Licensee a non-exclusive license under [\*CONFIDENTIAL\*] that are (i) Controlled by Licensor or its Affiliates during the Term and (ii) necessary to Develop, Manufacture and Commercialize the Compound and the Product in the Licensed Field in the Territory.

**2.2.3** No Implied Licenses; Retained Rights. Except as explicitly set forth in this Agreement, Licensor does not grant any license, express or implied, under its intellectual property rights to Licensee, whether by implication, estoppel or otherwise.

#### 2.3 Performance by Affiliates and Sublicensees.

2.3.1 Performance by Affiliates. The Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates; provided, however, that each Party shall remain responsible for the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Each Party hereby expressly waives any requirement that the other Party exhausts any right, power or remedy, or proceed against an Affiliate, for any obligation or performance hereunder prior to proceeding directly against such Party with respect to such obligation or performance. Wherever in this Agreement the Parties delegate responsibility to Affiliates, the Parties agree that such entities may not amend the terms of this Agreement or act contrary to its terms in any way. Notwithstanding the foregoing, or anything to the contrary herein, an Affiliate of Licensee shall not have the right to promote, market or sell the Product to end users unless such Affiliate is a Sublicensee under and in accordance with Section 2.3.2; provided, that, Licensee's Affiliates may sell (including related distribution, exporting and importing of) Compound and Product to other Affiliates of Licensee and Sublicensees (and, for clarity, which sales are not Net Sales).

2.3.2 Sublicensees. Licensee shall have the right (but not the obligation) to sublicense those rights granted to it under Section 2.1.1 and Section 2.2.2 to (i) any Affiliate or Third Party outside of the United States, without the prior written consent of Licensor, (ii) a Qualified Sublicensee [\*CONFIDENTIAL\*], without the prior written consent of Licensor, and (iii) any other Third Parties [\*CONFIDENTIAL\*], with Licensor's prior written consent, not to be unreasonably withheld or delayed (each of (i) through (iii), a "Sublicensee"), which sublicenses may include the right of such Sublicensees to grant further sublicenses on terms consistent with this Section 2.3.2 (and any such sub-sublicensees, regardless of the number of tiers, shall be a "Sublicensee"). Each sublicense granted by Licensee or its Sublicensees shall be consistent with the terms and conditions of this Agreement. Licensee shall provide Licensor notice of each sublicensee promptly after the execution, and prior to any public disclosure, thereof identifying the Sublicensee, the countries involved and whether such Sublicensee is being granted the right(s) to Develop, Manufacture and/or Commercialize the Compound and/or Product. Licensee shall remain responsible for the performance or non-performance of all of its obligations under this Agreement by any Sublicensees as if such actions or inactions were being taken, or omitted, directly by Licensee and, accordingly, Licensee shall have such cure rights, if any, as are provided to Licensee hereunder in connection with any such actions or inactions as may constitute a breach of this Agreement. Without limiting Licensee's obligations under this Agreement, Licensee shall enforce the terms of each relevant sublicense agreement as Licensee will deem appropriate in the best interest of the Product. Licensee hereby expressly waives any requirement that Licensee exhaust any right, power or remedy, or proceed against a subcontractor, for any obligation or performance hereunder prior to proceeding directly ag

with respect to any one or more countries, Licensee will remain directly responsible for all amounts owed to Licensor under this Agreement.

## 2.4 [\*CONFIDENTIAL\*].

2.5 Technology Transfer. In accordance with the transfer plan set forth on Schedule 2.5 hereto (the "Technology Transfer Plan"), Licensor shall transfer to Licensee, and Licensee shall accept, the Licensor Know-How, Regulatory Materials, Regulatory Data and other technical information that is described in the Technology Transfer Plan and other, if any, Licensor Know-How, Regulatory Materials and Regulatory Data Controlled by Licensor as of the Effective Date, to permit and enable Licensee or its Affiliates to Develop and Manufacture the Compound and the Product pursuant to the terms of this Agreement. The implementation and transfer of information and materials pursuant to this Section 2.5 shall be conducted through electronic, email and teleconference consultation between the Parties as set forth in the Technology Transfer Plan. Without limiting the foregoing, subject to the availability of Licensor's personnel, Licensor shall provide reasonable assistance to Licensee, upon Licensee's reasonable request therefor, for a period not to exceed [\*CONFIDENTIAL\*] following the Effective Date, in interpreting and understanding the Licensor Know-How to facilitate the effective adoption thereof. In addition, Licensor shall, [\*CONFIDENTIAL\*]. For clarity, in the event that [\*CONFIDENTIAL\*], then [\*CONFIDENTIAL\*]. In addition to the foregoing transfer obligations, the Parties will take such steps as are necessary for Licensor to continue conducting the On-Going Studies and the POC Study under the IND(s) transferred to Licensee. Licensee may only use the Regulatory Materials and Regulatory Data provided by Licensor hereunder in accordance with the rights granted to Licensee under Section 2.1.1.

2.6 Access to Raw Data. If reasonably required by Licensee and not previously provided, Licensor shall, upon reasonable notice from Licensee, provide Licensee with an opportunity to review and use any original documentation and raw data related to the Compound and/or the Product that is in Licensor's or its Affiliates' Control on the Effective Date or at the time of Licensee's request; provided, that the foregoing obligation to provide any such raw data shall not include raw data that was generated prior to Licensor coming to Control the Compound and Product and that was never in Licensor's possession (the "External Data"). If Licensee or Licensor becomes aware of the existence of such External Data after the Effective Date, then upon request by Licensee, Licensor shall provide reasonable assistance to Licensee in locating and acquiring access to such External Data from the entity in possession of such External Data. For clarity, Licensor shall have no obligation under this Section 2.6 to generate any new documentation, raw data or analysis thereof.

## 2.7 Ongoing Agreements.

2.7.1 Licensor shall comply with the relevant terms and conditions of the Ongoing Agreements and shall use Commercially Reasonable Efforts to complete, or cause the completion of, the activities provided for in each Ongoing Agreement (i.e., the completion of the activities under the specific work orders identified in Schedule 1.46) as expeditiously as possible. Licensor shall regularly discuss with Licensee and shall keep Licensee informed regarding

relevant activities under each Ongoing Agreement as reasonably requested by Licensee. Licensee shall also be entitled to [\*CONFIDENTIAL\*] with the Third Party counter-parties to the Ongoing Agreements and will [\*CONFIDENTIAL\*] of any such [\*CONFIDENTIAL\*]. In case of any disagreement between the Parties with respect to any such activity, [\*CONFIDENTIAL\*] shall have the right to make the final decision; provided, that [\*CONFIDENTIAL\*] cannot exercise its decision-making authority in any way that (i) would cause [\*CONFIDENTIAL\*] to be in breach of [\*CONFIDENTIAL\*] or (ii) would impose upon [\*CONFIDENTIAL\*] any additional obligations (e.g., in terms of employee allocation) without [\*CONFIDENTIAL\*] prior written consent. All fees and payments incurred by Licensor in connection with the Ongoing Agreements shall be borne by Licensee and shall be reimbursed upon presentation by Licensor of the relevant invoice accompanied by appropriate written evidence of the expenses incurred, provided however that Licensee shall not be obliged to reimburse any amount that (i) was not contemplated in the relevant Ongoing Agreement, and (ii) was not previously authorized in writing by Licensee (provided, further, that, the Parties acknowledge and agree that all amounts in connection with activities planned or ongoing under the Ongoing Agreements as of the Effective Date and already disclosed to Licensee prior to the Effective Date have been previously authorized by Licensee). Licensee may request changes to an Ongoing Agreement and Licensor will use Commercially Reasonable Efforts to cause any such change to be implemented under the applicable Ongoing Agreement, subject to Licensee's payment of all documented fees and payments incurred by Licensor in connection with such change.

- **2.7.2** All results, information, and data arising out of the activities conducted under the Ongoing Agreements shall be timely communicated to Licensee and put at Licensee's disposal for use by Licensee in accordance with the terms and conditions of this Agreement.
- **2.8 Improvements.** Subject to the terms and conditions of this Agreement, Licensee shall have the right to develop and carry out, directly or indirectly, and to license to its Affiliates and Third Parties, whatever improvement, addition, refinement, modification or development, whether patentable or not, it deems fit with respect to the Compound and the Product.
- 2.8.1 Licensee will be the exclusive owner of any and all Inventions generated with regard to the Compound and/or the Product which are conceived, reduced to practice or otherwise developed by Licensee and/or any of its Affiliates or Sublicensees or any employee, agent or other person acting on behalf of Licensee, and of any resulting Patent (which shall be a Licensee Patent).
- 2.8.2 Licensee will be the sole owner of all Joint Inventions generated with regard to the Compound and/or the Product. Licensor may be listed as inventor so as to establish joint inventorship in the case of any relevant Patent or Collaboration Patent claiming a Joint Invention, which shall in any event constitute a Licensee Patent. For clarity, the Parties hereby acknowledge and agree that Licensor shall have no right to conduct any activities with respect to the Compound and the Product after the Effective Date, except as expressly provided

for under this Agreement, including activities in connection with the Ongoing Studies, the POC Study and the Ongoing Agreements.

- 2.8.3 For clarity, [\*CONFIDENTIAL\*] shall at any time have the right to decide whether to file any application for a [\*CONFIDENTIAL\*] Patent, including any [\*CONFIDENTIAL\*] Patent, as well as to maintain, prosecute and enforce any such [\*CONFIDENTIAL\*] Patent (including [\*CONFIDENTIAL\*] Patent) in any country of the Territory at its sole discretion, and [\*CONFIDENTIAL\*] shall use Commercially Reasonable Efforts to support and/or assist, bearing exclusively [\*CONFIDENTIAL\*] own internal costs, as may be reasonably required by [\*CONFIDENTIAL\*] in connection therewith.
- 2.8.4 [\*CONFIDENTIAL\*] hereby assigns to [\*CONFIDENTIAL\*] all right, title and interest that it or its Affiliates or their respective employees or contractors may have in and to the [\*CONFIDENTIAL\*] Patents, together with the right to sue for past, present, and future infringement thereof. With respect to agreements executed after the Effective Date, if any, [\*CONFIDENTIAL\*] shall require that all of its and its Affiliates' employees and contractors conducting any activities with respect to the Compound or Product execute a written agreement with [\*CONFIDENTIAL\*] pursuant to which (i) such employees and contractors assign to [\*CONFIDENTIAL\*] all of their right, title and interest that they may have with respect to any Invention pertaining to the Compound or Product, and (ii) agree to maintain the confidentiality of all such Inventions on terms consistent with the provisions of ARTICLE 12.

# ARTICLE 3 GOVERNANCE

**3.1 Joint Steering Committee.** Promptly following the Effective Date, Licensee and Licensor will establish a joint steering committee ("JSC"), consisting of six (6) people, with three (3) representatives appointed by Licenser and three (3) representatives appointed by Licensee. The JSC will be chaired by one of Licensee's representatives. The role of the JSC shall be advisory in nature, with the main purpose of serving as a forum for the sharing of information and facilitating communications between the Parties regarding Development Activities and Commercialization.

## 3.2 Meetings and Minutes.

- 3.2.1 The JSC shall meet at least quarterly for the first two (2) Calendar Years, and thereafter twice per Calendar Year, or as often as needed and as agreed by the Parties, with each Party bearing its own costs and expenses for organization and participation. Meetings may be in-person, or by telephone conference call, or internet meeting, as determined by the JSC members for each meeting. Employees or consultants of a Party who are not representatives of the Parties on the JSC may attend JSC meetings; provided, however, that such attendees are bound by obligations of confidentiality and non-disclosure consistent with ARTICLE 12.
- 3.2.2 Licensee will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect material decisions made and action items identified at such meetings. Definitive minutes of all JSC meetings shall be finalized no later

than ten (10) Business Days after the meeting to which the minutes pertain. If at any time during the preparation and finalization of the meeting minutes, the Parties do not agree on any issue with respect to the minutes, such issue shall be recorded in the finalized minutes for said meeting.

#### 3.3 Decision Making.

- **3.3.1** Without prejudice to the provisions of Section 3.3.2 below, the JSC shall attempt to make decisions by consensus of the representatives present, with each Party having a single vote irrespective of the number of representatives of such Party in attendance or by a written resolution signed by at least one (1) representative appointed by each Party.
- 3.3.2 If the JSC cannot, or does not, reach consensus on an issue which has been discussed during a meeting of the JSC, within five (5) Business Days after the matter has first been discussed by the JSC, or any shorter term which is required by specific circumstances, then such issue will first be referred to the respective Executive Officers of the Parties to try to reach a mutually acceptable resolution. In the event that the Executive Officers of each Party are unable to resolve such dispute in good faith within five (5) Business Days, and provided that the Executive Officers have discussed such matter, then [\*CONFIDENTIAL\*] shall have the sole authority to decide such matter; provided that any final determination made by [\*CONFIDENTIAL\*] under this Section 3.3.2 shall (i) be consistent with the terms of this Agreement (and shall not amend this Agreement) and (ii) not require [\*CONFIDENTIAL\*] to conduct any activities or bear any additional expense without the [\*CONFIDENTIAL\*] prior written consent. For the avoidance of any doubt, it is hereby expressly agreed that Licensee shall have the right to decide on all steps to be taken in connection with the Development and/or the Commercialization of the Product; provided, that all such Development and/or Commercialization shall be conducted in accordance with the terms and conditions of this Agreement.

## ARTICLE 4 DEVELOPMENT

- **4.1 Development Progress Updates.** At the end of each [\*CONFIDENTIAL\*], Licensee shall provide Licensor with a report regarding the progress of Development Activities during the previous [\*CONFIDENTIAL\*]. Without limiting the foregoing, reasonably prior to each meeting of the JSC, each Party shall provide the other Party with a written summary regarding material Development activities that it has directly or indirectly conducted, if any, since the previous JSC meeting, and shall provide copies of any specific information that the other Party may reasonably request with respect such summary.
- **4.2 Overview of Development.** Subject to the terms and conditions of this Agreement, Licensee shall be responsible for the Development of the Product as set forth herein. Licensee shall use Commercially Reasonable Efforts to perform Development Activities for the Product to achieve the development milestones set forth in Section 8.2.
  - 4.3 Development Plan.

- 4.3.1 Licensee shall (i) use Commercially Reasonable Efforts to carry out Development Activities (other than those constituting Essential Development Elements) pursuant to a development plan (as amended from time to time pursuant to this Section 4.3, the "Development Plan") in accordance with the tentative time frames indicated in the Development Plan and (ii) carry out the Essential Development Elements pursuant to the Development Plan in accordance with the tentative time frames indicated in the Development Plan. Subject to Section 4.3.2, the Development Plan shall be provided by Licensee to Licensor and the JSC within [\*CONFIDENTIAL\*] of the Effective Date.
- 4.3.2 The Development Plan shall in any and all events be consistent with Schedule 4.3.2 (the subject matter of such Schedule, "Essential Development Elements"). In addition, the Development Plan shall include CMC activities, preclinical studies and Clinical Trials necessary for obtaining and maintaining Regulatory Approval, with respect to the Product and the projected timeline for completing such Development Activities. Licensee may update the Development Plan from time-to-time to reflect any material changes, reprioritizations of, or additions to the Development Plan. Such updated Development Plan shall be discussed in the following JSC meeting and Licensee will consider (but will [\*CONFIDENTIAL\*]) any comments provided by the JSC in good faith. Once Licensee has considered, and to the extent applicable, incorporated any comments by the JSC, it shall provide Licensor with a copy of such amended Development Plan. Notwithstanding anything to the contrary in this Agreement, the Development Plan shall continue to include the Essential Development Elements, except to the extent that Licensor grants its consent to the modification of any Essential Development Element, which consent shall not be unreasonably withheld or delayed.
- 4.3.3 Licensee shall conduct the Development Activities in accordance with sound and ethical business and scientific practices, and in compliance with all Applicable Law, including GCPs and GLPs, and also including all applicable data privacy and data protection laws. In addition, Licensee shall not use in any capacity, in connection with its Development of the Compound or Product hereunder, any Person who has been debarred pursuant to Section 306 of the FD&C Act (or similar Applicable Law outside of the U.S.), or who is the subject of a conviction described in such section, and Licensee shall inform Licensor in writing immediately if it or any Person who is performing services for Licensee hereunder is debarred or is the subject of a conviction described in Section 306 (or similar Applicable Law outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to Licensee's knowledge, is threatened, relating to the debarment of Licensee or any Person used in any capacity by Licensee in connection with its Development of the Compound or Product hereunder.
- **4.4 Development Costs.** As between the Parties, Licensee shall be solely responsible for one hundred percent (100%) of all Development costs incurred by or on behalf of Licensee or its Affiliates or Sublicensees, with respect to any Development Activities, except to the extent otherwise set forth in the Technology Transfer Plan and excluding, for clarity, Development Activities with respect to the On-Going Studies and the activities set forth at Section 4.7 with respect to the POC Study for the Second Indication.

#### 4.5 Records, Reports and Information.

- **4.5.1 General.** Each Party shall maintain current and accurate records (in sufficient detail and in good scientific manner appropriate for regulatory and patent purposes) of all work conducted by it or on its behalf (including, with respect to Licensee, work conducted by its Affiliates and Sublicensees in accordance with Section 2.3) under the Development Plan or in connection with the On-Going Studies, the On-Going Agreements and the POC Study in full compliance with GxPs and any and all Applicable Laws.
- 4.5.2 Access to Records. [\*CONFIDENTIAL\*] shall have the right to review all records in connection with the [\*CONFIDENTIAL\*], the activities performed under [\*CONFIDENTIAL\*], and the [\*CONFIDENTIAL\*] Controlled by [\*CONFIDENTIAL\*] upon written request and the Parties' reasonable agreement regarding an appropriate time for such audit.
- 4.6 On-Going Studies. Licensor will use Commercially Reasonable Efforts to conduct, or have conducted, and finalize the On-Going Studies as soon as reasonably possible. Licensor has conducted and shall conduct the Ongoing Studies in accordance with sound and ethical business and scientific practices, and in compliance with all Applicable Law, including GCPs and GLPs, and also including all applicable data privacy and data protection laws. In addition, Licensor has not used and shall not use in any capacity, in connection with the Ongoing Studies, any Person who has been debarred pursuant to Section 306 of the FD&C Act (or similar Applicable Law outside of the U.S.), or who is the subject of a conviction described in such section, and Licensor shall inform Licensee in writing immediately if it or any Person who is performing services for Licensor hereunder is debarred or is the subject of a conviction described in Section 306 (or similar Applicable Law outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to Licensor's knowledge, is threatened, relating to the debarment of Licensor or any Person used in any capacity by Licensee in connection with the On-Going Studies. Licensee shall have the right to review and comment on the clinical study report and/or appendices of the On-Going Studies.

## 4.7 POC Study for the Second Indication.

4.7.1 Promptly following the Effective Date, the Parties shall discuss and seek agreement in good faith on the protocol for the performance of the POC Study, the contract research organization to be engaged and the relevant budget for such POC Study. Licensor shall be responsible for performance of the POC Study in accordance with Applicable Laws and subject to Section 4.6 applied *mutatis mutandis* with respect to the POC Study; provided, that, in the event that the external costs associated with the POC Study exceed USD [\*CONFIDENTIAL\*], then the Parties shall confer and shall seek an agreement in good faith following the procedure described at Section 3.3.2, provided however that in case that the Parties are unable to find such an agreement then none of the Parties will have a casting vote and the POC Study will be discontinued (subject to compliance with any Applicable Laws and regulatory requirements).

- **4.7.2** The Parties shall on a regular basis exchange information and updates on the POC Study through meetings of the JSC, including by way of Licensor's reporting obligations under Section 4.1.
- **4.7.3** Licensee will reimburse Licensor for [\*CONFIDENTIAL\*] of all documented external costs and expenses incurred by Licensor in connection with the POC Study, up to USD [\*CONFIDENTIAL\*]. Licensor shall invoice Licensee from time-to-time in connection with such amounts, and Licensee shall pay such invoices within [\*CONFIDENTIAL\*] of receipt of an invoice therefor.
- **4.7.4** For clarity, following completion of the POC Study, Licensee will be free to decide whether or not to pursue the further Development of the Product for the Second Indication (and to [\*CONFIDENTIAL\*] any relevant [\*CONFIDENTIAL\*]) and any and all subsequent activities will be governed by the terms and conditions of this Agreement.

## ARTICLE 5 REGULATORY

### 5.1 Regulatory Filings and Regulatory Approvals.

- **5.1.1 General Responsibilities; Ownership of Regulatory Approvals.** Subject to Section 2.5, Licensee or its nominee shall be responsible for the preparation of all Regulatory Materials necessary or desirable for obtaining and maintaining the Regulatory Approvals for the Compound (to the extent necessary) and Product (including in connection with Patient Information Leaflets, labeling and packaging for the Product) and Licensee shall, directly or through any of its nominees, submit such Regulatory Materials, as applicable, to the applicable Governmental Authorities.
- **5.1.2 Pricing Approvals.** To the extent that a given country or regulatory jurisdiction requires Pricing Approval for sale of the Product, Licensee shall (to the extent permitted by Applicable Laws), directly and/or through any of its nominees, be solely responsible for (and shall use Commercially Reasonable Efforts toward) obtaining and maintaining Pricing Approvals in all such countries and regulatory jurisdictions.
- **5.1.3** Cost of Regulatory Activities. Subject to Section 2.5, all regulatory costs incurred in connection with the preparation of Regulatory Materials, and obtaining of Regulatory Approvals, for the Compound and Product shall be borne solely by Licensee. Licensee shall be responsible for all regulatory costs involved in the maintenance of all Regulatory Approvals for the Compound and Product.
- **5.1.4 Reporting and Review.** Starting from the date of the first MAA submission in any country of the Territory, Licensee shall send Licensor a report every two Calendar Quarters setting forth all MAAs and Regulatory Approvals that have been submitted for approval or received approval for, in each case with respect to the Product (and whether submitted or received by or on behalf of Licensee or its Affiliate or Sublicensee); provided, that, in any event, Licensee shall notify Licensor within five (5) Business Days regarding its or its

Affiliate's or Sublicensee's receipt of Regulatory Approval for the Product and an indication in each of the United States, Japan, China, the United Kingdom, Spain, Italy, Germany or France.

#### 5.2 Pharmacovigilance and Medical Inquiries.

- **5.2.1 Pharmacovigilance.** Subject to Section 2.5 and the Parties' transition of the global safety database (including relevant information related to adverse events) on timing agreed by the Parties, Licensee shall be responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with the Product (whether or not Regulatory Approval has been achieved), in each case in accordance with Applicable Law and this Agreement (and Licensee shall ensure that, in the Development and Commercialization of the Product, it will record, investigate, summarize, notify, report and review all adverse events in accordance with Applicable Law). While the On-Going Agreements, On-Going Studies and the POC Study continue, Licensor shall be responsible for the collection and transmission to Licensee of information related to adverse events associated with the Product arising from such On-Going Agreements, On-Going Studies and POC Study as required by Applicable Laws and the Parties will work together in good faith to ensure that each has access to such safety data as is required by Applicable Law and in order enable each Party to satisfy any regulatory requirements.
- **5.2.2 Medical Inquiries for the Product.** Following the Effective Date, subject to Section 5.1.1, Licensee shall be responsible for handling all medical questions or inquiries in each country, including all Product Complaints, with regard to Product sold by or on behalf of Licensee (or any of its Sublicensees), in each case in accordance with Applicable Law and this Agreement.

## 5.3 Regulatory Authority Communications Received by a Party.

**5.3.1 General.** Each Party shall use Commercially Reasonable Efforts to promptly inform the other Party of notification of any action by, or notification or other information that it receives (directly or indirectly) from, any Regulatory Authority that (i) raises any material concerns regarding the safety or efficacy of the Product or Compound, (ii) indicates a potential material liability of either Party to Third Parties in connection with the Product or Compound, (iii) is reasonably likely to lead to a recall, market withdrawal or market notification with respect to the Product or Compound, or (iv) relates to expedited and periodic reports of adverse events with respect to the Product or Compound, or Product Complaints, and which may have an adverse impact on Regulatory Approval or the continued Commercialization of the Product or Compound. Licensee shall be solely responsible for responding to any such communications relating to the Product, and the Parties shall reasonably cooperate with and assist each other in complying with regulatory obligations. Each Party shall also promptly provide the other Party with a copy of all material correspondence received from a Regulatory Authority specifically regarding the matters referred to above to the extent reasonably requested by such other Party.

- **5.3.2 Disclosures.** In addition to its obligations under this Agreement, each Party shall use Commercially Reasonable Efforts to promptly disclose to the other Party the following regulatory information:
- (a) All material information pertaining to material actions taken by Regulatory Authorities, in connection with the Product or Compound, including notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the Product or Compound, notice of violation letter (i.e., an untitled letter), warning letter, service of process or other material inquiry.
- (b) All material information pertaining to notices from Regulatory Authorities, regarding non-compliance with Applicable Law in connection with the Product or Compound as soon as reasonably possible.
- **5.4 Recall, Withdrawal, or Market Notification of Product.** In the event that (i) any Governmental Authority threatens or initiates any action to recall or withdraw the Product from the market, or to cause a market notification (e.g., by requiring the issuance of a "Dear Doctor" letter) or (ii) Licensee makes the determination to initiate any action to recall or withdraw the Product from the market, or to cause a market notification, Licensee shall notify Licensor of such communication or determination, as applicable, promptly and without delay after receipt or determination, as applicable, thereof. Licensee shall determine whether to initiate any recall, withdrawal or market notification of the Product. Licensee shall at all times utilize a batch tracing system which will enable the Parties to identify, on a prompt basis, customers who have been supplied with Product of any particular batch, and to recall such batch of Product from such customers as set forth in this Section 5.4. All costs and expenses associated with implementing a recall, withdrawal or market notification with respect to the Product shall be borne by Licensee.

# ARTICLE 6 COMMERCIALIZATION

- **6.1 Commercialization.** During the Term, Licensee shall be solely responsible for Commercializing the Compound and Product, which Commercialization shall be in accordance with this Agreement and with all Applicable Laws. As between the Parties, Licensee shall be responsible for one hundred percent (100%) of the expenses (including Pre-Marketing and other Commercialization expenses) incurred by or on behalf of Licensee or its Sublicensees in connection with the Commercialization of the Compound and Product, including any expenses incurred by or on behalf of Licensee or its Affiliates in connection with selling (including related exporting and importing of) Compound and Product in unfinished form to other Affiliates of Licensee and Sublicensees. Without limiting the foregoing, Licensee shall use Commercially Reasonable Efforts to Commercialize the Product throughout the Territory.
- **6.2 Commercialization Progress Updates.** Licensee shall regularly inform and update Licensor on the status of its and its Sublicensees Pre-Marketing and Commercialization of the Product. Such updates and information, and any relevant discussion on the status of such Pre-Marketing and Commercialization shall be made in the course of meetings of the JSC

starting from the date indicated above, and Licensee will consider (but will not be obliged to follow) any comments provided by the JSC in good faith.

#### 6.3 Licensee's Performance.

- **6.3.1 Specific Commercialization Obligations.** Without limiting the generality of the provisions of Section 6.1, in connection with the Commercialization of the Compound and Product by or on behalf of Licensee hereunder:
- (a) Licensee shall (i) use Commercially Reasonable Efforts to Commercialize the Product for the Target Indication throughout the Territory and to maximize the commercial potential for the Product and (ii) not sell or distribute the Product in the [\*CONFIDENTIAL\*] in such a manner as to decrease the revenue attributable to the Product in the interest of benefiting another product being sold or distributed by or on behalf of Licensee.
- (b) Licensee shall not utilize deceptive, misleading or unethical business practice in connection with the Commercialization of the Compound or Product hereunder.
- (c) Licensee shall be solely responsible, directly or through its Affiliates or Sublicensees, as applicable in accordance with such activities as Affiliates or Sublicensees may conduct in accordance with the terms of this Agreement, for (i) receiving, accepting and filling orders for the Compound and Product, (ii) handling all returns of the Compound and Product, (iii) controlling invoicing, order processing and collection of accounts receivable for the sales of the Compound and Product, and (iv) distributing and managing inventory of the Compound and Product.
- **6.3.2 Compliance.** Licensee shall not use in any capacity, in connection with its Commercialization of the Compound or Product hereunder, any Person who has been debarred pursuant to Section 306 of the FD&C Act (or similar Applicable Law outside of the U.S.), or who is the subject of a conviction described in such section, and Licensee shall inform Licensor in writing immediately if it or any Person who is performing services for Licensee hereunder is debarred or is the subject of a conviction described in Section 306 (or similar Applicable Law outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to Licensee's knowledge, is threatened, relating to the debarment of Licensee or any Person used in any capacity by Licensee in connection with its Commercialization of the Compound or Product hereunder.

#### 6.4 Promotional Materials.

- **6.4.1 Creation of Promotional Materials.** Licensee will create, directly or through its Sublicensees or other nominees, and develop Promotional Materials for the Product in accordance with the Regulatory Approvals and Applicable Law.
- **6.4.2 No Inclusion of Licensor Logos on Packaging and Promotional Materials.** Notwithstanding anything to the contrary herein, Licensee shall not use any Licensor

trademark, names, logos or housemark in connection with any Promotional Materials or the Product without Licensor's prior written consent, which consent shall not be withheld or delayed in the event that Applicable Laws requires the use of any such Licensor marks.

**6.4.3 Licensee Ownership of Promotional Materials.** Licensee shall own all right, title and interest in and to any Promotional Materials created by or on behalf of Licensee hereunder relating to the Product including copyrights, but excluding trademarks, names, logos and other marks Controlled by Licensor or its Affiliates.

#### 6.5 Product Trademarks and Product Trade Dress.

- **6.5.1 Product Trademark.** Licensee shall Commercialize the Product under the trademark and the trade dress selected by Licensee (the "**Product Trademark**" and the "**Product Trade Dress**", respectively).
- **6.5.2** Use and Ownership of Product Trademarks and Product Trade Dress. All uses of the Product Trademark and Product Trade Dress by Licensee, its Affiliates and Sublicensees to identify and/or in connection with the Commercialization of the Product shall be in accordance with Regulatory Approvals and all Applicable Law. Licensee shall own and retain all rights to the Product Trademark and Product Trade Dress (in each case, together with all goodwill associated therewith). Licensee shall also own rights to any internet domain names incorporating the Product Trademark or any variation or part of such trademark as its URL address.
- **6.5.3 Maintenance of Product Trademark.** During the Term, Licensee will use Commercially Reasonable Efforts to establish, maintain and enforce the Product Trademarks as it deems appropriate in connection with the Commercialization of the Product, and will bear all costs and expenses relating thereto.
- **6.6 Commercialization Data.** Licensee shall own all marketing and sales data and information resulting from its Commercialization of the Product during the Term (the "Commercialization Data"), including promotional materials, marketing strategies and market research data.

### ARTICLE 7 SUPPLY

7.1 Transfer of Existing Materials. Within [\*CONFIDENTIAL\*] of the Effective Date, Licensor shall provide a one-time supply of Product and Compound to Licensee, without further consideration by Licensee to Licensor, other than that set forth in Section 8.1 below, up to the amounts and in the forms set forth on Schedule 7.1, which Licensee agrees to accept on an as-is basis. Licensor shall make available to Licensee the Product and Compound up to the amounts and in the forms specified on Schedule 7.1 with appropriate documentation (i.e., appropriate certificates of analysis or compliance, as applicable) following receipt of a written request therefor from Licensee that specifies the quantities and forms desired. The Product and Compound shall be made available to Licensee EXW (as defined in INCOTERMS 2010) at the

warehouse locations specified in <u>Schedule 7.1</u>. For clarity, Licensee shall bear all costs related to shipping, taxes, and acceptance testing associated with such supply. In the event that Licensee does not provide such a written request, or if there are any quantities of Compound or Product remaining after such [\*CONFIDENTIAL\*] period, and subject to Section 7.3 below, Licensor will destroy any such remaining quantities and will inform Licensee of such destruction.

7.2 Subsequent Supply; Packaging and Labeling; Certain Other Manufacturing Activities. Licensee or its designated Third Party shall be responsible (at its sole cost and expense) for all Product and Compound supply (other than Product and Compound supplied by Licensor under Section 7.1) and all final product labeling and packaging (whether in commercial or clinical packaging presentation), including insertion of materials such as patient inserts, 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 (collectively, "Packaging and Labeling"). For clarity, Licensee's Packaging and Labeling responsibilities apply to the Product and Compound supplied by Licensor under Section 7.1. Licensee or its designated Third Party shall ensure that all such Packaging and Labeling complies with Applicable Laws, GMPs and the Regulatory Approvals for the Product. To the extent that a Third Party is involved in Packaging and Labeling or other activities described in this Section 7.2, Licensee shall be wholly responsible for, and bear one hundred percent (100%) of the costs related to, qualifying such Third Party to perform such activities.

**7.3 MEI Supplies.** Notwithstanding Sections 2.5 and 7.1, the Parties acknowledge and agree that Licensor will retain those quantities of Compound and Product as are set forth on <u>Schedule 7.3</u> in connection with Licensor's obligations to perform the Ongoing Studies and to complete activities under the Ongoing Agreements. In addition, the Parties shall work together in good faith to ensure that Licensor is allocated and receives a sufficient quantity of Compound and Product to perform the POC Study from the supply generated under those certain On-Going Agreements identified on <u>Schedule 1.46</u> with agreement identifiers **|\*CONFIDENTIAL\*|**.

# ARTICLE 8 PAYMENTS

**8.1 Upfront Payments.** Licensee shall pay to Licensor by wire transfer of immediately available funds, into an account designated in writing by Licensor, an amount equal to (i) fifteen million dollars (\$5,000,000), within ten (10) Business Days of the Effective Date, and (ii) five million dollars (\$5,000,000), within ten (10) Business Days of the earlier of (a) the date when Licensee (or its Affiliate, Sublicensee or other nominee) becomes aware of the first dosing of a patient with the Product in the Clinical Trial internally designated by Licensor as MEI 009 or (b) March 1, 2017 (together, clauses (i) and (ii), the "**Upfront Payment**"). The Upfront Payment shall be (i) non-refundable and non-creditable against any other payments due hereunder and (ii) inclusive of the consideration for the Compound and Product supply to be made by Licensor to Licensee pursuant to Section 7.1 above.

**8.2 Milestone Payments.** Licensee shall pay to Licensor the milestone payments described in this Section 8.2 following achievement (and only upon the first occurrence) of the corresponding milestone event. Licensee shall promptly notify Licensor in writing of, but in no event later than [\*CONFIDENTIAL\*] after, the achievement of each such milestone event (each, a "Milestone Notification Notice"). Licensee shall pay the applicable milestone payment by wire transfer of immediately available funds into an account designated by Licensor within [\*CONFIDENTIAL\*] days after the achievement (and only upon the first occurrence) of the applicable milestone event; provided, however, that in no event shall a failure to deliver a Milestone Notification Notice relieve Licensee of its obligation to pay Licensor the milestone payments described in this Section 8.2. Each such milestone payment is nonrefundable and non-creditable against any other payments due hereunder.

	Milestone Event	Part A - Development Milestone	Milestone Payment
[*CONFIDENTIAL*]		Ture A Development winestone	[*CONFIDENTIAL*]
[*CONFIDENTIAL*]			[*CONFIDENTIAL*]
		Part B - Sales Milestones*	
[*CONFIDENTIAL*]			[*CONFIDENTIAL*]

Milestone Event Milestone Payment

[\*CONFIDENTIAL\*]

[\*CONFIDENTIAL\*]

In the event that more than one sales milestone is achieved in a given Calendar Year, only the first such milestone shall be due during such Calendar Year and the subsequent milestone(s) shall be paid at the end of the second Calendar Quarter of the next Calendar Year. For example, if cumulative, worldwide Calendar Year Net Sales of the Product in a given Calendar Year equal [\*CONFIDENTIAL\*], then [\*CONFIDENTIAL\*] will be paid following the Calendar Quarter during which cumulative worldwide Net Sales of the Product equal [\*CONFIDENTIAL\*] and [\*CONFIDENTIAL\*] will be paid [\*CONFIDENTIAL\*] (for clarity, this example would only apply to the first Calendar Year during which Net Sales exceed both [\*CONFIDENTIAL\*] and [\*CONFIDENTIAL\*]).

#### 8.3 Royalty Payments.

- **8.3.1 Product.** On a country-by-country basis during the Royalty Term applicable to such country, Licensee shall pay to Licensor in accordance with Section 8.5 the following royalties on Net Sales of the Product, subject to Sections 8.3.3 and 8.3.4:
- (a) Royalties for Net Sales of Product (i) [\*CONFIDENTIAL\*] or (ii) directly Commercialized by Licensee or its Affiliates shall be payable at the following rates:

Aggregate Annual Global Net
Sales of Product

[\*CONFIDENTIAL\*] and/or
directly Commercialized by
Licensee or its Affiliates

[\*CONFIDENTIAL\*]

|\*CONFIDENTIAL\*| |\*CONFIDENTIAL\*| |\*CONFIDENTIAL\*| Royalty Rate on Net Sales of Product [\*CONFIDENTIAL\*] and/or directly Commercialized by Licensee or its Affiliates in Tier 1 Countries

[\*CONFIDENTIAL\*] [\*CONFIDENTIAL\*] [\*CONFIDENTIAL\*] Royalty Rate on Net Sales of Product directly Commercialized by Licensee or its Affiliates in Tier 2 Countries

[\*CONFIDENTIAL\*] [\*CONFIDENTIAL\*] [\*CONFIDENTIAL\*]

- (b) For Net Sales of Product [\*CONFIDENTIAL\*] and not directly Commercialized by Licensee or its Affiliates in Tier 1 Countries: [\*CONFIDENTIAL\*] of Net Sales of Product in each such country.
- (c) For Net Sales of Product [\*CONFIDENTIAL\*] and not directly Commercialized by Licensee or its Affiliates in Tier 2 Countries: [\*CONFIDENTIAL\*] of Net Sales of Product in each such country.

For example purposes only, if aggregate annual global Net Sales equal [\*CONFIDENTIAL\*], with [\*CONFIDENTIAL\*] of such sales [\*CONFIDENTIAL\*] and Tier 1 Countries where Licensee or its Affiliates are directly Commercializing the Product, then Licensor would receive total royalties for that year equal to [\*CONFIDENTIAL\*], calculated as follows:

- (1) Sales [\*CONFIDENTIAL\*] and Tier 1 Countries where Licensee or its Affiliates are directly Commercializing the Product: [\*CONFIDENTIAL\*]; PLUS
- (2) sales in Tier 1 Countries ([\*CONFIDENTIAL\*]) where Licensee and its Affiliates are not directly Commercializing: [\*CONFIDENTIAL\*].

### 8.3.2 Royalties in connection with [\*CONFIDENTIAL\*].

- (a) On such timing as the Parties may agree in good faith, Licensee shall engage a Third Party expert selected by Licensee, and reasonably acceptable to Licensor, to evaluate, at Licensee's sole expense, the [\*CONFIDENTIAL\*] by Licensee (or its Sublicensees) of [\*CONFIDENTIAL\*]. Licensee shall share such expert's determination with Licensor.
- (b) Regardless of such expert's determination, Licensee shall have the right to decide at its discretion whether or not to [\*CONFIDENTIAL\*] (including direct Commercialization or through its Affiliates, Sublicensees or other nominees). If Licensee's decision is positive, then (i) the licensee granted to Licensee in Sections 2.1.1 and 2.2.2 under the Licensor Technology shall, to the extent applicable, automatically be expanded from just the Product to also include [\*CONFIDENTIAL\*], and (ii) Licensee shall pay to Licensor during the Royalty Term a royalty on Net Sales [\*CONFIDENTIAL\*] at a rate of [\*CONFIDENTIAL\*] where such sales are [\*CONFIDENTIAL\*]. Notwithstanding any other provision of this Agreement, the Parties acknowledge and agree that for purposes of calculating the royalties due under this Section 8.3.2(b), in each country in which Licensee or its Affiliate or Sublicensee is [\*CONFIDENTIAL\*] royalties will be payable [\*CONFIDENTIAL\*]. For example, if Licensee or its Sublicensee is [\*CONFIDENTIAL\*] in a given country, and such Person(s) sells [\*CONFIDENTIAL\*], then there will be deemed to be [\*CONFIDENTIAL\*] that are subject to royalty payments under this Section 8.3.2(b).
- 8.3.3 Royalty Reductions in the United States and Countries Where Licensee or its Affiliates are Directly Commercializing the Product. On a country-by-country basis, if at any time during the Royalty Term in the United States or any country where Licensee and its Affiliates are directly Commercializing the Product a Generic Product is commercially sold and remains on the market in such country for a period of [\*CONFIDENTIAL\*], then the royalty rate applicable for such country shall be reduced, starting [\*CONFIDENTIAL\*] from the day when the Generic Product is commercially sold, by [\*CONFIDENTIAL\*]. Such [\*CONFIDENTIAL\*] application shall be accomplished by way of the Parties calculating the overall amount of overpaid royalties based on such [\*CONFIDENTIAL\*] reduction, and Licensee shall have the right to offset any such amount against further payments to be paid to Licensor under this Agreement; provided, that when applying any such offset Licensee shall advise Licensor thereof in writing, including the amount of such offset remaining. Thereafter,
- (a) for so long as such Generic Product remains on the market in such country, if the cumulative Net Sales in such country during a Calendar Quarter are equal to or exceed [\*CONFIDENTIAL\*], but are less than [\*CONFIDENTIAL\*], of the Baseline Quarter

Net Sales, then the royalty rate will be further reduced by [\*CONFIDENTIAL\*] in addition to the [\*CONFIDENTIAL\*] reduction mentioned at Section 8.3.3 above; or

- (b) for so long as such Generic Product remains on the market in such country, if the cumulative Net Sales in such country during a Calendar Quarter are less than [\*CONFIDENTIAL\*], of the Baseline Quarter Net Sales, then the royalty rate will be further reduced by [\*CONFIDENTIAL\*] in addition to the [\*CONFIDENTIAL\*] reduction mentioned at Section 8.3.3.
- 8.3.4 Royalty Reductions in Countries Where Licensee or its Affiliates are not Directly Commercializing the Product (other than the United States). On a country-by-country basis, if at any time during the Royalty Term with respect to any country where Licensee or its Affiliates are not directly Commercializing the Product (other than the United States), a Generic Product is commercially sold and remains on the market in such country for a period of [\*CONFIDENTIAL\*], then the royalty rate applicable for such country shall be reduced, starting [\*CONFIDENTIAL\*] from the day when the Generic Product is commercially sold, by [\*CONFIDENTIAL\*]. Such [\*CONFIDENTIAL\*] application shall be accomplished by way of the Parties calculating the overall amount of overpaid royalties based on the such [\*CONFIDENTIAL\*] reduction, and Licensee shall have the right to offset any such amount against further payments to be paid to Licensor under this Agreement; provided, that when applying any such offset Licensee shall advise Licensor thereof in writing, including the amount of such offset remaining. Thereafter, and for so long as such Generic Products remain on the market, if cumulative Net Sales in such country during a Calendar Quarter are less than [\*CONFIDENTIAL\*] of the Baseline Quarter Net Sales, then the royalty rate will be reduced to [\*CONFIDENTIAL\*].
- **8.3.5 Royalty Minimum.** Notwithstanding the foregoing Sections 8.3.3 and 8.3.4, or Sections 9.2(c), 9.2(d) and 9.3(c)(iii), on a country-by-country basis and for the shorter of (i) the Royalty Term in each such country or (ii) [\*CONFIDENTIAL\*], in no event shall the royalties payable by Licensee to Licensor be reduced to less than [\*CONFIDENTIAL\*] of Net Sales in such country.
- **8.4 Royalties due under the S\*BIO Agreement.** [\*CONFIDENTIAL\*] shall be responsible for any payments due to S\*BIO in connection with Development, Manufacture, and Commercialization of the Product, including payments associated with Net Sales of any given Product in any country. Throughout the Term, Licensor agrees to comply with its obligations under the S\*BIO Agreement to the extent necessary to preserve Licensee's rights with respect to the Compound and the Product in the Territory under this Agreement, and not take any action that would result in the loss of [\*CONFIDENTIAL\*] rights held by Licensor thereunder.
- **8.5 Royalty Payments and Reports.** Licensee shall calculate all Royalty Payments payable to Licensor pursuant to Section 8.3 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 8.7. Licensee shall pay to Licensor the royalty payment due for Net Sales during a given Calendar Quarter within [\*CONFIDENTIAL\*] after the end of such Calendar Quarter;

provided, that, Licensee may make such payments through any of its Affiliates; provided, further, that, and notwithstanding Section 8.6, in the event that payment through any such Affiliate results in any given tax (or incremental tax increase) that would not have been payable had Licensee not made such payment through such Affiliate, then Licensee shall be solely responsible for such tax (or incremental tax increase). Licensee shall also provide Licensor with a good faith estimate of all Net Sales and the Royalty Payments due in connection therewith within [\*CONFIDENTIAL\*] following the end of each Calendar Quarter, provided however that this will not create any liability on Licensee in connection with any inaccuracy which may be included in such estimate. Each royalty payment due shall be accompanied by (i) a statement of the amount of gross sales of each Royalty Product, (a) as a whole and (b) on a country-by-country basis during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars), (ii) an itemized calculation of Net Sales (a) as a whole and (b) on a country-by-country basis, showing for both (a) and (b) deductions 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 Royalty Products sold. Licensee shall be responsible for the proper accounting of Net Sales by or on behalf of its Sublicensees.

## 8.6 Taxes and Withholding.

**8.6.1 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 Licensee to Licensor 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, Licensee shall pay such VAT, and (i) if such VAT is owing as a result of any action by Licensee, including any assignment or sublicense (including assignment to, or payment hereunder by, a Licensee-related entity or Affiliate), or any failure on the part of Licensee 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 Licensor 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 Licensee, Licensee shall promptly reimburse Licensor for the deducted amount. For the sake of clarity, any increase in payments to Licensor under this Section 8.6.1 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, Licensor will provide to Licensee tax invoices showing the correct amount of VAT in respect of such payments hereunder.

**8.6.2 Withholding Tax Matters.** If Licensee is required to make a payment to Licensor subject to a deduction of tax or withholding tax, the sum payable by Licensee (in respect of which such deduction or withholding is required to be made) shall be made to Licensor 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 Licensor, subject to Section 8.6.1, and the obligation of Licensee to assume the responsibility of such expense in the event that such expense arises as a result of any action by Licensee.

- **8.6.3 Tax Cooperation.** To the extent Licensee is required to deduct and withhold taxes on any payments to Licensor, Licensee shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Licensor an official tax certificate or other evidence of such withholding reasonably sufficient to enable Licensor to claim such payments of taxes. Licensor shall provide to Licensee any tax forms that may be reasonably necessary in order for Licensee not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Licensor shall use reasonable efforts to provide any such tax forms to Licensee at least thirty (30) days prior to the due date for any payments for which the Licensor desires that Licensee 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.
- **8.7 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 Licensee'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 Licensee's discretion.
- **8.8 Late Payments.** Any amount required to be paid by Licensee 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 ("LIBOR") as quoted in the Wall Street Journal (or if it no longer exists, similarly authoritative source) plus four hundred (400) 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 Licensor 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.
- **8.9 Records**; Audits. Licensee 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 Licensor hereunder (including records of Net Sales), during the Term and for two (2) years thereafter or such longer period as required by Applicable Laws. Licensor shall have a right to request one audit of Licensee in each Calendar Year throughout the Term in order to confirm the accuracy of the foregoing (an "Audit"); provided, that, such one audit per Calendar Year limitation shall not apply in the event of any subsequent "for cause" audit. Upon the written

request by Licensor to Audit Licensee, Licensor shall have the right to engage an independent, internationally recognized accounting firm reasonably acceptable to Licensee 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 Licensor. Licensee, 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 ten (10) Business Days 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 Licensee shall be paid to Licensor within five (5) Business Days of notification of the results of such Audit. Any overpayments made by Licensee shall be refunded by Licensor within five (5) Business Days of notification of the results of such Audit. The cost of the accountants shall be the responsibility of Licensor 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 Licensee for the period subject to the Audit, in which case Licensee shall bear the costs of the accountants. Any information obtained during such audit shall be treated as Confidential Information. In the event that Licensor has a good faith basis, which shall be shared with Licensee, for believing that a Sublicensee of Licensee is not accurately reporting Net Sales (and thus that Licensee is not making appropriate royalty payments hereunder), then at Licensor's request, Licensee shall enforce its audit rights with res

#### **ARTICLE 9**

## PROSECUTION, MAINTENANCE AND ENFORCEMENT OF LICENSOR PATENTS

#### 9.1 Licensor Patents.

- **9.1.1 Licensor Responsibility and Ownership of Intellectual Property.** Licensor shall prosecute, maintain and, subject to Section 9.4, extend the Licensor Patents, including conducting any interferences, reexaminations, reissues, opposition proceedings, or request for patent term extension relating thereto, at its sole cost and expense. Licensor shall provide Licensee with an updated <u>Schedule 1.41</u> on an annual basis or more frequently upon Licensee's reasonable request.
- **9.1.2 Licensee's Cooperation.** At Licensor's request, Licensee shall reasonably cooperate with the prosecution of the Licensor Patents. Licensor shall give Licensee the opportunity to discuss and comment on the matter, it being understood that Licensor shall have the right to ultimately decide on all steps to be taken, and shall be solely responsible, for the maintenance, prosecution or extension of the Licensor Patents.

- 9.1.3 Discontinuation of Prosecution or Maintenance of the Licensor Patents. If, during the Term, Licensor decides to no longer prosecute or maintain any Licensor Patent, Licensor shall notify Licensee in writing of such decision as soon as possible (but in no event less than [\*CONFIDENTIAL\*]) prior to any filing or payment due date, or any other date that requires action, in connection with such Licensor Patent and Licensee shall thereupon have the right, but not the obligation, to assume responsibility for the filing, prosecution or maintenance thereof in the name of Licensor and at Licensee's cost and expense. If Licensee elects to exercise such right, Licensor shall execute such assignments and other documents and perform such acts at Licensee's reasonable expense as may be reasonably necessary to allow Licensee to file, maintain and prosecute such Patents in Licensee's name, and such Patents shall cease to be Licensor Patents and thereafter shall be deemed Licensee Patents for all purposes of this Agreement (including, for clarity, for the purpose of Section 1.63.1 above). Licensor will use good faith efforts to make available to Licensee its authorized attorneys, agents or representatives, or such of its employees as are reasonably necessary to assist Licensee in exercising its rights described under this Section 9.1.3. Licensor will sign, or will have signed, all legal documents as are reasonably necessary to enable Licensee to prosecute and maintain such Patents.
- **9.1.4 Patents listed in Schedule 1.14**. Licensor hereby assigns and transfers to Licensee the Patents listed in Schedule 1.14. Promptly following the Effective Date, the Parties shall execute and file as appropriate such assignment and other documents as may be required to fully and effectively vest all rights, title, and interests in and to such Patents in Licensee.

### 9.2 Infringement by Compound or Product.

- (a) Each of the Parties shall promptly, but in any event no later than ten (10) Business Days after receipt of notice thereof, notify the other Party in writing in the event of any notice or claim by a Third Party of alleged patent or other intellectual property infringement by Licensee or its Affiliates or Sublicensees with respect to the manufacture, use, sale, offer for sale or importation of the Compound or Product (each, an "Infringement Claim"). With respect to any Infringement Claim, the Parties shall attempt to negotiate in good faith an amicable resolution with respect thereto with the appropriate Third Party. If the Parties cannot settle such Infringement Claim with the appropriate Third Parties within fifteen (15) Business Days after the receipt of the notice pursuant to this Section, then, (i) Section 9.2(c) shall first apply, and (ii) if no agreement is entered pursuant to Section 9.2(c), then Licensee shall have the right and obligation to defend any such suit or action and, and the Parties shall reasonably cooperate in the defense of such suit or action, each bearing its own expenses, subject to Section 9.2(d).
- (b) Neither Licensor nor Licensee shall take a position in connection with an Infringement Claim, including defense, settlement or compromise of any such suit or action without the consent of the other Party (which consent shall not be unreasonably withheld) if the position, including defenses or settlement or compromise, would have a material adverse impact on the other Party (in which case the consent of such other Party shall be required). For

purposes of this Section 9.2(b), any settlement in connection with an Infringement Claim that would involve the waiver of rights (including the rights to receive payments) of such other Party shall be deemed a material adverse impact and shall require the consent of such other Party, such consent not to be unreasonably withheld.

- (c) If necessary to avoid infringement of intellectual property owned or controlled by a Third Party through the Manufacture, use or Commercialization of the Compound or the Product (as the Product and/or Compound (i) are described and/or claimed in the Licensor Patents and (ii) are being Developed and Manufactured by or on behalf of Licensor as of the Effective Date) for the Target Indication or Second Indication in the Territory, Licensee and Licensor shall use Commercially Reasonable Efforts to obtain a license for Licensee under the Third Party's intellectual property right. In particular, Licensor shall have the first right to negotiate and acquire rights to such intellectual property through a license or otherwise (including pursuant to any settlement agreement); provided, that, if Licensor declines to exercise such right, Licensor shall promptly inform Licensee thereof and Licensee shall have the right to conduct such negotiations and acquire such rights and to deduct, subject to Section 8.3.5, any and all payments made to any Third Party under this Section 9.2(c) against any [\*CONFIDENTIAL\*] to be made by Licensee to Licensor under this Agreement, provided, however, that in no event shall such offset reduce any payment to be made to Licensor hereunder by more than [\*CONFIDENTIAL\*] of the amount otherwise payable.
- (d) Licensee shall, subject to Section 8.3.5, have the right to offset against [\*CONFIDENTIAL\*] to be made by Licensee to Licensor under this Agreement [\*CONFIDENTIAL\*] of all costs and expenses (for clarity, not including any settlement costs or damages) incurred in defending any suit or action by a Third Party that claims that the use, Manufacture or Commercialization of the Compound and/or the Product (as the Compound and/or the Product (i) are described and/or claimed in the Licensor Patents and (ii) are being Developed and Manufactured by or on behalf of Licensor as of the Effective Date) infringes any issued patent claim in a Third Party's Patent covering the use of the Compound or of the Product in the Target Indication or Second Indication.

## 9.3 Infringement or Invalidation Actions by Third Parties.

(a) **Notice.** If either Party becomes aware, or otherwise receives notice, of any patent nullity, invalidity or unenforceability actions, any declaratory judgment actions, or any alleged or threatened infringement, in each case, of or involving any Licensor Patents, including, any claims arising under the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended, or its equivalent in a country other than the United States it will promptly (but in any case no later than five (5) Business Days from becoming aware of any such action) notify in writing the other Party thereof.

#### (b) Enforcement of Patents.

(i) **Licensee Action.** Licensee shall have the first right to initiate a suit or take other appropriate action it believes is required against any Third Party with respect to infringement or misappropriation of the Licensor Technology, after having conferred

with Licensor. Licensee shall have the right to be assisted by and cooperate with its local Affiliates and/or Sublicensees if this is deemed useful or appropriate by Licensee in the interest of an effective enforcement of rights.

(ii) **Licensor Action.** If Licensee fails to institute such litigation or otherwise take steps to remedy the applicable infringement within thirty (30) days of the date that Licensee becomes aware of such action or infringement (including by way of the Licensor providing notice thereof pursuant to Section 9.3(a)), then Licensor will have the right (but not the obligation), at its own expense, to bring any such suit, action or proceeding by counsel of its own choice.

#### (c) Cooperation; Costs; Damages.

- (i) If one Party brings any suit, action or proceeding under Section 9.3(b), the other Party agrees to be joined as party plaintiff if necessary to prosecute the suit, action or proceeding and to give the first Party authority to file, prosecute and control the suit, action or proceeding; provided, however, that neither Party will be required to transfer any right, title or interest in or to any property to the other Party or any other party to confer standing on a Party hereunder, and provided further that such other Party shall in any case have the right to be represented by its own counsel at its cost and expense.
- (ii) The Party not pursuing the suit, action or proceeding hereunder will provide reasonable assistance to the other Party, including by executing any and all reasonably necessary documents as may be required to bring such suit, action or proceeding, providing access to relevant documents and other evidence and making its employees available, subject to the other Party's reimbursement of any reasonable external costs incurred by the non-enforcing or defending Party in providing such assistance.
- (iii) The Party initiating the suit, action or proceeding under Section 9.3(b) shall assume and pay all costs and expenses related thereto, including fees and expenses of counsel selected by it and shall have control over the suit, action or proceeding; provided, that (A) in the case of any such suit, action or proceeding [\*CONFIDENTIAL\*], then the other Party shall reimburse to the Party initiating the action [\*CONFIDENTIAL\*], or (B) in the case of any such suit, action or proceeding in countries other than [\*CONFIDENTIAL\*], then the other Party shall reimburse to the Party initiating the action [\*CONFIDENTIAL\*] of all documented external fees, costs and expenses incurred in connection with such suit, action or proceeding, such reimbursement payment to be made on a quarterly basis within [\*CONFIDENTIAL\*] of submission by the Party initiating the suit of the relevant invoice and accompanying documentation, provided however that if Licensee is the Party initiating the action, then Licensor's reimbursement of [\*CONFIDENTIAL\*] or [\*CONFIDENTIAL\*], as applicable, of all reasonable, documented external fees, costs and expenses incurred in connection with such suit, action or proceeding shall be effected by Licensee deducting such amounts from [\*CONFIDENTIAL\*] otherwise payable to Licensor hereunder in connection with Net Sales, or [\*CONFIDENTIAL\*], in the country in which such action under this Section 9.3 is pursued (and subject to Section 8.3.5). [\*CONFIDENTIAL\*].

- (iv) The Party controlling an action shall not, without the prior written consent of the non-controlling Party (which shall not be unreasonably withheld), enter into any compromise or settlement relating to any claim, suit or action that it brought under Section 9.3 that admits the invalidity or unenforceability of any Licensor Patent, or requires the non-controlling Party to pay any sum of money, or otherwise adversely affects the rights of the non-controlling Party hereunder (including the rights to receive payments), provided however that this sub-section (iv) shall not apply in the event Licensor has exercised its right to [\*CONFIDENTIAL\*].
- (v) Any settlements, damages or other monetary awards (a "Recovery") recovered pursuant to a suit, action or proceeding brought pursuant to this Section 9.3 will be allocated between the Parties *pro rata* based on the respective costs and expenses incurred by each Party with respect thereto; provided, that, Licensor shall not share in any such Recovery if Licensor has [\*CONFIDENTIAL\*].
- **9.4 Patent Term Extensions.** Licensee and Licensor shall cooperate in good faith throughout the Territory in filing for and obtaining patent term extensions and supplementary or complementary protection certificates, if available, in respect of the Licensor Patents. Such cooperation may include: (i) advising each other in a timely manner of any action by any Regulatory or other competent Governmental Authority that is pertinent to any such extension; (ii) reasonably supplying each other with all information in its control pertaining to the extension of any such Licensor Patent; (iii) cooperating with each other to prepare and execute in due time all supporting documents required in connection with the extension of any such Licensor Patent; and (iv) keeping the other Party timely informed and updated on the relevant procedures in connection with such extension.
- **9.5 Patent Marking.** Licensee shall mark the Product marketed and sold by Licensee (or its Sublicensees) hereunder with appropriate patent numbers or indicia in accordance with Applicable Laws.
- **9.6 Patent Challenge.** Licensor will be permitted to terminate this Agreement upon written notice to Licensee, effective upon receipt, if Licensee or any of its Sublicensees or Affiliates, directly or indirectly, (i) initiate or request an interference or opposition proceeding with respect to, (ii) make, file or maintain any claim, demand, lawsuit or cause of action to challenge the validity or enforceability of, or (iii) oppose any extension of, or the grant of a supplementary protection certificate with respect to, any Licensor Patent.

# ARTICLE 10 REPRESENTATIONS, WARRANTIES AND COVENANTS; COMPLIANCE

- 10.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows, as of the Effective Date:
- 10.1.1 Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and

operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

- 10.1.2 Authority and Binding Agreement. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, except as enforcement may be affected by bankruptcy, insolvency or other similar laws and by general principles of equity.
- **10.1.3** No Conflicts. The execution, delivery and performance of this Agreement by it do not (i) conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound or (ii) violate any Applicable Law.
- 10.1.4 All Consents and Approvals Obtained. Except with respect to Regulatory Approvals for the Development, Manufacturing or Commercialization of the Product or as otherwise described in this Agreement, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by such Party with, all Governmental Authorities and other Persons required to be obtained or provided by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those approvals, if any, not required at the time of execution of this Agreement.
- **10.2** Additional Representations, Warranties and Covenants of Licensor. Licensor hereby represents and warrants as of the Effective Date and, to the extent applicable, covenants, to Licensee that:
  - 10.2.1 Licensor has not filed any Marketing Authorization Applications with a Governmental Authority for the sale of the Product.
- 10.2.2 Licensor is the owner of the Licensor Patents and owner or licensee of the Licensor Know-How and has full right and power to grant the licenses set forth in ARTICLE 2, free and clear of any adverse assignment, grant, restriction on use or other encumbrances inconsistent with such grant, in the manner, for the duration of and to the extent set forth in this Agreement, except such non-exclusive rights as have been granted to Third Parties solely to perform their obligations to Licensor under the On-Going Agreements or in connection with the performance of the On-Going Studies or POC Study.
- 10.2.3 Licensor has complied with all Applicable Laws in all material respects, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the Licensor Patents owned by Licensor.
- 10.2.4 Neither Licensor nor, to the knowledge of Licensor, its subcontractors, has received written notice of any action, suit, investigation or proceedings

pending before or threatened by any Governmental Authority with respect to the Compound and/or the Product.

- 10.2.5 To the best of Licensor's knowledge, the use and practice of the Licensor Technology and the Development, Manufacture, and Commercialization of the Compound and Product (as the Product and Compound (i) are described and/or claimed in the Licensor Patents and (ii) are being Developed and Manufactured by or on behalf of Licensor as of the Effective Date) do not infringe the intellectual property rights of any Third Party, and no Third Party has made any assertion in writing to the contrary.
- 10.2.6 To Licensor's knowledge, (i) no Third Party is infringing any Licensor Patents], and (ii) [no Third Party has challenged the scope, duration, validity, enforceability, priority, or Licensor's right to use or license any Licensor Patent.
- 10.2.7 Other than the Licensor Patents and Licensor Know-How, (i) none of Licensor nor any of its Affiliates nor employees owns or holds any rights with respect to any Patent or Know-How that is necessary for, or would be infringed by, the Development, Manufacture or Commercialization of the Compound or Royalty Products, and (ii) none of Licensor's subcontractors owns or holds any rights with respect to any issued Patent that is necessary for, or would be infringed by, the Development, Manufacture or Commercialization of the Compound or Product (as the Product and Compound (x) are described and/or claimed in the Licensor Patents and (y) are being Developed and Manufactured by or on behalf of Licensor as of the Effective Date).
- 10.2.8 Except with respect to Licensor Know-How that was generated prior to Licensor coming to Control the Compound and Product and that was never in Licensor's possession ("External Know-How"), all Licensor Know-How existing as of the Effective Date has been made available to Licensee, or will be made available to Licensee in accordance with the Technology Transfer Plan, and, to Licensor's best knowledge, is free from any material inaccuracies. If Licensee or Licensor becomes aware of the existence of such External Know-How after the Effective Date, then upon request by Licensee, Licensor shall provide reasonable assistance to Licensee in locating and acquiring access to such External Know-How from the entity in possession of such External Know-How.
- 10.2.9 None of the Confidential Information relating to Licensor Know-How has been disclosed to any Third Party other than under written confidentiality and non-use commitments.
- 10.2.10 To the best of the knowledge of Licensor, all raw data developed by or on behalf of Licensor or its Affiliates and supporting Licensor Know-How or otherwise relating to the Compound or the Product are available and free from any material inaccuracies.
- 10.2.11 To Licensor's best knowledge, none of the materials and documents provided to Licensee in the course of Licensee's due diligence preceding execution of this Agreement contained any untrue statement of material fact.

- 10.2.12 Licensor has informed Licensee of any pre-clinical or clinical data or information concerning the Compound and/or the Product and that to the knowledge of Licensor reasonably suggests that there may exist quality, toxicity, safety and/or efficacy concerns which may materially impair the safety of the Compound and/or the Product.
- 10.2.13 Licensor has conducted all Development of the Compound and the Product prior to the Effective Date in accordance with sound and ethical business and scientific practices, and in compliance with all Applicable Law, including GCPs and GLPs, and also including all applicable data privacy and data protection laws. In addition, Licensor has not used in any capacity, in connection with the Development of the Compound and the Product prior to the Effective Date, any Person who has been debarred pursuant to Section 306 of the FD&C Act (or similar Applicable Law outside of the U.S.), or who has been the subject of a conviction described in such section, and Licensor shall inform Licensee in writing immediately if it or any Person who has performed any such Development is debarred or is the subject of a conviction described in Section 306 (or similar Applicable Law outside of the U.S.), or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to Licensor's knowledge, is threatened, relating to the debarment of Licensor or any Person used in any capacity by Licensee in connection with such Development.
- 10.2.14 Licensor has received no notice from S\*BIO that it is in breach of any of its obligations under the S\*BIO Agreement, and, as of the Effective Date, Licensor is not aware of any breach of the S\*BIO Agreement nor of any other circumstance on which Licensor might cease to hold and enjoy the rights granted to it with respect to Licensor Technology under the S\*BIO Agreement, and Licensor shall not amend, modify or waive any of its rights under the S\*BIO Agreement in a manner that would have an adverse effect on the interests of Licensee hereunder without the prior written consent of Licensee.
- 10.2.15 Other than as has been made available to Licensee via [\*CONFIDENTIAL\*], and with the sole exceptions of that certain agreement in negotiation with [\*CONFIDENTIAL\*] and that certain [\*CONFIDENTIAL\*], there are no binding contracts or agreements to which Licensor is a Party, other than the S\*BIO Agreement and the On-Going Agreements, [\*CONFIDENTIAL\*].
- 10.3 Additional Representations, Warranties and Covenants of Licensee. Licensee hereby represents and warrants as of the Effective Date and, to the extent applicable, covenants, to Licensor that:
- **10.3.1** Licensee's compensation programs for its Sales Representatives do not, and will not, provide financial incentives for the promotion, sales, and marketing of the Product in violation of any Applicable Laws or any professional requirements.
- 10.3.2 Licensee's medical, regulatory and legal teams will review all training materials and programs prior to use by Licensee to ensure that all training materials and programs are in accordance with the Regulatory Approvals and Applicable Laws.

10.3.3 Licensee and its Affiliates Control no Know-How or Patents that Cover or are otherwise necessary for the Development, Manufacture, use or Commercialization of the Compound or Royalty Products.

10.4 Anti-Sandbagging; Disclaimer. Neither Party shall bring any claim or pursue any remedy against the other Party for breach of any of such other Party's representations or warranties under this ARTICLE 10 to the extent that the first Party had knowledge that such other Party was in breach of such representations or warranties as of the Effective Date. Subject to the representations and warranties set forth in Sections 10.1 and 10.2 above, Licensee understands that the Compound and Product are the subject of ongoing clinical research and development and that Licensor cannot ensure the safety or usefulness of the Compound or Product or that the Compound or Product will receive Regulatory Approvals. In addition, Licensor makes no warranties except as set forth in this ARTICLE 10 concerning the Licensor Technology.

10.5 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

#### 10.6 Compliance.

10.6.1 Compliance with Anti-Corruption Laws. In connection with this Agreement, each of the Parties represents, warrants and covenants that it has complied and will comply with all Applicable Laws, including those Applicable Laws (and industry codes) dealing with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and any laws enacted to implement the Organisation of Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

10.6.2 Prohibited Conduct. In connection with this Agreement, each of the Parties represents, warrants and covenants that it has not made, offered, given, promised to give, or authorized, and will not make, offer, give, promise to give, or authorize, any bribe, kickback, payment or transfer of anything of value, directly or indirectly, to any person or to any Government Official for the purpose of: (i) improperly influencing any act or decision of the person or Government Official; (ii) inducing the person or Government Official to do or omit to do an act in violation of a lawful or otherwise required duty; (iii) securing any improper advantage; or (iv) inducing the person or Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, in order to assist Licensee or Licensor in obtaining or retaining business.

10.6.3 Compliance by Licensor. Licensor shall use Commercially Reasonable Efforts, prior to Licensee filing for the first Regulatory Approval for the Product, to adopt or make conforming changes to its comprehensive compliance program so as to be in compliance with the United States Department of Health and Human Services Office of Inspector General (OIG)'s April 2003 publication "Compliance Program Guidance for Pharmaceutical Research and Manufacturers, Code on Interactions with Health Care Professionals" and with the Conduct of Clinical Trials".

# ARTICLE 11 INDEMNIFICATION

11.1 Indemnification by Licensor. Licensor hereby agrees to save, indemnify, defend and hold Licensee, its Affiliates, and their respective directors, officers, agents and employees harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a Third Party (each a "Claim") to the extent resulting or otherwise arising from (i) any breach by Licensor of any of its representations, warranties, covenants or obligations pursuant to this Agreement or (ii) the negligence or willful misconduct by Licensor or its Affiliates, sublicensees or subcontractors or their respective officers, directors, employees, agents or consultants in performing any obligations under this Agreement or under any other agreement which may have an impact on the Licensor Technology, the Compound, or Royalty Products, except to the extent such Losses as are caused by instructions provided by Licensee and implemented by Licensor.

11.2 Indemnification by Licensee. Licensee hereby agrees to save, indemnify, defend and hold Licensor, its Affiliates, and their respective directors, agents and employees harmless from and against any and all Losses arising in connection with any and all Claims to the extent resulting or otherwise arising from (i) any breach by Licensee of any of its representations, warranties, covenants or obligations pursuant to this Agreement, (ii) the negligence or willful misconduct by Licensee (or its Affiliates, Sublicensees, subcontractors, wholesalers or distributors) or their respective officers, directors, employees, agents or consultants in performing any obligations under this Agreement or under any other agreement which may have an impact on the Licensor Technology, the Compound, or Royalty Products, or (iii) the Development, Manufacturing, or Commercialization of the Compound or a Royalty Product hereunder (including, for clarity, any product liability Losses resulting therefrom) by Licensee (or its Affiliates, Sublicensees, subcontractors, wholesalers or distributors) or their respective officers, directors, employees, agents or consultants.

#### 11.3 Indemnification Procedures.

11.3.1 A Party believing that it is entitled to indemnification under, as applicable, Section 11.1 or Section 11.2 (an "Indemnified Party") shall give prompt written notification to the other Party (the "Indemnifying Party") of the commencement of any Claim for which indemnification may be sought or, if earlier, upon the assertion of any such Claim by a

Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Claim as provided in this Section 11.3.1 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually materially prejudiced as a result of such failure to give notice). Within thirty (30) days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Claim with counsel reasonably satisfactory to the Indemnified Party. If a Party believes that a Claim presented to it for indemnification is one as to which the Party seeking indemnification is not entitled to indemnification under, as applicable, Section 11.1 or Section 11.2, it shall so notify the Party seeking indemnification.

- 11.3.2 If the Indemnifying Party elects to assume the defense of such Claim, the Indemnified Party may participate in such defense at its own expense; provided, that if the interests of the Indemnified Party and the Indemnifying Party with respect to such Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith.
- 11.3.3 The Indemnifying Party shall keep the Indemnified Party advised of the status of such Claim and the defense thereof and shall consider recommendations made by the Indemnified Party with respect thereto.
- 11.3.4 The Indemnified Party shall not agree to any settlement of such Claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld. The Indemnifying Party shall not agree to any settlement of such Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party or adversely affects the Indemnified Party without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld.
- 11.3.5 For clarity, neither Party shall have any indemnification obligation pursuant to Section 11.1 or Section 11.2 to the extent the applicable Claim results or otherwise arises from the breach of this Agreement, negligence, or willful misconduct of the other Party or its Affiliates, sublicensees or subcontractors or their respective officers, directors, employees, agents or consultants.
- 11.4 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY LOST PROFITS, OR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER

SECTION 11.1 or 11.2 WITH RESPECT TO AMOUNTS OWED TO A THIRD PARTY, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12.

- 11.5 Insurance. Each Party shall procure and maintain insurance, including, as applicable, clinical trials insurance and product liability insurance, adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which the Compound or Product is being clinically tested in human subjects or commercially distributed or sold by or on behalf of such Party pursuant to this Agreement. Without limiting the foregoing:
- (a) each Party shall procure and maintain clinical trials insurance coverage, which prior to the First Commercial Sale of the Product, shall be in accordance with the minimum requirements by Applicable Law and industry standards in each country where the clinical trials are carried out; and
- (b) Licensee shall procure and maintain product liability insurance coverage, which upon First Commercial Sale of the Product, shall in no event be less than [\*CONFIDENTIAL\*] per loss occurrence and [\*CONFIDENTIAL\*] in the aggregate.

It is understood that such insurance shall not be construed to create a limit of a Party's liability with respect to its indemnification obligations under this ARTICLE 11. Each Party shall provide the other Party with written evidence of such insurance prior to commencement of this Agreement and upon expiration of any one (1) coverage. Each Party shall provide the other Party with written notice at least thirty (30) days prior to the cancellation, nonrenewal or material change in such insurance or self-insurance which materially adversely affects the rights of the other Party hereunder.

### ARTICLE 12 CONFIDENTIALITY

#### 12.1 Confidential Information.

12.1.1 The Parties agree that during the Term, and for a period of [\*CONFIDENTIAL\*] years thereafter, a Party receiving Confidential Information of the other Party will (X) maintain in confidence such Confidential Information to the same extent such Party maintains its own proprietary information of similar kind and value, and, in any event, no less than a reasonable standard of care, (Y) not disclose such Confidential Information to any Third Party without the prior written consent of the other Party, except as otherwise expressly permitted below and, in the case of Licensee, except as necessary or useful for a proper and full performance of its rights and obligations hereunder, and (Z) not use such Confidential Information for any purpose except those permitted by this Agreement. As used herein, "Confidential Information" means all Know-How and other information and materials received by either Party from the other Party or its Affiliates pursuant to this Agreement. The foregoing obligations and the other obligations set forth in this Section 12.1 shall not apply with respect to any portion of such Confidential Information which:

- (a) is publicly disclosed by the disclosing Party, either before or after it becomes known to the receiving Party;
- (b) was known to the receiving Party or any or its Affiliates, without any obligation to keep it confidential, prior to when it was received from the disclosing Party;
- (c) is subsequently disclosed to the receiving Party or any of its Affiliates by a Third Party that is lawfully in possession thereof without obligation to keep it confidential;
- (d) has been published by a Third Party or otherwise enters the public domain through no fault of the receiving Party or any of its Affiliates in breach of this Agreement; or
- (e) has been independently developed or acquired by the receiving Party or any of its Affiliates without the aid, application or use of the disclosing Party's Confidential Information.

Notwithstanding clauses (a) through (e) above, both Parties shall be bound to the obligations of this Article 12 (as the receiving Party hereunder) with respect to all Licensor Know-How to the extent such Licensor Know-How (i) was confidential prior to the Effective Date and (ii) specifically relates to the Compound or Product.

- 12.1.2 The receiving Party shall have the right to disclose any Confidential Information provided by the other Party hereunder if, in the reasonable opinion of the receiving Party's legal counsel, such disclosure is necessary to comply with the terms and conditions of this Agreement, or the requirements of any law or rule imposed by the U.S. Securities and Exchange Commission or any securities exchange or other Applicable Law, but only to the extent of such necessity or requirements; and no such disclosure shall cause any such information to cease to be Confidential Information hereunder, except to the extent such disclosure results in a public disclosure of such information. Where reasonably possible, the receiving Party shall notify the disclosing Party of the receiving Party's intent to make such disclosure of Confidential Information pursuant to the preceding sentence sufficiently prior to making such disclosure so as to allow the disclosing Party adequate time to take whatever action the disclosing Party may deem to be appropriate to protect the confidentiality of the Confidential Information.
- 12.1.3 Except as set forth above, each Party agrees that it shall provide or permit access to Confidential Information of the other Party only to (i) the receiving Party's attorneys, independent accountants and financial advisors for the sole purpose of enabling such attorneys, independent accountants and financial advisors to provide advice to the receiving Party and (ii) the receiving Party's Affiliates, directors, officers, employees, consultants, advisors and permitted subcontractors, sublicensees and subdistributors, and to the directors, officers, employees, consultants, advisors and permitted subcontractors, sublicensees, subdistributors and other Third Parties, who have a need to know such Confidential Information to assist the receiving Party with the activities contemplated or required of it by this Agreement; provided

that in each case the Person to whom Confidential Information is being disclosed is subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and nonuse of the receiving Party pursuant to this Section 12.1; and provided further, that each Party shall remain responsible for any failure by its attorneys, independent accountants and financial advisors, Affiliates, and its and its Affiliates' respective directors, officers, employees, consultants, advisors and permitted subcontractors, sublicensees and subdistributors, to treat such Confidential Information as required under this Section 12.1.

For clarity, either Party may disclose without any limitation such Party's U.S. federal income tax treatment and the U.S. federal income tax structure of the transactions relating to such Party that are based on or derived from this Agreement, as well as all materials of any kind (including opinions, other tax analyses, or a complete copy of this Agreement and any amendments thereto) relating to such tax treatment or tax structure, except to the extent that nondisclosure of such matters is reasonably necessary in order to comply with applicable securities laws.

- 12.1.4 Each Party acknowledges that a Party in breach of any of its obligations under this Section 12.1 may cause the non-breaching Party irreparable harm, for which monetary damages will be an inadequate remedy. Therefore, notwithstanding anything to the contrary in this Agreement in the event of any such breach, the non-breaching Party shall be entitled, in addition to any other remedy available to it under this Agreement, at law or in equity, to seek injunctive relief, including an accounting for profits, specific performance of the terms hereof and other equitable relief for such breach, without the posting of bond or other security.
- 12.2 Publicity. Any press releases or other public statements or disclosures regarding the subject matter of this Agreement shall be subject to the express prior written consent of each of the Parties, which consent shall not be unreasonably withheld or delayed; provided that a disclosure shall be permitted without the other Party's consent to the extent that it does not contain information beyond that included in a prior disclosure approved in writing by both Parties. Notwithstanding the foregoing, any disclosure which is required by Applicable Law or the rules of the U.S. Securities and Exchange Commission or any securities exchange, as reasonably advised by the disclosing Party's counsel, may be made without the prior consent of the other Party, although, prior to making any such legally required disclosure, the Party making such disclosure shall give the other Party prompt notice and an opportunity to comment on the proposed disclosure.
- 12.3 Securities Filings. In the event Licensee 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, Licensee shall notify Licensor of such intention and shall provide Licensor with a copy of relevant portions of the proposed filing not less than three (3) Business Days prior to such filing (or such shorter period of time as may be required in the circumstances, and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), and shall use

reasonable efforts to obtain confidential treatment of any information concerning Licensor that Licensor requests be kept confidential, consistent with Licensee's disclosure obligations under applicable securities laws. Licensor 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. Licensor shall provide Licensee with a copy of relevant portions of the proposed filing reasonably in advance of making such filing, and shall use Commercially Reasonable Efforts to obtain confidential treatment of any information concerning Licensee that Licensee reasonably requests be kept confidential, consistent with Licensor's disclosure obligations under applicable securities laws. For clarity, in no event shall Licensor be obligated to delay or withhold such a filing in order to comply with the foregoing sentence if such compliance would result in Licensor being in violation of any Applicable Law.

#### 12.4 Publications.

- 12.4.1 Licensee shall be free at all times to make publications or presentations with regard to the Compound and/or the Product, as it shall deem appropriate for the effective management of the Development and Commercialization of the Compound and Product throughout the Territory; provided, that Licensee shall (a) provide Licensor every [\*CONFIDENTIAL\*] throughout the Term with a publication strategy plan and (b) a copy of said publications or material presentations intended to be given to a public international audience for Licensor's information reasonably prior to the public disclosure thereof.
- 12.4.2 The Parties acknowledge and agree that certain Third Parties counterparties to the agreements included in the Licensor's data room prior to the Effective Date may have been granted publication rights related to the Compound and Product, and publications by such Persons in compliance with the provisions of the relevant agreements shall be permitted; provided, that Licensor shall advise Licensee reasonably prior to the public disclosure thereof regarding any anticipated publications by such Persons.
- 12.5 Use of Names. Except as otherwise set forth in this Agreement, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the written consent of such other Party, which consent shall not be unreasonably withheld; provided, however, that subject to Section 12.2, either Party may use the name of the other Party in any document filed with any Regulatory Authority or Governmental Authority, including the Securities and Exchange Commission.
- 12.6 Unauthorized Disclosure of Confidential Information. Each Party shall have a response plan in place for any disclosure of Confidential Information that is not authorized or otherwise permitted under this Agreement. Such plan shall include considerations of, among other things, notification, remediation and retrieval. In the event that a Party becomes aware of an unauthorized disclosure of Confidential Information, then such Party shall notify the other Party promptly in writing.

- 12.7 Survival. The obligations and prohibitions contained in this ARTICLE 12 as they apply to Confidential Information shall survive the expiration or termination of this Agreement for a period of [\*CONFIDENTIAL\*] years.
- 12.8 Prior CDA. The Parties acknowledge and agree that any and all information exchanged or otherwise disclosed, and discussions, between themselves prior to the Effective Date shall remain subject, to the extent applicable, to the terms and conditions of the Prior CDA. Information exchanged or otherwise disclosed, and discussions, between the Parties following the Effective Date under or related to this Agreement or its subject matter shall be subject to the terms and conditions of this Agreement and not the Prior CDA. Furthermore, the Parties hereby acknowledge and agree that this Agreement constitutes an amendment to the Prior CDA (which satisfies the requirements of Section 13 of the Prior CDA), which amendment provides for the Parties to be able to mutually agree to terminate the Prior CDA immediately, and the Parties hereby agree that, without limiting the provisions thereof that survive termination thereof, the Prior CDA shall be deemed terminated as of the Effective Date.

## ARTICLE 13 TERM AND TERMINATION

13.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this ARTICLE 13, shall remain in effect on a country-by-country basis until the expiration of the Royalty Term applicable to such country as set forth at Section 1.63 of this Agreement (the "Term").

#### 13.2 Termination for Breach.

- 13.2.1 Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement upon written notice to the other Party in the event that the other Party (the "Breaching Party") shall have materially breached this Agreement. The Breaching Party shall have ninety (90) days (thirty (30) days in the event of non-payment) after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default; provided, however, that if such breach is capable of being cured but cannot be cured within such cure period and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have an additional ninety (90) days (for a total of one hundred eighty (180) days) to cure such breach (except in the event of non-payment, in which such case no additional time period shall apply). Unless the Breaching Party has cured any such breach or default prior to the expiration of such applicable cure period, such termination shall become effective upon receipt of the written notice of termination by the Breaching Party to be given within ten (10) days of the end of such period.
- 13.2.2 In the event of an uncured material breach by Licenser giving Licensee the right to terminate this Agreement under Section 13.2.1, then as an alternative to its right to terminate this Agreement as described above, Licensee may in its discretion elect to continue this Agreement and to exercise its rights pursuant to Section 15.1.2 to refer the measure of its damages to determination pursuant to arbitration, which arbitration may determine a one-

time payment or going-forward reduction in payments as an appropriate remedy for the material breach giving rise to such right to terminate.

- 13.2.3 Notwithstanding the foregoing, in the event that Licensor's material breach compromises the fundamental purpose of this Agreement and the ability of Licensee to continue the Development, Manufacture and Commercialization of the Compound and/or Product, and Licensee has no alternative but to terminate this Agreement, then in such case Licensee shall receive from Licensor appropriate payments (as determined pursuant to Article 15.13 below) to compensate Licensee for losses or damages, if any, suffered as a result of such material breach and termination of this Agreement (including as a result of Third Parties' actions in connection therewith).
- 13.3 Claims for damages. Without limitation of any other remedy available hereunder, nothing in this Agreement shall limit a Party's right to bring a claim for damages in the event of a breach of this Agreement by the other Party.
- 13.4 Termination as a Result of Bankruptcy. Each Party shall have the right to terminate this Agreement upon written notice as a result of the 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 that such termination shall be effective only if such proceeding is not dismissed within ninety (90) days after the filing thereof.
- 13.5 Discontinuation by Licensee. Notwithstanding any other provision of this Agreement, Licensee shall at any time have the right to discontinue the Development of the Compound and Product and relinquish all the rights and the licenses granted to it under this Agreement and terminate this Agreement by giving thirty (30) days advance written notice to Licensor, in the event that in Licensee's reasonable judgment after diligent consideration and consultation with Licensor, it is not reasonably viable for Licensee to carry out further Development of the Compound and Product.

# ARTICLE 14 EFFECTS OF EXPIRATION OR TERMINATION

- 14.1 Licenses upon Expiration. Upon the expiration (but not termination) of this Agreement, in its entirety, or with respect to any given country(ies), Licensee's license under Section 2.1.1 shall survive and become a [\*CONFIDENTIAL\*], exclusive license not requiring any [\*CONFIDENTIAL\*] under this Agreement.
  - 14.2 Effects of Termination for Cause by Licensee. Upon the termination of this Agreement by Licensee pursuant to Sections 13.2 or 13.3,
    - (a) Licensee shall have the rights described in Section 13.2.2;
- (b) all rights and licenses granted to Licensee hereunder shall immediately terminate and be of no further force and effect and Licensee shall cease Developing,

Commercializing, Manufacturing and Packaging and Labeling the Product in and for all applicable countries; and

(c) at Licensor's request, the Parties shall negotiate in good faith a license agreement pursuant to which (i) Licensor would be granted rights under and to Licensee Technology and (ii) Licensee would transfer to Licensor all of Licensee's right, title and interest in and to any and all regulatory filings, Regulatory Approvals and other Regulatory Materials Controlled by Licensee for the Product, for consideration consistent with then-prevailing market conditions, on customary terms and conditions. In the event that the Parties cannot finalize such an agreement within sixty (60) days of commencing negotiations with respect thereto, the agreement shall be referred for resolution pursuant to Section 15.13 applied *mutatis mutandis* to such agreement.

### 14.3 Effects of Other Terminations. Upon the termination of this Agreement other than by Licensee pursuant to Sections 13.2 or 13.3,

- (a) except to the extent that may be required in connection with the activities described at Section 14.4 below, all rights and licenses granted to Licensee hereunder shall immediately terminate and be of no further force and effect and Licensee shall cease Developing, Commercializing, Manufacturing and Packaging and Labeling the Product in and for all applicable countries;
- (b) effective on the date of such termination, Licensee hereby grants to Licensor an exclusive, irrevocable, perpetual, royalty-free and fully paid-up, license, with the right to sublicense (subject however to the provisions of Section 14.4 below), under and with respect to the Licensee Technology to Develop, Manufacture and Commercialize the Compound and Product;
- (c) Licensee will assign to Licensor all of Licensee's right, title and interest in and to any (i) Promotional Materials, (ii) copyrights and trademarks (including the Product Trademarks and Product Trade Dress), including any goodwill associated therewith, and any registrations and design patents for the foregoing, and (iii) any internet domain name registrations for such trademarks and slogans, all to the extent solely related to the Product; provided, however, in the event Licensor exercises such right to have assigned such Promotional Materials, Licensee shall grant, and hereby does grant, a royalty-free right and license to any housemarks, trademarks, names and logos of Licensee contained therein for a period of [\*CONFIDENTIAL\*] for the sole and exclusive purpose of using such assigned Promotional Materials in connection with the Commercialization of the Product, after which Licensor shall immediately cease using any materials bearing such housemarks, trademarks, name and logo of Licensee;
- (d) subject to Section 14.4, Licensee will assign to Licensor, at Licensor's sole discretion and direction and to the extent permissible under each respective agreement, all of Licensee's right, title and interest in and to any agreements (or portions thereof) between Licensee and Third Parties that relate to the Development or Manufacture of the Product;

- (e) Licensee will assign to Licensor, at Licensor's sole discretion and direction, the management and continued performance of any clinical trials for the Product ongoing hereunder as of the effective date of such termination in respect of which Licensor shall assume full financial responsibility from and after the effective date of such termination; and
- (f) Licensee will transfer to Licensor all of Licensee's right, title and interest in and to any and all Development Data, Commercialization Data, regulatory filings, Regulatory Approvals and other Regulatory Materials Controlled by Licensee for the Product, and material embodiments thereof to the extent specifically related to the Compound and Product. Such transfer, including the transfer of relevant Licensee Know-How, will be undertaken in accordance with a transition plan to be reasonably agreed to by the Parties acting in good faith.

Licensee shall also cause its Affiliates to transfer and assign to Licensor all of such Affiliates' right, title and interest in and to the foregoing items set forth in this Section 14.3

### 14.4 Rights of Licensee's Sublicensees Upon Termination and Supply Obligations.

14.4.1 In the event of termination of this Agreement by Licensor pursuant to Section 13.2 for Licensee's uncured material breach, Licensee's Third Party Sublicensees' (as opposed to its Affiliates) rights in the Compound and the Product shall survive and Licensee's rights as [\*CONFIDENTIAL\*] shall be [\*CONFIDENTIAL\*] free of charge and shall become direct licenses from Licensor to the Sublicensees; provided, however, that, such direct license shall be regulated by either (a) [\*CONFIDENTIAL\*] or (b) another mutually agreed agreement between Licensor and such Sublicensee; provided, further, that, for a period of [\*CONFIDENTIAL\*] following the termination of this Agreement by Licensor pursuant to Section 13.2 for Licensee's uncured material breach, Licensee shall continue to provide such support services to its Sublicensees as it was providing under its sublicense agreements. Notwithstanding the foregoing, this Section 14.4.1 shall not apply to any Sublicensee (i) whose actions or omissions caused this Agreement to be terminated or who was otherwise in breach of this Agreement or the relevant sublicense agreement at the time of termination, or (ii) that is also an Affiliate of Licensee. If Licensor steps-in to directly license one or more Sublicensees under this Section 14.4.1, then upon Licensor's request and expense Licensee shall provide management services in relation to overseeing the activities of any such Sublicensee(s) pursuant to an agreement that the Parties will negotiate in good faith.

14.4.2 Licensee undertakes, upon Licensor's reasonable request, to manufacture and supply the Compound and/or the Product, directly or through its nominee, in accordance with Licensor's and/or the Sublicensees' reasonable requirements for a period and at a price to be reasonably agreed upon in good faith between the Parties, and Licensor hereby grants to Licensee all rights with respect to the Licensor Technology as may be necessary in order for Licensee to perform such manufacture and supply.

14.5 Accrued Rights. Expiration or termination this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to the effective date of such expiration or termination. Such expiration or termination will not relieve a

Party from obligations that are expressly indicated to survive the expiration or termination of this Agreement.

14.6 Survival. Notwithstanding anything to the contrary contained herein, the following provisions shall survive any expiration or termination of this Agreement: ARTICLES: 1 (to the extent necessary to give effect to other surviving provisions, 6.4.3, 6.5.2, 6.6, 8 (with respect to amounts due or accrued prior to the expiration or termination of this Agreement), 11 (except for Section 11.5), 12 (for the period set forth in Sections 12.1.1 and 12.7, provided, that, the paragraph at the end of Section 12.1.1 and immediately above Section 12.1.2 shall have no further force or effect), 13.3, 14 (to the extent applicable) and 15. Except as set forth in this ARTICLE 14 or otherwise expressly set forth herein, upon expiration or termination of this Agreement all other rights and obligations of the Parties shall cease.

14.7 Rights in Bankruptcy. All rights and licenses of whatever type and nature granted under or pursuant to this Agreement by Licensor and Licensee are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code, and any equivalent law in the United States or any other country. The Parties agree that each Party, solely in its capacity as licensee of certain rights under this Agreement, hereby retains and has the right, but not the obligation, to exercise any or all of its rights and elections under the U.S. Bankruptcy Code and any equivalent law. This Section 14.7 is without prejudice to any rights that a Party may have under the Bankruptcy Code or other applicable law. The Parties further agree that, in the event of the commencement of a bankruptcy case by or against a Party (such Party, the "Bankrupt Party") under the U.S. Bankruptcy Code, (a) the other Party (the "Non-Bankrupt Party") shall be entitled to a complete duplicate of (or complete access to, as appropriate) all intellectual property, licensed to the Non-Bankrupt Party hereunder and all embodiments of such intellectual property, which, if not already in the Non-Bankrupt Party's possession, shall be promptly delivered to it (x) upon any such commencement of a bankruptcy case and upon the Non-Bankrupt Party's written request therefore, unless the Bankrupt Party assumes this Agreement pursuant to Section 365 of the Bankruptcy Code or otherwise elects to continue to perform all of its obligations under this Agreement or (y) if not delivered under clause (x), following the rejection of this Agreement by the Bankrupt Party under Section 365 of the Bankruptcy Code and upon the Non-Bankrupt Party's written request therefore and (b) the Bankrupt Party shall not interfere with the Non-Bankrupt Party's rights to such intellectual property and all embodiments of such intellectual property, and shall use Commercially Reasonable Efforts to assist and not interfere with the Non-Bankrupt Party in obtaining such intellectual property and all embodiments of such intellectual property from all other entities. The "embodiments" of intellectual property include all tangible, intangible, electronic or other embodiments of rights and licenses hereunder, including all compounds and products embodying intellectual property, Product, filings with Regulatory Authorities and related rights and Licensor Know-How in the case that Licensor is the Bankrupt Party and Licensee Know-How in the case Licensee is the Bankrupt Party.

> ARTICLE 15 MISCELLANEOUS

#### 15.1 Disputes.

15.1.1 The Parties recognize that, from time to time, disputes, controversies or claims may arise which stem from or are related to a Party's respective rights or obligations under this Agreement or a Party's actual or alleged breach of this Agreement (a "Dispute"). It is the desire of the Parties to establish procedures to facilitate the resolution of Disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to arbitration or litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 15.1.1 if and when a Dispute arises under this Agreement. If the Parties are unable to resolve any Dispute within [\*CONFIDENTIAL\*] after such Dispute is submitted to it, either Party may, by written notice to the other Party, have such dispute referred to the Parties' designated Executive Officers or their delegates for attempted resolution. In the event the designated Executive Officers or their delegates are not able to resolve such dispute within such [\*CONFIDENTIAL\*] period after receipt of written notice, then each Party is free to pursue any remedy at law or in equity available to such Party; provided, that Section 15.1.2 shall apply in the event of a Dispute related to Section 13.2.2.

15.1.2 If Licensee elects to exercise its rights under Section 13.2.2, it shall submit the question of Licensee's damages to be finally settled by arbitration administered in accordance with the procedural rules of the American Arbitration Association (the "AAA") in effect at the time of submission, as modified by this Section 15.1.2. The arbitration will be governed by the Laws of the State of New York. The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least twenty (20) years of relevant experience in the pharmaceutical and biotechnology industry, each of whom will be impartial and independent and will not have worked for or on behalf of either Party for at least five (5) years. Each Party will appoint one (1) arbitrator and the third arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within thirty (30) days following appointment of the second arbitrator, by the AAA. Such arbitration will take place in New York, New York. The arbitration award so given will, absent manifest error, be a final and binding determination, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 11.4. Licensor will pay the fees, costs and expenses for the arbitrator it chooses, Licensee will pay the fees, costs and expenses for the arbitrator it chooses, and the Parties will share payment for the third arbitrator. Except in a proceeding to enforce the results of the arbitration hereunder without the prior written consent of both Parties.

15.2 Entire Agreement; Amendment. This Agreement, together with the Schedules hereto (but excluding Schedule 1.64, i.e., the S\*BIO Agreement), contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof are superseded by the terms of this Agreement. The Schedules and Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof

modified, only by a written instrument duly executed by authorized representatives of each of the Parties.

15.3 Force Majeure. No Party shall be liable for any failure to perform, or be considered in breach of, its obligations under this Agreement (other than obligations to make payments of money) to the extent such performance has been delayed, interfered with or prevented by an event of Force Majeure, and the obligations of such Party under this Agreement (other than obligations to make payments of money) whose performance is affected by Force Majeure shall be suspended for so long as its performance remains affected by the event of Force Majeure. Any Party that experiences an event of Force Majeure shall provide prompt notice of such event to the other Party, including an estimate of the likely period of time during which its performance will be affected, and shall use reasonable efforts to remove the condition constituting Force Majeure. In the event of a prolonged condition of Force Majeure that makes it unreasonable to continue to perform other activities then being performed by the Parties and their Affiliates pursuant to this Agreement, the Parties shall consult directly or through the appropriate Committees and may appropriately scale back their respective activities in order to avoid waste or inappropriate usage of resources under the circumstances, and neither Party shall be liable for any such reasonable scale back, or be considered in breach of its obligations under this Agreement (other than obligations to make payments of money to the other Party) as a result of such reasonable scale back.

15.4 Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if mailed by first class certified or registered mail, postage prepaid (which notice shall be effective five (5) Business Days after such mailing); express delivery service (which notice shall be effective on the first Business Day after delivery to such service); or personally delivered to the appropriate addresses (which notice shall be effective upon delivery to such addresses) set forth below or to such other addresses or numbers for a Party as such Party may inform the other Party by giving five (5) Business Days' prior written notice:

If to Licensor: MEI Pharma, Inc.

11975 El Camino Real, Suite 101

San Diego, CA 92130

Attention: Chief Executive Officer

Fax: +1 858-792-5406

With copies to (which shall not constitute notice):

MEI Pharma, Inc. 11975 El Camino Real, Suite 101 San Diego, CA 92130 Attention: General Counsel Fax: +1 858-792-5406

If to Licensee: Helsinn Healthcare SA

Via Pian Scairolo 9

CH – 6912 Pazzallo Lugano

Attention: General Manager and Chief Operating Officer

Fax: +4191 993 00 40

With copies to (which shall not constitute notice):

Helsinn Healthcare SA Via Pian Scairolo 9 CH – 6912 Pazzallo Lugano

Attention: General Counsel and Chief Legal Officer

Fax: +4191 993 00 40

15.5 Maintenance of Records. Each Party shall keep and maintain all records required by Applicable Law or regulation (including records for intellectual property protection purposes) with respect to its activities hereunder pertaining to the Compound and Product and shall make copies of such records available to the other Party as required herein. Each Party must maintain such records for the greater of [\*CONFIDENTIAL\*] or the time period required by Applicable Law.

15.6 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, except that a Party may make such an assignment or transfer without the other Party's written consent to any of its Affiliates or to a successor to substantially all of the business of such Party to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction, provided that such Affiliate, permitted successor or assignee of rights and/or obligations hereunder assumes, in writing to the other Party, performance of such rights and/or obligations in accordance with the terms and conditions of this Agreement. Any assignment or transfer, or attempted assignment or transfer, by either Party in violation of the terms of this Section 15.6 shall be null and void and of no legal effect. This Agreement shall be binding on, and inure to the benefit of, each Party, its successors and permitted assigns.

15.7 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.

15.8 Severability. If any one (1) or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, such provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

- 15.9 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.
- 15.10 Ambiguities; No Presumption. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party hereto as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.
- 15.11 Headings. The headings for each ARTICLE and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular ARTICLE or Section.
- 15.12 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 "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

15.13 Governing Law; Equitable Relief; and Jurisdiction.

- 15.13.1 Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed entirely within such state, without regard to the conflicts of law principles of such state, other than Section 5-1401 of the New York General Obligations Applicable Law; provided that any matters relating to the construction or effect of any patent will be governed by the patent laws of the United States. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.
- **15.13.2 Equitable Relief.** Notwithstanding anything in this Agreement to the contrary, each Party shall have the right to seek injunctive or other equitable relief from a court of competent jurisdiction pursuant to Section 15.13.3 that may be necessary to avoid irreparable harm or to maintain the status quo.
- 15.13.3 Jurisdiction. Without limiting the provisions of Section 15.1, each Party (a) irrevocably submits to the exclusive jurisdiction of the United States District Court for the Southern District of New York and the Supreme Court of the State of New York, New York County (collectively, the "Courts"), for purposes of any action, suit or other proceeding arising out of this Agreement, (b) agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of such Courts, and (c) irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Courts do not have any jurisdiction over such Party. Each Party further agrees that service or any process, summons, notice or document by U.S. registered mail to such Party's notice address provided for in this Agreement shall be effective service of process for any action, suit or proceeding in New York with respect to any matters to which it has submitted to jurisdiction in this Section 15.13.3. Notwithstanding the forgoing, nothing contained in this Agreement will deny any Party the right to seek injunctive relief or other equitable relief from a court of competent jurisdiction applying the laws of the court in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any other ongoing proceeding.
- **15.14 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.
- **15.15 No Third Party Beneficiaries.** No person or entity other than Licensee, Licensor and their respective Affiliates, successors and permitted assignees hereunder, shall be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.
- **15.16 Independent Contractors.** It is expressly agreed that Licensee and Licensor shall be independent contractors and that the relationship between Licensee and Licensor shall not constitute a partnership, joint venture or agency. Neither Licensee nor Licensor shall have the authority to make any statements, representations, or commitments of any kind, or to take

any action, which shall be binding on the other Party, without the prior written consent of such other Party.

**15.17 Counterparts; Facsimile Signatures.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by delivery of electronically scanned copies of original signatures delivered by facsimile or electronic mail, and such signatures shall be deemed to bind each Party as if they were original signatures.

[No Further Text on This Page]

IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized representatives as of the date first written above.

HELSINN HEALTHCARE SA

MEI PHARMA, INC.

By: /s/ Riccardo Braglia By: /s/ Daniel P. Gold

Name:Riccardo BragliaName:Daniel P. Gold, Ph.D.Title:Member of the Board of DirectorsTitle:President and CEO

Signature Page to License, Development and Commercialization Agreement

### Schedule 1.14: Certain Patents

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### Schedule 1.40: Licensor Know-How

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#### Schedule 1.41: Licensor Patents

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## Schedule 1.46: On-Going Agreements

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Schedule 1.64: S\*BIO Agreement

### Schedule 2.5: Technology Transfer Plan

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## Schedule 4.3.2: Essential Development Elements

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#### Schedule 7.1: Existing Product and Compound Available for Transfer to Licensee

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### Schedule 7.3: Existing Product and Compound to be Retained by Licensor

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## ASSET PURCHASE AGREEMENT

by and between

MEI Pharma, Inc. as Purchaser,

and

S\*BIO Pte Ltd. as Seller

Dated as of August 7, 2012

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Exhibit C – Program Patents

Exhibit D - Form of Registration Rights Agreement

Exhibit E – Program Compound Structures

Exhibit F – IND Acknowledgement Letter

Exhibit G – IND Letter

## **SCHEDULES**

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Schedule 2.1(d) - Inventory

Schedule 2.9 – Purchase Price Allocation

Schedule 7.5 – Pending and In-Process Publications

Seller Disclosure Schedules

#### ASSET PURCHASE AGREEMENT

**THIS ASSET PURCHASE AGREEMENT** is made as of August 7, 2012 by and between MEI Pharma, Inc., a Delaware corporation ("<u>Purchaser</u>"), and S\*Bio Pte Ltd., a Singapore private limited company ("<u>Seller</u>").

#### **RECITALS:**

Subject to the terms and conditions set forth herein, Seller desires to sell, convey, transfer, assign and deliver to Purchaser, and Purchaser desires to purchase and acquire from Seller, free and clear of all Liens other than the Assumed Liabilities and the Permitted Liens, all of Seller's and its Subsidiaries' right, title and interest in and to all of the Purchased Assets (the "Acquisition").

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby expressly acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

## ARTICLE 1 DEFINITIONS

- 1.1 Definitions. As used herein, the following terms shall have the following meanings:
- "Accounts Receivable" shall mean: (i) all trade accounts receivable and other rights to payment from customers of Seller; (ii) all other accounts or notes receivable of Seller and the full benefit of all security for such accounts or notes; and (iii) any Claim, remedy or other right related to any of the foregoing.
  - "Acquisition" shall have the meaning given to such term in the Recitals.
- "Affiliate" shall mean 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, shall mean (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.
  - "Agreement" shall mean this Asset Purchase Agreement.
  - "Allocation Statement" shall have the meaning given to such term in Section 2.9.
  - "Assumed Liabilities" shall have the meaning given to such term in Section 2.3.
  - "Bankruptcy Exception" shall have the meaning given to such term in Section 3.2.

"Business Day" shall mean any day other than a Saturday, Sunday or a day on which banks in California are obligated by applicable Law or executive Order to close or are otherwise generally closed.

"Change of Control Transaction" shall have the meaning given to such term in Section 7.2(a).

"Claim" shall have the meaning given to such term in Section 3.9.

"Clinical Data" shall mean data or results generated in or resulting from any non-clinical, pre-clinical study or clinical trial of any Program Compound, conducted by or on behalf of Seller or its Subsidiaries, together with the applicable protocol for each such study or trial, as well as all associated site related documentation, investigator brochures, investigational review board correspondence, data monitoring committee minutes and documentation, Chemistry, Manufacturing and Controls (CMC) data and SAS files.

"Closing" shall have the meaning given to such term in Section 2.10.

"Closing Stock Payment" shall have the meaning set forth in Section 2.5.

"Closing Date" shall have the meaning given to such term in Section 2.10.

"Code" shall mean the Internal Revenue Code of 1986, as it may be amended from time to time, and any successor thereto.

"Combination Product" shall mean a Product that is comprised of or contains a Program Compound as an active ingredient together with one or more active ingredients that are Proprietary Compounds, when such active ingredients are either sold together in one (1) package or formulated together in one (1) therapeutic formulation.

"Competing Business" shall have the meaning given to such term in Section 7.2(a).

"Competing Compound" shall have the meaning given to such term in Section 7.2(a).

"Confidential Information" shall have the meaning given to such term in Section 7.5.

"Confidentiality Agreement" shall have the meaning given to such term in Section 7.5.

"Contract" shall mean any contract, arrangement, agreement, purchase order, license or other binding commitment, whether oral or written.

"Control" or "Controlled" shall mean with respect to any Know-How or any Intellectual Property, possession by a Person of the ability (whether by ownership, license, covenant not to sue or otherwise) to grant access to, to grant use of, or to grant a license or a sublicense or other right of or under such Know-How or Intellectual Property without violating the terms of any agreement or other arrangement with any Third Party.

"Copyrights" shall mean copyrights and registrations and applications therefor, works of authorship, content (including website content) and mask work rights.

"Cover" or "Covered" or "Covering" shall mean, (a) with respect to a Product and a Program Patent that is an issued patent, that, in the absence of ownership of or a license granted under a Valid Claim of such Program Patent, the manufacture, use, offer for sale, sale or importation of such Product would infringe such Valid Claim; and (b) with respect to a Product and a Program Patent that is a patent application, that, in the absence of ownership of or a license granted under a Valid Claim of such Program Patent, the manufacture, use, offer for sale, sale or importation of such Product would infringe such Valid Claim if such patent application were to issue as a patent.

"<u>Damages</u>" shall mean all damages, losses, charges, liabilities, payments, judgments, settlements, assessments, deficiencies, Taxes, interest, penalties, and costs and expenses (including removal costs, remediation costs, closure costs, fines, penalties and expenses of investigation and ongoing monitoring, reasonable attorneys' fees, and out of pocket disbursements), but excluding unforeseeable, speculative, special, indirect, consequential, exemplary and punitive damages ("<u>Special Damages</u>"), except in the case of Special Damages imposed on, sustained, incurred or suffered by, or asserted against, any Indemnified Party in respect of a Third Party Claim.

"Development" shall mean research, pre-clinical and clinical drug development activities, including clinical trials, relating to the development of pharmaceutical compounds and pharmaceutical products and submission of information to a Regulatory Authority for the purpose of obtaining Regulatory Approval of a pharmaceutical product, and activities to develop manufacturing capabilities for pharmaceutical products. Development includes optimization and pre-clinical activities, statistical analysis and report writing, pharmacology studies, toxicology studies, formulation, process development and manufacturing scale-up (including bulk compound production), test method development, stability testing, quality assurance and quality control, qualification and validation, technical support, pharmacokinetic studies, clinical trials and regulatory affairs activities.

"EMA" shall mean the European Medicines Agency or any successor agency thereof.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

"Excluded Assets" shall have the meaning given to such term in Section 2.2.

"Exploit" or "Exploitation" shall mean Develop, design, test, modify, improve, make, have made, use, sell, offer sale, have sold, import, reproduce, market, distribute, and commercialize.

"EU" shall mean the European Union.

"FDA" shall mean the Food and Drug Administration of the United States Department of Health and Human Services or any successor agency thereof performing similar functions.

"First Commercial Sale" shall mean, with respect to a Product in a country, the first sale of such Product for monetary value for end use or consumption in such country after receipt of Regulatory Approval for such Product in such country.

"First EU Indication" shall have the meaning given to such term in Section 2.6(a).

"Form S-3" shall have the meaning given to such term in Section 2.6(c).

"Fundamental Representations" shall have the meaning given to such term in Section 8.1.

"Governmental Authorities" shall mean all agencies, authorities, bodies, boards, commissions, courts, instrumentalities, legislatures and offices of any nature whatsoever of any government or political subdivision, whether supranational, foreign, federal, state, provincial, county, district, municipality, city or otherwise, including any Regulatory Authority.

"Healthcare Laws" shall mean any U.S., foreign or other Law or regulation related to the development, manufacturing or commercialization of healthcare products and services, including, without limitation, (i) the U.S. Federal Food, Drug and Cosmetic Act and any regulations promulgated thereunder and any amendments or successors thereto, (ii) the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)) and any regulations promulgated thereunder and any amendments or successors thereto, the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)) and any regulations promulgated thereunder and any amendments or successors thereto, (iii) the civil False Claims Act (31 U.S.C. §§ 3729 et seq.) and any regulations promulgated thereunder and any amendments or successors thereto, (iv) the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)) and any regulations promulgated thereunder and any amendments or successors thereto, (v) the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.) and any regulations promulgated thereunder and any amendments or successors thereto, and (vi) any foreign equivalents of any of the above.

"IND" shall mean an Investigational New Drug Application filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations (or its successor regulation) with respect to any of the Program Compounds, or the equivalent application or filing filed with any equivalent agency or Governmental Authority outside the United States of America (including any supra-national agency such as the EMA), and all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

"IND Acknowledgement Letter" means the letter, together with FDA Form 1571, in substantially the form attached hereto as Exhibit F.

"IND Letter" means the letter, together with FDA Form 1571, in substantially the form attached hereto as Exhibit G.

"Indemnification Cap" shall have the meaning given to such term in Section 8.5.

"Indemnified Party" shall have the meaning given to such term in Section 8.4.

"Indemnifying Party" shall have the meaning given to such term in Section 8.4.

"Indication" shall mean a specific disease, infection or other condition which is recognized by a Regulatory Authority as being a disease, infection or condition. For avoidance of doubt, the term "Indication" includes each of myelodysplastic syndrome, acute myeloid leukemia, peripheral T-cell lymphoma, Hodgkins lymphoma, non-Hodgkin's lymphoma, Kaposi's sarcoma, gastric carcinoma, nasopharyngeal carcinoma, sarcoma, myelofibrosis, HIV infection, HBV infection, bone marrow transplant and organ transplant. All variants of a single disease, infection or condition (whether classified by severity or otherwise) will be treated as the same Indication, except that different types of cancer (e.g., as defined by site or cancer cell origin) will be treated as different Indications. The treatment or prevention of a disease, infection or other condition in adults and the treatment or prevention of the same disease, infection or other condition in a pediatric population will not be treated as separate Indications.

"Intellectual Property" shall mean all worldwide intellectual property rights, including rights in and to the following: (a) Patents; (b) Marks; (c) Copyrights; (d) Know-How; (e) data exclusivity, databases and data collections; and (f) any similar, corresponding or equivalent rights to any of the foregoing.

"Inventory" shall mean all quantities of SB939 drug substance in the possession or Control of Seller or any of its Subsidiaries as of immediately prior to the Closing.

"IRS" shall mean the United States Internal Revenue Service.

"Know-How" shall mean inventions (whether or not patentable), invention disclosures, processes, methods, algorithms and formulae, know-how, trade secrets, technology, information, knowledge, practices, formulas, instructions, skills, techniques, technical data, designs, drawings, computer programs, apparatus, results of experiments, test data, including pharmacological, toxicological and Clinical Data, analytical and quality control data, manufacturing data and descriptions, market data, devices, assays, chemical formulations, notes of experiments, specifications, compositions of matter, physical, chemical and biological materials and compounds, whether in intangible, tangible, written, electronic or other form.

"Knowledge" shall mean (a) with respect to Seller, the actual knowledge of a particular fact or other matter being possessed as of the pertinent date by Dr. Forrest H. Fuller, Dr. Kantharaj Ethirajulu and Tamar Howson, and (b) with respect to Purchaser, the actual knowledge of a particular fact or other matter being possessed as of the pertinent date by the Purchaser's Chief Executive Officer, Chief Financial Officer and Chief Medical Officer.

"Laboratory Notebooks" shall mean Seller's original laboratory notebooks that contain information relating to any Program Compound and/or Product.

"Laws" shall mean any statute, law, ordinance, regulation, rule, code, Order, other requirement or rule of law enacted, issued, promulgated, enforced or entered by a Governmental Authority.

"<u>Liability</u>" shall mean any direct or indirect indebtedness, liability, assessment, expense, claim, loss, damage, deficiency, obligation, Tax or responsibility, known or unknown, disputed or undisputed, joint or several, vested or unvested, executory or not, fixed or unfixed, choate or inchoate, liquidated or unliquidated, secured or unsecured, determinable or undeterminable,

accrued or unaccrued, absolute or not, actual or potential, contingent or otherwise (including any liability under any guarantees, letters of credit, performance credits or with respect to insurance loss accruals), whenever or however arising (including, whether arising out of any contract or tort based on negligence or strict liability) and whether or not the same would be required by GAAP to be reflected in financial statements or disclosed in the notes thereto.

"LIBOR" shall have the meaning given to such term in Section 2.8(a).

"Lien" shall mean any mortgage, lien, pledge, charge, claim, equitable interest, right-of-way, easement, encroachment, security interest, preemptive right, right of first refusal or similar restriction or right, including any restriction on use, option, judgment, title defect or encumbrance of any kind other than Permitted Liens.

"Marketing Approval" shall mean, with respect to any Product in a country or jurisdiction, any and all approvals, registrations, licenses or authorizations of the applicable Regulatory Authority(ies) necessary for the marketing and sale of such Product for a particular Indication in such country or jurisdiction, including, where applicable, approval of Product labeling for such Indication.

"Marks" shall mean all United States and foreign trademarks, service marks, trade names, service names, brand names, trade dress rights, logos, Internet domain names and corporate names, together with the goodwill associated with any of the foregoing, and all applications, registrations and renewals thereof.

"Material Adverse Effect" shall mean an effect that is materially adverse to the Program or could reasonably be expected to impair the ability of Seller to consummate the Acquisition or performance of obligations under this Agreement; provided, however, that none of the following (individually or in combination) shall be deemed to constitute, or shall be taken into account in determining whether there has been, a Material Adverse Effect: (a) any adverse effect resulting directly from general business or economic conditions, except to the extent such general business or economic conditions have a disproportionate effect on the Program; (b) any adverse effect resulting directly from conditions generally affecting any industry or industry sector to which the Program relates, except to the extent such adverse effect has a disproportionate effect on the Program; (c) any adverse effect resulting directly from the announcement, execution or delivery of this Agreement or the pendency or consummation of the transactions contemplated hereunder; (d) any adverse effect resulting directly from any change in accounting requirements or principles or any change in applicable Laws or the interpretation thereof; (e) any adverse effect resulting directly from any breach by Purchaser of any provision of this Agreement; or (f) any adverse data, event or outcome, arising out of or related to the Program, including pre-clinical and clinical trials, which data, event or outcome is disclosed in the Clinical Data or Regulatory Materials made available by Seller to Purchaser prior to the date of this Agreement.

"Milestone Event" shall have the meaning given to such term in Section 2.6(a).

"Milestone Payment" shall have the meaning given to such term in Section 2.6(a).

"Milestone Stock Payment" shall have the meaning given to such term in Section 2.6(a).

"NDA" shall mean a New Drug Application (as more fully described in 21 CFR 314.50 et seq. or its successor regulation), or any amendment or supplement thereto, with respect to a Program Compound or Product for an Indication, submitted to the FDA.

"Net Sales" shall mean the gross amount invoiced for sales of Product by Selling Persons to Third Parties, less the following deductions from such gross amounts to the extent attributable to such Product and to the extent actually incurred, allowed, accrued or specifically allocated:

- (a) trade, cash and quantity discounts actually given;
- (b) price reductions or rebates, retroactive or otherwise, or charge backs actually granted or paid to Governmental Authorities, group purchasing organizations, Third Party payors (including managed health care organizations) or trade customers;
  - (c) amounts repaid or credited by reason of rejections, defects, return goods allowance, recalls or returns;
- (d) reasonable and customary freight, shipping insurance and other transportation charges directly related to the sale of the Product separately stated on the invoice to the Third Party;
  - (e) fees for any services provided by wholesalers and warehousing chains related to the distribution of such Product; and
- (f) sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, to the extent that such items are included in the gross invoice price of the Product and actually borne by Selling Persons without reimbursement from any Third Party (but not including taxes assessed against the income derived from such sale);

all as determined in accordance with GAAP on a basis consistent with Purchaser's annual audited financial statements.

The transfer of Product between or among Purchaser and its Affiliates and Selling Persons for resale (which resale will give rise to Net Sales), use in a clinical trial, or use as free marketing samples will not be considered a sale.

Upon the sale or other disposal of 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 Product for or use of 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 Purchaser, its Affiliates and Selling Persons maintained in accordance with GAAP, consistently applied throughout the organization.

"Net Sales Milestone Events" shall have the meaning given to such term in Section 2.6(a).

"Notice of Claim" shall have the meaning given to such term in Section 8.4.

"Orders" shall have the meaning given to such term in Section 3.8.

"OIG" shall have the meaning given to such term in Section 3.8.

"Other Program Materials" shall mean, to the extent in the possession of or Controlled by Seller or its Subsidiaries as of the Closing, (i) all research and development reports and disclosure memoranda relating to the Program Compounds, including study reports, clinical trial related documents including consent forms, study contracts, site agreements, manuscripts and in process publications, (ii) all of the marketing and promotional documents, such as customer lists, marketing and promotional plans, documents and materials, field force training manuals and materials, and the like, to the extent relating to the Program Compounds, (iii) all worldwide safety reports with respect to the Program Compounds in existence as of the Closing, and (iv) all manufacturing information used in connection with the Program Compounds.

"Party" shall mean Seller or Purchaser, individually, as the context so requires, and the term "Parties" shall mean collectively, Seller and Purchaser.

"Patent Files" shall mean, with regard to a Program Patent: (a) the complete file histories for such Program Patent in the possession of Seller; and (b) all files relating to such Program Patent that are held or maintained on Seller's behalf by Seller's outside patent counsel, Phillips Ormonde Fitzpatrick, including all contents of such files.

"<u>Patents</u>" shall mean all United States and foreign patents and applications, including any and all divisionals, continuations and continuations-in-part of the patents and patent applications therefor and reissues, reexaminations, restorations (including supplemental protection certificates) and extensions thereof.

"Permitted Liens" shall mean any: (a) liens for current Taxes not yet due and payable or that are otherwise not material; (b) statutory or common law liens in favor of carriers, warehousemen, mechanics and materialmen, to secure claims for labor, materials or supplies, and other like liens arising in the ordinary course of business and consistent with past practices for sums not yet due and payable or which are being contested in good faith; and (c) liens in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods.

"Person" shall mean 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.

"Phase 2 Trial" shall mean a human clinical trial that would satisfy the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or its successor regulation).

"Phase 3 Milestone Event" shall have the meaning given to such term in Section 2.6(a).

"Phase 3 Trial" shall mean a human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or its successor regulation).

"Pivotal Trial" shall mean, with respect to a Product, a Phase 2 Trial of such Product that is intended to form the primary basis of an efficacy claim in an NDA submission and/or is the subject of a special protocol assessment agreement with the FDA.

"Pricing Approval" shall mean, with respect to a Product in a country or jurisdiction, the approval, agreement, determination or governmental decision establishing the price or level of reimbursement for such Product, if legally required in the relevant country or jurisdiction before any sale of such Product may occur in such country or jurisdiction.

"Product" shall mean any pharmaceutical product containing or comprising any Program Compound, whether or not as the sole active ingredient and in any dosage, form or formulation.

"Program" shall mean: (a) in the case of Seller, all of Seller's and its Subsidiaries' activities (including activities performed by any Third Party on behalf of Seller) directed to the Development and manufacture (including synthesis, formulation, finishing or packaging), use, offer for sale, sale, import or other Exploitation of the Program Compounds, up to the Closing Date; and (b) in the case of Purchaser, all of Purchaser's and its Affiliates' and Third Party licensees' activities (including activities performed by any Third Party on behalf of any of them) directed to the Development and manufacture (including synthesis, formulation, finishing or packaging), use, offer for sale, sale, import or other Exploitation of the Program Compounds following the Closing Date.

"Program Compound" shall mean: (a) SB939, SB1304, SB1354 and SB1502; (b) any compound claimed generically or specifically or otherwise covered in any of the Program Patents; and (c) any derivative, analog, salt, hydrate, solvate, ester, polymorph, isomer, regioisomer or stereoisomer (including enantiomer and diastereoisomer) of any compound described in clause (a) or (b) above, whether existing on the Closing Date or generated or synthesized by or on behalf of Purchaser or any of its Affiliates or licensees after the Closing.

"Program Know-How" shall mean Know-How not included in the Program Patents, which Know-How is: (a) Controlled by Seller or its Subsidiaries immediately prior to the Closing; and (b) directed to the Development, manufacture (including synthesis, formulation, finishing or packaging), use, offer for sale, sale, import or other Exploitation of any Program Compound and/or Product, including the Clinical Data; but excluding, in any event, any Know-How that is an Excluded Asset.

"Program Notebooks" shall mean true and complete copies of those portions of the Laboratory Notebooks that relate to the Program Compounds and/or Products, excluding any portion of the Laboratory Notebooks relating to any compound that is not a Program Compound.

"Program Patents" shall mean inventions, applications, and patents set forth in Exhibit C and any and all applications filed in any country based thereon, including applications in countries other than the country of priority filing under the provisions of any international

convention; any and all patents, including reissues and extensions thereof, obtained in any country upon said inventions; any and all continuing applications, including divisional, continuation and continuation-in-part applications; any substitute applications; all prior applications disclosing said inventions to which the present application claims priority; and to any other applications claiming the benefit of said prior applications.

- "Program Technology" shall mean the Program Patents and the Program Know-How.
- "Proprietary Compound" shall mean any composition of matter, other than a Program Compound, that is covered by a valid claim (provided that, a valid claim shall mean a Valid Claim with the term "Program Patent" replaced with "patent or patent application"), and is not covered by a Program Patent.
  - "Purchased Assets" shall have the meaning given to such term in Section 2.1.
  - "Purchase Price" shall have the meaning given to such term in Section 2.5.
  - "Purchaser Common Stock," shall mean Purchaser's Common Stock, par value Common Stock, \$0.00000002.
  - "Purchaser Series A Preferred Stock" shall mean Purchaser's Series A Convertible Preferred Stock, par value \$0.01.
  - "Purchaser Series B Preferred Stock" shall mean Purchaser's Series B Preferred Stock, par value \$0.01.
  - "Purchaser" shall have the meaning given to such term in the preamble of this Agreement.
  - "Purchaser SEC Reports" shall have the meaning given to such term in Section 4.7(a).
  - "Purchaser Indemnitees" shall have the meaning given to such term in Section 8.2.
- "Regulatory Approval" shall mean, with respect to a Product in a country or jurisdiction, (a) Marketing Approval, and (b) all Pricing Approvals with respect to such Product in such country or jurisdiction.
- "Regulatory Authority" shall mean any regulatory agency, ministry, department or other governmental body having authority in any country or region to control the development, manufacture, marketing, and sale of Products, including the FDA and EMA.
- "Regulatory Materials" shall mean all U.S. and foreign regulatory applications, filings, submissions and approvals (including all INDs and NDAs, and foreign counterparts thereof, and all Regulatory Approvals) for Program Compounds and/or Products, and all correspondence with the FDA and other Governmental Authorities relating to the Program Compounds and/or Products or any of the foregoing regulatory applications, submissions and approvals; that, in each case, are in the possession of or Controlled by, or held by or for Seller or its Subsidiaries at the Closing Date, whether generated, filed or held by or for Seller or its Subsidiaries.

- "Regulatory Milestone Events" shall have the meaning given to such term in Section 2.6(a).
- "Representatives" shall mean directors, officers, members, managers, employees, attorneys, accountants, representatives and other agents.
- "Retained Liabilities" shall have the meaning given to such term in Section 2.4.
- "Second EU Indication" shall have the meaning given to such term in Section 2.6(a).
- "SB1304" shall mean the compound designated by Seller as "SB1304," the structure of which is described in Exhibit E.
- "SB1354" shall mean the compound designated by Seller as "SB1354," the structure of which is described in Exhibit E.
- "SB1502" shall mean the compound designated by Seller as "SB1502," the structure of which is described in Exhibit E.
- "SB939" shall mean the compound designated by Seller as "SB939," the structure of which is described in Exhibit E.
- "SEC" shall mean the U.S. Securities and Exchange Commission.
- "Securities Act" shall mean the Securities Act of 1933, as amended.
- "Seller" shall have the meaning given to such term in the preamble of this Agreement.
- "Seller Disclosure Schedules" shall have the meaning given to such term in the first paragraph of Article 3.
- "Seller Indemnitees" shall have the meaning given to such term in Section 8.3.
- "Selling Person" shall mean, with respect to a Product, Purchaser and its Affiliates and each licensee or sublicensee of rights to sell such Product.
- "Set-Off Right" shall have the meaning given to such term in Section 8.5.
- "Subsidiary" shall mean any Person of which a majority of the outstanding voting securities or other voting equity interests are owned, directly or indirectly, by Seller.
  - "Surviving Person" shall have the meaning given to such term in Section 2.6(c).
- "Taxes" shall mean: (i) any and all taxes, fees, levies, duties, tariffs, imposts and other charges of any kind, imposed by any taxing authority, including taxes or other charges on, measured by, or with respect to income, franchise, windfall or other profits, gross receipts, property, sales, use, value added, good and services, capital stock, payroll, employment, social security, workers' compensation, unemployment compensation, escheat, unclaimed property, real or personal property or net worth; taxes or other charges in the nature of excise, withholding,

ad valorem, stamp, transfer, value-added or gains taxes; (ii) any Liability for the payment of any amounts of the type described in (i) as a result of being a member of an affiliated, combined, consolidated or unitary group for any taxable period; (iii) any Liability for the payment of amounts of the type described in (i) or (ii) as a result of being a transferee of, or a successor in interest to, any Person or as a result of an express or implied obligation to indemnify any Person; and (iv) any and all interest, penalties, additions to tax and additional amounts imposed in connection with or with respect to any amounts described in (i), (ii) or (iii).

"<u>Tax Return</u>" shall mean any return, report, statement, form or other documentation (including any additional or supporting material and any amendments or supplements) filed or maintained, or required to be filed or maintained, with respect to or in connection with the calculation, determination, assessment or collection of any Taxes.

"Third Party," shall mean any Person other than Seller or Purchaser or an Affiliate of Seller or Purchaser.

"Third Party Acquiror" shall have the meaning given to such term in Section 7.2(a).

"Third Party Claim" shall have the meaning given to such term in Section 8.4(b).

"Transaction Documents" shall mean, collectively, this Agreement, the Assignment and Assumption Agreement, the Patent Assignment and the Registration Rights Agreement.

"Transaction Value" shall have the meaning set forth in Section 2.5.

"Update Report" shall have the meaning set forth in Section 2.6(c).

"Valid Claim" shall mean any claim in any unexpired and issued Program Patent that has not been disclaimed, revoked or held invalid or unenforceable by a decision of a court or other governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) any claim of a pending patent application within the Program Patents that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling, nor pending for five (5) or more years.

**1.2 Interpretation.** Unless the context otherwise requires, the terms defined in Section 1.1 shall have the meanings herein specified for all purposes of this Agreement, applicable to both the singular and plural forms of any of the terms defined herein. When a reference is made in this Agreement to Sections, such reference shall be to a Section of this Agreement unless otherwise indicated. Whenever the words "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation."

# ARTICLE 2 PURCHASE & SALE OF PURCHASED ASSETS

- **2.1 Purchased Assets.** Subject to the terms and conditions of this Agreement, at the Closing, Seller shall, or shall cause one or more of its Subsidiaries to, sell, convey, transfer, assign and deliver to Purchaser, and Purchaser shall purchase and acquire from Seller, free and clear of all Liens other than the Assumed Liabilities and Permitted Liens, all of Seller's and its Subsidiaries' right, title and interest in and to all of the following (collectively, the "Purchased Assets"):
  - (a) The Program Compounds;
- **(b)** All Program Technology and any Copyrights Controlled by Seller or its Subsidiaries immediately prior to the Closing in publications primarily related to the Program Compounds, and/or Products and/or the Program, and all rights to sue for or assert claims against and remedies against past, present or future infringements of the foregoing and rights of priority and protection of interests therein and to retain any and all amounts therefrom except any Excluded Assets;
  - (c) All Regulatory Materials, including the items listed on Schedule 2.1(c);
- (d) All Inventory, including, the items listed on <u>Schedule 2.1(d)</u>, but excluding any Inventory not manufactured in accordance with current good manufacturing practices;
  - (e) All Patent Files with respect to the Program Patents;
  - (f) All Program Notebooks, including the information contained therein;
  - (g) All Other Program Materials; and
- (h) all rights and claims to the extent relating to the items described in paragraphs (a) through (g) of this Section 2.1 or to any Assumed Liability, and all warranties, indemnities and similar rights in favor of Seller or any of its Subsidiaries to the extent related to any such Purchased Asset or any Assumed Liability.
- **2.2 Excluded Assets.** Notwithstanding anything to the contrary contained in Section 2.1 or elsewhere in this Agreement, the following (collectively, the "Excluded Assets") shall not be part of the sale and purchase contemplated hereunder, are excluded from the Purchased Assets, and shall remain the property of Seller after the Closing:
  - (a) All assets not specifically listed in Section 2.1;
- **(b)** All assets (including Intellectual Property) of the Seller used in the Seller's businesses and programs directed to the Development, manufacture, use, sale, offer for sale, import or other Exploitation of compounds other than the Program Compounds, including, without limitation, the Laboratory Notebooks, but excluding the information contained in the Program Notebooks (which information is included in the Purchased Assets):

- (c) All rights of Seller under this Agreement and the Transaction Documents;
- (d) All minute books and corporate seals, stock books, Tax Returns and similar records of Seller;
- (e) Accounts Receivable;
- (f) All cash, cash equivalents on hand or in bank accounts and short term investments, marketable securities and inter-company accounts receivable;
- (g) Any prepayment, refund, claim, offset or other right of Seller with respect to any Tax arising or resulting from or in connection with the ownership of the Purchased Assets or operation of the Program attributable to any Tax period ending on or prior to the Closing Date, or, in the case of any Tax period which includes but does not end on the Closing Date, the portion of such period up to and including the Closing Date;
  - (h) All other accounts or notes receivable of Seller with respect to the Program that were earned prior to the Closing Date;
- (i) All leasehold interests and, other than the Purchased Assets, all biological or chemical materials, machinery, equipment, furniture, furnishings, fixtures and other tangible property;
  - (i) All claims and counterclaims relating to Excluded Liabilities or Excluded Assets;
  - (k) All rights under insurance policies, including, without limitation, all claims, refunds and credits due or to become due under such policies; and
- (I) The claims, remedies, rights, consideration (including contractual and escrow rights) or any other right related to any of the foregoing of Seller pursuant to this Agreement.
- 2.3 Assumed Liabilities. Except for the Assumed Liabilities, Purchaser shall not, by virtue of its purchase of the Purchased Assets, assume or become responsible for any Liabilities of Seller or any other Person in connection with this Agreement. Upon and subject to the terms, conditions, representations and warranties of Seller contained herein, and subject to Section 2.4, Purchaser hereby assumes and agrees to pay, perform, and discharge in a timely manner when due, any Liabilities:
- (a) arising out of or relating to the prosecution, ownership, operation, maintenance, sale, lease or use of the Purchased Assets or the operation of the Program by or on behalf of Purchaser after the Closing Date;
- (b) for Taxes (i) related to the Purchased Assets or the operation of the Purchased Assets that are attributable to any taxable period (or portion thereof) beginning after the Closing Date or (ii) which are the responsibility of Purchaser under Section 2.11; and

(c) which the Purchaser specifically assumes pursuant to the terms of this Agreement;

(collectively, the "Assumed Liabilities").

- 2.4 Retained Liabilities. Except for the Assumed Liabilities, Purchaser shall not assume, and shall have no Liability for, any Liabilities of Seller or its Subsidiaries of any kind, character or description, whether accrued, absolute, contingent or otherwise (including any Liability for (i) broker's or finder's fees or commissions or similar payments to any agent, broker, investment banker or other Person retained by Seller or any of its Subsidiaries in connection with the Acquisition or any of the other transactions contemplated by this Agreement, or (ii) any matter relating to Seller's or its Subsidiaries' ownership, use or operation of the Purchased Assets on or prior to the Closing), it being understood that Purchaser is expressly disclaiming any express or implied assumption of any Liabilities other than the Assumed Liabilities (collectively, the "Retained Liabilities").
- 2.5 Purchase Price; Payment of Purchase Price. The aggregate consideration for the Purchased Assets shall be (i) the assumption of the Assumed Liabilities; (ii) an amount in Purchaser Common Stock with a Transaction Value equal to five hundred thousand U.S. dollars (\$500,000) (the "Closing Stock Payment"), and (iii) the Milestone Payments and Contingent Earnouts that become due pursuant to Section 2.6 (collectively, the "Purchase Price"). The value (the "Transaction Value") of Purchaser Common Stock issued for the purpose of the Closing Stock Payment or any Milestone Payment shall be determined based on the five (5) day volume weighted average purchase price for shares of Purchaser Common Stock on the NASDAQ Capital Market on the five (5) trading days immediately prior to (a) the signing of this Agreement in the case of the Closing Stock Payment, or (b) the achievement of the applicable Milestone Event in the case of a Milestone Payment; in each case, as determined by reference to Bloomberg. The shares of Purchaser Common Stock comprising the Closing Stock Payment will not be registered at the Closing under the Securities Act, but such shares and all shares of Purchaser Common Stock payable in connection with the achievement of Milestone Events will be covered by a Registration Rights Agreement between Purchaser and Seller, in the form attached hereto as Exhibit D, to be executed and delivered at Closing.

### 2.6 Milestone Payments.

(a) <u>Milestone Events</u>. Upon the first achievement of each of the events set forth in the table below (each, a "<u>Milestone Event</u>"), whether achieved by Purchaser or any of its Affiliates or Selling Persons, Purchaser shall pay to Seller the amount set forth opposite such Milestone Event in the table below (each such payment, a "<u>Milestone Payment</u>") in accordance with Section 2.6(b). Except as otherwise indicated, all such amounts shall be in cash. Each of the Milestone Payments set forth below shall be payable only one time. All Milestone Payments are non-refundable and non-creditable. Milestone Events (A) through (G) set forth in the table below are referred to in this Agreement as "<u>Regulatory Milestone Events</u>"; and Milestone Events (H) through (M) set forth in the table below are referred to in this Agreement as "<u>Net Sales Milestone Events</u>." For the avoidance of doubt, no amounts shall be due for subsequent or repeated achievements of such Milestone Event, whether for the same or a different Program Compound, Product or Indication.

Milestone Payment

Milestone Event

Regulatory Milestone Events	
(A) First dosing of a patient in a Phase 3 Trial or other Pivotal Trial of a Product for any Indication (the "Phase 3 Milestone Event")	\$200,000 <i>plus</i> an amount in Purchaser Common Stock with a Transaction Value equal to \$500,000 (the " <u>Milestone Stock Payment</u> ")
(B) First FDA approval of an NDA for a Product for any Indication (the "First US Indication")	\$15,000,000
(C) First FDA approval of an NDA for a Product for any Indication other than the First US Indication	\$7,500,000
(D) The earlier of: (x) first receipt of Regulatory Approval in the earlier of (i) the EU, or (ii) any two of England, France, Germany, Italy or Spain, for a Product for any Indication (the "First EU Indication"); or (y) the earlier of (i) First Commercial Sale of a Product in the EU after receipt of Marketing Approval in the EU for the First EU Indication, or (ii) First Commercial Sale of a Product in any two of England, France, Germany, Italy or Spain after receipt of Marketing Approval in such two countries for the First EU Indication	\$10,000,000
(E) The earlier of: (x) first receipt of Regulatory Approval in the earlier of (i) the EU, or (ii) in any two of England, France, Germany, Italy or Spain, for a Product for any Indication other than the First EU Indication (the "Second EU Indication"); or (y) the earlier of (i) First Commercial Sale of a Product in the EU after receipt of Marketing Approval in the EU for the Second EU Indication, or (ii) First Commercial Sale of a Product in any two of England, France, Germany, Italy or Spain after receipt of Marketing Approval in such two countries for the Second EU Indication	\$5,000,000
(F) First receipt of Regulatory Approval in Japan for a Product for any Indication (the "First Japan Indication")	\$4,500,000
(G) First receipt of Regulatory Approval in Japan for a Product for any Indication other than the First Japan Indication	\$2,500,000

#### Net Sales Milestone Events

(H) First calendar year in which aggregate Net Sales of all Products in the U.S., Canada and Mexicocced \$100 million	ico \$5,000,000
(I) First calendar year in which aggregate Net Sales of all Products in the U.S., Canada and Mexico exceed \$250 million	\$12,500,000
(J) First calendar year in which aggregate Net Sales of all Products in the EU exceed \$50 million	\$2,500,000
(K) First calendar year in which aggregate Net Sales of all Products in the EU exceed \$125 million	s6,000,000
(L) First calendar year in which aggregate Net Sales of all Products in Japan exceed \$25 million	\$1,000,000
(M) First calendar year in which aggregate Net Sales of all Products in Japan exceed \$60 million	\$3,000,000

- **(b)** Notice and Payment. No later than five (5) Business Days after the occurrence of each Regulatory Milestone Event, Purchaser shall: (i) provide written notice to Seller of the occurrence of such Regulatory Milestone Event; and (ii) subject to Section 2.6(d), pay the corresponding Milestone Payment by wire transfer of immediately available funds to an account specified by Seller. No later than forty-five (45) days after the end of the calendar quarter in which each Net Sales Milestone Event occurs, Purchaser shall: (x) provide written notice to Seller of the occurrence of such Net Sales Milestone Event; and (y) pay the corresponding Milestone Payment by wire transfer of immediately available funds to an account specified by Seller.
- (c) <u>Diligence</u>. Purchaser shall use commercially reasonable efforts to cause all of the Milestone Events to be achieved. For purposes of this Section 2.6(c), the term "<u>commercially reasonable efforts</u>" means, with respect to Purchaser's efforts to achieve the Milestone Events, the level of efforts 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 into account the stage of development or product lifecycle or other of Purchaser's product candidates, safety and efficacy, product profile, cost of goods, the competitiveness of the marketplace, Purchaser's patent position with respect to such product (including Purchaser's ability to obtain or enforce, or have obtained or enforced, such patent rights), the third-party patent landscape relevant to the product, 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. Seller

acknowledges that Purchaser will need to raise additional capital in order to pursue the Program. Nothing in this Agreement shall be construed to require Purchaser to pursue the Program in priority to any of Purchaser's other programs and product candidates. Until the earlier of (i) the termination of diligence obligations pursuant to this Section 2.6(c) and (ii) First Commercial Sale of a Product in each of the United States and the EU, Purchaser shall send to Seller a status report regarding the development, manufacture and commercialization of Program Compounds and Products, including the status of efforts to achieve the Milestone Events, in January and June of each year (each such report, an "<u>Update Report</u>"), with the first such Update Report due in January 2013. Within thirty (30) days after receipt of an Update Report, if Seller requests a meeting, upon reasonable notice during regular business hours, with representatives of Purchaser to discuss such report, Purchaser shall use its Commercially Reasonable Efforts to make available for such a meeting those of its employees and representatives as are responsible for the applicable activities set forth in the Update Report. Purchaser's obligations under this Section 2.6(c) shall terminate and be of no further effect as of expiration of all Contingent Earnouts obligations of Purchaser under Section 2.5, provided that if there has been no commercial sale of a Product before expiration of the last-to-expire Valid Claim of the Program Patents, then Purchaser's obligations under this Section 2.6(c) shall terminate and be of no further effect as of expiration of the last-to-expire Valid Claim of the Program Patents.

(d) Phase 3 Milestone Event Payment. Purchaser may pay the Milestone Stock Payment through the issuance of shares of Purchaser Common Stock; provided, that, at the time of any such issuance, (i) such shares have been registered for resale under the Securities Act pursuant to a registration statement on Form S-3 filed by Purchaser (the "Form S-3"), at Purchaser's sole expense, (ii) the Form S-3 is effective under the Securities Act and is not the subject of any stop order or proceedings seeking a stop order, and (iii) Purchaser Common Stock is listed for trading on the NASDAQ Capital Market. In the event Purchaser Common Stock is not listed on the NASDAQ Capital Market or another national securities exchange at the time of achievement of the Phase 3 Milestone Event, the Milestone Stock Payment shall be paid entirely in a cash payment equal to five hundred thousand U.S. dollars (\$500,000). In addition, if any issuance of Purchaser Common Stock pursuant to this Article 2 would require stockholder approval under the rules of the NASDAQ Capital Market or any other securities exchange on which the shares are then listed, and such approval has not been obtained, then the applicable Closing Stock Payment or Milestone Stock Payment shall be paid entirely in cash.

(e) Survival. The obligations set forth in this Section 2.6 shall survive the Closing.

## 2.7 Contingent Earnouts.

(a) <u>Contingent Earnout Rate</u>. In addition to the Milestone Payments, Purchaser will pay to Seller payments in the amount of two percent (2%) of Net Sales of Products ("<u>Contingent Earnouts</u>"); *provided, however,* that no Contingent Earnouts shall be payable with respect to Net Sales of a Product in a country if: (i) such Product is not Covered by a Valid Claim in such country; and (ii) no Clinical Data is included in the regulatory filings for such Product in such country; *provided, further, however,* if the Product is a Combination Product, Purchaser will pay to Seller Contingent Earnouts in the amount of one and one half percent (1.5%) of Net Sales of such Combination Product.

- **(b)** Contingent Earnout Term. Contingent Earnouts shall be payable on a Product-by-Product and country-by-country basis, from First Commercial Sale of a Product in a country until the later of (i) expiration or invalidation of the last Valid Claim that Covers such Product in such country, and (ii) ten (10) years after the First Commercial Sale of such Product in such country (in each case, the "Contingent Earnout Term").
- (c) Contingent Earnout Reports and Payment. Within forty-five (45) days after the end of each calendar quarter, Purchaser shall deliver to Seller a written report indicating, on a Product-by-Product and country-by-country basis, gross sales and Net Sales (including deductions, itemized by major category), a calculation of the Contingent Earnouts due on such Net Sales, and the prices and the number of units of Product sold. Such amounts shall be expressed in U.S. dollars, and such reports shall include the rates of exchange used to convert to U.S. dollars from the currency in which such sales were made or payments received. Contingent Earnouts due to Seller will be paid on the date of delivery of such report.
  - (d) Survival. The obligations set forth in this Section 2.7 shall survive the Closing.

#### 2.8 Payments; Audits.

- (a) Exchange Rate; Manner and Place of Payment. Except for the Closing Stock Payment and the Milestone Stock Payment, all payments hereunder shall be payable in U.S. dollars. With respect to each quarter, for countries other than the United States, whenever conversion of payments from any foreign currency shall be required, such conversion shall be made at the rate of exchange used throughout the accounting system of Purchaser and its Affiliates for such quarter. All payments owed under this Agreement shall be made by wire transfer to a bank and account designated in writing by Seller, unless otherwise specified in writing by Seller.
- **(b)** Responsibility for Payments. Purchaser shall not consolidate with or merge into any other Person, assign, convey or transfer its properties and assets substantially as an entirety to any Person or assign, convey or transfer substantially all the Purchased Assets or substantially all the assets of the Program as operated by Purchaser following the Closing Date, to any Person, unless: (i) the Person formed by such consolidation or into which Purchaser is merged or the Person that acquires by conveyance or transfer, the properties and assets of Purchaser (the "Surviving Person") has expressly assumed the obligation to pay all Contingent Earnouts and each previously unpaid Milestone Payment when due and the obligation to perform every other surviving duty and covenant of Purchaser under this Agreement; provided, however; that any such Person that receives rights in respect of one or more geographic regions, but not the entire world, will not be liable for the payment of Contingent Earnouts with respect to Net Sales outside of such geographic region(s) or for Milestone Events occurring outside of such geographic region(s); and (ii) in the event Purchaser conveys, transfers, licenses or leases its properties and assets in accordance with the terms and conditions of this Section 2.6(c), Purchaser shall remain liable for the payment of Contingent Earnouts when due and each previously unpaid Milestone Payment when due and the performance of every duty and covenant of Purchaser under this Agreement.

- (c) Withholding. If Purchaser is required by Law to withhold Taxes of any type from the Purchase Price, Contingent Earnouts or Milestone Payments payable hereunder to Seller, Purchaser shall (i) deduct such Tax from the payment made to Seller, (ii) timely pay such Taxes for and on behalf of Seller to the proper Governmental Authority, and (iii) furnish Seller with documentation of such payment within thirty (30) days following such payment.
- (d) <u>Late Payments</u>. In the event that any Milestone Payment or Contingent Earnouts due under this Agreement is not made when due, the payment shall accrue interest from the date due at the rate of the one-month London Interbank Offered Rate ("<u>LIBOR</u>") as quoted in the Wall Street Journal (or if it no longer exists, similarly authoritative source) plus four hundred (400) 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 Seller from exercising any other rights it may have as a consequence of the lateness of any payment.
- (e) No Projections. Purchaser and Seller acknowledge and agree that nothing in this Agreement shall be construed as representing an estimate or projection of anticipated sales of any Product, and that the Net Sales levels set forth in Section 2.6 or elsewhere in this Agreement or that have otherwise been discussed by the parties are merely intended to define the Milestone or Contingent Earnout obligations to Seller in the event such Net Sales levels are achieved. PURCHASER MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY COMMERCIALIZE ANY PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR NET SALES LEVEL OF SUCH PRODUCT WILL BE ACHIEVED.
- **2.9** Allocation of Purchase Price. The Purchase Price shall be allocated in accordance with Schedule 2.9. The parties hereto further agree that: (a) the agreed upon allocation of Purchase Price shall be used in filing all Tax Returns; and (b) they will not take any position inconsistent with such allocation upon any examination of any such Tax Return, in any refund claim or in any tax litigation.
- **2.10 Closing.** The consummation of the purchase and sale of the Purchased Assets and the Assumption of the Assumed Liabilities in accordance with this Agreement (the "Closing") shall take place at the offices of Cooley LLP, 4401 Eastgate Mall, San Diego, CA 92121, no later than two (2) Business Days following the date on which the conditions set forth in Sections 6.1 and 6.2 have been satisfied or waived (other than those conditions that by their nature are to be satisfied at the Closing but subject to the fulfillment or waiver of those conditions) or at such other time and place as the parties hereto may mutually agree. The date of the Closing shall be referred to as the "Closing Date."
- 2.11 Tax Matters; Transfer Taxes. Seller shall reimburse Purchaser for any amount required to be withheld under applicable Law, excluding interest and penalties (to the extent the Purchaser does not so withhold). All federal, state, local or foreign or other excise, sales, use, value added, transfer (including real property transfer or gains), stamp, documentary, filing, recordation and other similar taxes and fees that maybe imposed or assessed as a result of the Transaction, together with any interest, additions or penalties with respect thereto and any interest in respect of such additions or penalties ("Transfer Taxes"), shall be borne equally by Purchaser and Seller on a timely basis. Any Tax Returns that must be filed in connection with

Transfer Taxes shall be prepared and filed by Seller, at its expense, and Seller will use its commercially reasonable best efforts to provide such Tax Returns to Purchaser at least ten (10) Business Days prior to the date such Tax Returns are due to be filed. Seller shall provide Purchaser with an IRS Form W-8 BEN.

2.12 Set-off. Purchaser shall have the set-off rights set forth in Section 8.5 in respect of the Contingent Earnouts and Milestone Payments.

## ARTICLE 3 REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Purchaser that the statements contained in this Article 3 are true and correct as of the date of this Agreement and as of the Closing Date, except as specifically disclosed in a document of even date herewith and delivered by Seller to Purchaser referring to the representations and warranties in this Agreement (the "Seller Disclosure Schedules").

- **3.1 Organization and Qualification.** Seller is a private limited company duly organized, validly existing and in good standing under the Laws of Singapore, and has all requisite power and authority to own, operate or lease the Purchased Assets, and to carry on the Program in all material respects as currently conducted. Neither Seller nor any Subsidiary of Seller is affiliated with or owns any interest in SBIO Holdings Corporation.
- 3.2 Authority Relative to this Agreement. Seller has all requisite corporate power and authority to execute and deliver this Agreement and the other Transaction Documents to which it is a party, to perform its obligations hereunder and to consummate the Acquisition. The execution, delivery and performance of this Agreement and the other Transaction Documents by Seller and the consummation by Seller of the Acquisition have been duly and validly authorized by all necessary corporate action of Seller, and no other corporate action on the part of Seller is necessary to authorize this Agreement and the other Transaction Documents or to consummate the Acquisition. This Agreement and the other Transaction Documents have been duly executed and delivered by Seller and, assuming the due authorization, execution and delivery by the other Parties hereto, each such agreement constitutes a legal, valid and binding obligation of Seller, enforceable against Seller in accordance with its terms, subject to the effect of any applicable bankruptcy, moratorium, insolvency, reorganization or other similar law affecting the enforceability of creditors' rights generally and to the effect of general principles of equity which may limit the availability of remedies (whether in a proceeding at Law or in equity) (collectively, the "Bankruptcy Exception").
- 3.3 No Conflict. Except as set forth on Schedule 3.3 of the Seller Disclosure Schedules, the execution and delivery of this Agreement and the other Transaction Documents by Seller do not, and the performance by Seller of its obligations hereunder and the consummation of the Acquisition and the transactions contemplated by the other Transaction Documents will not: (a) conflict with or violate any provision of the organizational documents of Seller or any of its Subsidiaries; (b) conflict with or violate any Law or Order applicable to Seller or by which any of the Purchased Assets or Seller is bound or affected; or (c) result in any breach of or constitute a default (or an event which with the giving of notice or lapse of time or both

would reasonably be expected to become a default) under any Contract to which Seller is a party or by which any of the Purchased Assets are bound, or give to others any right of termination, amendment, acceleration or cancellation of, or result in the creation of a Lien on any of the Purchased Assets.

- **3.4 Required Filings and Consents.** The execution and delivery of this Agreement and the other Transaction Documents by Seller do not, and the performance by Seller of its obligations hereunder and the consummation of the Acquisition will not, require any consent, approval, authorization or permit of, or filing by Seller with or notification by Seller to, any Governmental Authority or any Third Party.
- 3.5 Title to Purchased Assets. Seller has good, valid and marketable title to the Purchased Assets free and clear of all Liens other than Permitted Liens. The Purchased Assets constitute all of the assets (including Intellectual Property) owned or Controlled by Seller and/or its Subsidiaries that are primarily used or held by Seller and/or its Subsidiaries for use in, or are necessary for, the Program, except that Seller will retain the Laboratory Notebooks (it being understood that the information contained in the Program Notebooks is included in the Purchased Assets). Neither Seller nor any Subsidiary has granted any security interests, whether registered or unregistered in or to the Purchased Assets.

#### 3.6 Intellectual Property.

(a) <u>Disclosure and Ownership of Seller Patents</u>. <u>Schedule 3.6(b)(i)</u> of the Seller Disclosure Schedules lists all of the Program Patents existing as of the date of this Agreement, setting forth in each case the jurisdictions in which the Program Patents have been filed. Seller is the sole and exclusive owner of, and has good, valid and marketable title to, free and clear of all Liens (other than Permitted Liens), the Program Patents.

## (b) Disclosure of Agreements.

- (i) Schedule 3.6(b)(i) of the Seller Disclosure Schedules lists any existing Contract:
- (1) granting any Person any right to make, manufacture, use, sell or otherwise distribute any Program Compound, with or without the right to sublicense the same;
- (2) granting any Person any license under, any covenant not to assert/sue or other immunity from suit under, or any other rights to, any Program Technology;
  - (3) by which Seller or any of its Subsidiaries is assigned or granted an ownership interest in any Program Technology; or
- (4) limiting Seller's or any of its Subsidiaries' ability to transact business exclusively related to the Program Technology or Program Compounds in any market, field or geographical area or with any Person, or that restricts the use, sale, transfer, delivery or licensing of the Program Technology or Program Compounds, including without limitation any covenant not to compete;

provided, however, that Schedule 3.6(b)(i) of the Seller Disclosure Schedules need not list (1) non-disclosure agreements, (2) materials transfer agreements on customary terms, (3) licenses for off-the-shelf software or generally available software, and (4) invention assignment agreements with employees, consultants and contractors that assign or grant to Seller or any of its Subsidiaries ownership of inventions and intellectual property developed in the course of providing services to Seller or any of its Subsidiaries by such employees, consultants and contractors.

- (ii) <u>Royalties</u>. Except as set forth in <u>Schedule 3.6(b)(ii)</u> of the Seller Disclosure Schedules, neither Seller nor any of its Subsidiaries' is a party to any Contract or subject to any Order obligating Seller or any of its Subsidiaries to pay any royalties, license fees or other amounts to any Person by reason of the ownership, use, exploitation, practice, sale or disposition of Program Technology or any Program Compound.
  - (c) No Third Party Rights in Program Technology. Except as set forth in Schedule 3.6(c) of the Seller Disclosure Schedules:
- (i) No Employee Ownership. No current or former officer, director, employee, consultant or independent contractor of Seller or any of its Subsidiaries has any right, title or interest in, to or under any Program Technology developed by such person in the course of providing services to Seller that has not been either (A) irrevocably assigned or transferred to Seller or any of its Subsidiaries or (B) licensed (with the right to grant sublicenses) to Seller or any of its Subsidiaries under an exclusive, irrevocable, worldwide, royalty-free, fully-paid and assignable license.
- (ii) No Third Party Claims. Neither Seller nor any of its Subsidiaries has received any written communication from any Person claiming or alleging, nor is Seller or any of its Subsidiaries a party to any pending and served proceeding or, to Seller's Knowledge, any pending but not served proceeding, in which any Person is claiming or alleging, that it has any right, title or interest in, to or under any Program Technology or that Seller's use, transfer, sale or licensing of the Program Technology is restricted in any manner.
- (iii) No Restrictions. Neither Seller nor any of its Subsidiaries is subject to any outstanding decree, order, judgment or stipulation restricting in any manner the use, transfer, sale or licensing of the Program Technology.
  - (d) Patents. Except as set forth in Schedule 3.6(d) of the Seller Disclosure Schedules:
- (i) <u>Proper Filing</u>. All Program Patents listed in <u>Schedule 3.6(b)(i)</u> of the Seller Disclosure Schedules have been duly filed and maintained, including the timely submission of all necessary filings and fees in accordance with the legal and administrative requirements of the appropriate Governmental Authority, and have not lapsed (other than lapsed provisional applications that have been converted to non-provisional applications), expired or been abandoned.

- (ii) No Challenges. Neither Seller nor any of its Subsidiaries has received any written notice of any inventorship challenge, interference, invalidity or unenforceability with respect to Program Patents.
- (iii) <u>Validity.</u> To Seller's Knowledge, no issued and unexpired Program Patent listed in Schedule 3.6(b)(i) of the Seller Disclosure Schedules is invalid. To Seller's Knowledge, each U.S. patent application and issued and unexpired U.S. patent listed in Schedule 3.6(b)(i) of the Seller Disclosure Schedules was filed within one year of each invention claimed in such U.S. patent being made available to the public by Seller by printed publication, public use, or offer for sale of each invention described in such U.S. patent application or U.S. patent. To Seller's Knowledge, each foreign patent application and issued and unexpired foreign patent listed in Schedule 3.6(b)(i) of the Seller Disclosure Schedules was filed or claims priority to a patent application filed prior to each invention claimed described in such foreign patent application or foreign patent being made available to the public by Seller.
- (e) <u>Infringement</u>. Neither Seller nor any of its Subsidiaries has received any written communication (i) alleging that Seller's or any of its Subsidiaries' use of any Program Technology infringes, or constitutes contributory infringement, inducement to infringe, misappropriation or unlawful use of, the intellectual property rights of any Person, or (ii) notifying Seller or any of its Subsidiaries that the use of any Program Technology requires a license to any Person's intellectual property rights.
- (f) <u>Confidentiality</u>. Seller has taken all commercially reasonable and customary measures and precautions necessary to protect and maintain the confidentiality of the Program Know-How.
- (g) Employee, Consultant and Contractor Agreements. Except as set forth in Schedule 3.6(g) of the Seller Disclosure Schedules, each current and former employee, consultant and contractor of Seller or any of its Subsidiaries who is or was involved in, or who has contributed to, the creation or development of any Program Technology, has executed a written agreement (i) expressly assigning to Seller all right, title and interest in any Program Technology invented, created, developed, conceived or reduced to practice by such employee, consultant or contractor; and (ii) obligating such employee, consultant or independent contractor to maintain the confidentiality of confidential Program Technology. To Seller's Knowledge, no current or former employee, consultant or contractor is in violation of any term of any such agreement. No Government Authority, university, college or other educational or non-profit institution or research center has any claim of right to ownership of or other liens, claims or interests with respect to the Program Technology, other than Permitted Liens.
- (h) No Government Funding. Except as set forth in Schedule 3.6(h) of the Seller Disclosure Schedule, no funding, facilities or personnel of any Governmental Authority were used in the creation or development of any Program Technology or Program Compound.
- 3.7 Contracts. Schedule 3.7 of the Seller Disclosure Schedules contains a true and accurate list of all Contracts pursuant to which Seller enjoys any right or benefit or undertakes any obligation related in any way to the Purchased Assets or the Program, other than (i) non-disclosure agreements, (ii) materials transfer agreements on customary terms,

- (iii) licenses for off-the-shelf software or generally available software, and (iv) invention assignment agreements with employees, consultants and contractors that assign or grant to Seller ownership of inventions and intellectual property developed in the course of providing services to Seller by such employees, consultants and contractors. Schedule 3.7 of the Seller Disclosure Schedules identifies each such Contract requiring Seller to obtain the consent of the counterparty thereto to the consummation of the transactions contemplated hereby.
- 3.8 Compliance with Laws. Except as set forth on Schedule 3.8 of the Seller Disclosure Schedules, neither Seller nor any of its Subsidiaries is in conflict in any respect with or in default or violation of any material (a) order, judgment, preliminary or permanent injunction, temporary restraining order, award, citation, decree, consent decree or writ (collectively, "Orders") of any Governmental Authority, materially affecting or relating to the Purchased Assets or the Program; or (b) except for any violation that gives rise to an Excluded Liability, Laws of any Governmental Authority, materially affecting or relating to the Purchased Assets or the Program. Except as set forth on Schedule 3.8 of the Seller Disclosure Schedules, neither Seller nor any of its Subsidiaries has received from any Governmental Authority any notification in writing with respect to possible conflicts, defaults or violations of Laws materially affecting or relating to the Purchased Assets or the Program.

#### 3.9 Regulatory Compliance.

- (a) The use and operation of the Purchased Assets and the operation of the Program by and on behalf of Seller and its Subsidiaries are in compliance in all material respects with all applicable Laws, there are no material violations of any such Laws, and neither Seller nor any of its Subsidiaries has received any written notice from the FDA or any other Regulatory Authority alleging any existing material non-compliance with any Laws applicable to the conduct of the Program.
- **(b)** There are no pending or, to Seller's Knowledge, threatened in writing actions by the FDA or other Regulatory Authorities which would prohibit or impede the conduct of the Program as currently conducted or contemplated to be conducted. Seller and its Subsidiaries have timely filed all forms, applications, statements, reports, data and other information required to be filed with any Regulatory Authority in connection with the conduct of the Program except where a failure to file timely would not reasonably be expected to have a Material Adverse Effect. Neither Seller nor any of its Subsidiaries has made any material false statements on, or, to Seller's Knowledge, material omissions from, the applications, approvals, reports and other submissions Seller or any Subsidiary has made to the FDA or other Regulatory Authorities prepared or maintained to comply with the requirements of the FDA or such other Regulatory Authorities relating to the Program that would reasonably be expected to provide a basis for the FDA to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," or similar policies, or for any other Regulatory Authority to invoke any similar policies, set forth in any applicable Laws.
- (c) No employee, and, to Seller's Knowledge, no independent contractor, of Seller or its Subsidiaries has been excluded from participating in the Medicare program or any other program of a Governmental Authority. None of Seller's or its Subsidiaries' officers, directors, agents or management employees (as that term is defined in 42 U.S.C. § 1320a 5(b)),

have been excluded from participating in the Medicare program or any other Government Program or been subject to sanction pursuant to 42 U.S.C. § 1320a 7a or 1320a 8 or been convicted of a criminal offense under the Anti-Kickback Statute (42 U.S.C. § 1320a 7b).

- (d) Seller (i) is not a party to a corporate integrity agreement with the United States Office of Inspector General ("OIG") regarding the Program, (ii) has no reporting obligations regarding the Program pursuant to any settlement agreement entered into with any Government Authority, (iii) has not made any disclosures, reports or any other filings, including disclosures or reports under the OIG's Provider Self-Disclosure Protocol, to any Government Authority related to any violation of Law or potential violation of Law relating to the Program, (iv) to the Knowledge of Seller, has not been the subject of any government payor program investigation conducted by any federal or state enforcement agency related to the Program, (v) to the Knowledge of Seller, has not been a defendant in any qui tam/False Claims Act litigation related to the Program, and (vi) has not been served with or received any written search warrant, subpoena, civil investigative demand or contact letter from any federal or state enforcement agency related to the Program.
- 3.10 Clinical Studies. The preclinical studies and clinical trials of the Program Compounds conducted by or on behalf of Seller and its Subsidiaries were and, if still ongoing, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all Laws and Authorizations applicable to such studies and trials, including the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder. All materials used in such trials materially complied with applicable authorization and Laws, and there have not been any material deficiencies or defects in such materials. Seller and its Subsidiaries have not received any notices or correspondence from the FDA or any other Government Authority requiring the termination, suspension or material modification of any preclinical study or clinical trial of a Program Compound conducted by or on behalf of Seller or its Subsidiaries. Neither Seller nor any of its Subsidiaries has received any communication from any Person threatening any claim or lawsuit against Seller or any of its Subsidiaries arising from the administration of a Program Compound or Product to any Person in the course of any clinical trial conducted by or on behalf of Seller or its Subsidiaries.
- **3.11 Inventory.** The quantities of SB939 drug substance set forth in <u>Schedule 3.11</u> of the Seller Disclosure Schedules are the only inventory of any Program Compound in Seller's or any of its Subsidiaries' possession or control.
- 3.12 Claims and Proceedings. Except as set forth on Schedule 3.12 of the Seller Disclosure Schedules, there is no outstanding Order of any Governmental Authority against or involving the Purchased Assets, the Assumed Liabilities or any Program Compound. To Seller's Knowledge, and except as set forth on Schedule 3.12 of the Seller Disclosure Schedules, there is no action, arbitration, hearing, claim, counterclaim, litigation or suit (whether civil, criminal, administrative, judicial or investigative, whether public or private) or legal, administrative or arbitral proceeding or investigation, in each case, before any Governmental Authority, arbitrator or arbitration panel (collectively, "Claim") (whether or not the defense thereof or Liabilities in respect thereof are covered by insurance), pending or threatened against or involving the Purchased Assets, the Assumed Liabilities or any Program Compound.

3.13 Securities Law Matters. Seller is an "accredited investor" within the meaning of Rule 501 of Regulation D under the Exchange Act, as presently in effect. Seller understands that the shares of Purchaser Common Stock issued by Purchaser as part of the Closing Stock Payment and Milestone Stock Payment are characterized as "restricted securities" under the federal securities Laws inasmuch as they are being acquired from Purchaser in a transaction not involving a public offering and that under such Laws and applicable regulations such securities may be resold without registration under the Securities Act, only in certain limited circumstances. Seller acknowledges that the Purchaser Common Stock is being purchased for investment and not with a view towards a distribution. Seller further acknowledges that Seller has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of acquiring the Purchaser Common Stock. Seller understands that any shares issued as part of the Closing Stock Payment and the Milestone Stock Payment may bear the following or a similar legend:

"THE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION IS NOT REQUIRED UNDER SUCH ACT OR UNLESS SOLD PURSUANT TO RULE 144 UNDER SUCH ACT."

- **3.14** No Finder. Except as set forth in Schedule 3.14 of the Seller Disclosure Schedules, no agent, broker, investment banker or other Person is or will be entitled to any broker's or finder's fee or any other commission or similar fee from Seller or its Subsidiaries in connection with the Acquisition or any of the other transactions contemplated by this Agreement.
- **3.15 Absence of Certain Changes and Events.** Since June 30, 2012, Seller has not experienced any event or condition, and to Seller's Knowledge no event or condition is threatened, that, individually or in the aggregate, has had or is reasonably likely to have, a Material Adverse Effect on the Purchased Assets.
- 3.16 Solvency. Seller is not now insolvent and will not be rendered insolvent by the Transaction (excluding any amounts reflected as liabilities in the financial statements of Seller but which are in the nature of accrued (and undeclared) dividends on preference shares or amounts payable to preference shareholders on a redemption of preference shares in Seller or a liquidation of Seller). As used in this Section, "insolvent" means that the sum of the debts and other Liabilities of Seller (excluding any amounts reflected as liabilities in the financial statements of Seller but which are in the nature of accrued (and undeclared) dividends on preference shares or amounts payable to preference shareholders on a redemption of preference shares in Seller or a liquidation of Seller) exceeds the present fair saleable value of Seller's assets.
- **3.17 Foreign Corrupt Practices.** Seller does not own any securities of Purchaser. Neither Seller, nor, to the Knowledge of Seller, any agent or other Person acting on behalf of Seller, has, in connection with the Program, (i) directly or indirectly, used any funds for unlawful

contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by Seller (or made by any person acting on its behalf of which Seller is aware) which is in violation of Law, or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.

3.18 Taxes. Except as set forth on Schedule 3.18, (a) Seller has properly filed on a timely basis all Tax Returns that it was required to file with respect to the Purchased Assets that are required to be filed on or before the Closing, (b) all such Tax Returns are true, correct and complete in all respects and were prepared in compliance with all applicable Laws and regulations, (c) Seller has paid on a timely basis all Taxes with respect to the Purchased Assets, whether or not shown on any Tax Return, that were due and payable, (d) all Taxes that are required to have been withheld with respect to the Purchased Assets have been withheld and timely paid to the appropriate authorities in compliance with all Tax withholding provisions (including income, social security and employment Tax withholding for all types of compensation), (e) there is no lien for Taxes upon any of the Purchased Assets nor, to the Knowledge of Seller, is any taxing authority in the process of imposing any lien for Taxes on any of the Purchased Assets, other than liens for Taxes that are not yet due and payable, (f) no issues that have been raised by the relevant taxing authority in connection with any examination of the Tax Returns are currently pending, and all deficiencies asserted or assessments made, if any, as a result of such examinations have been paid in full, (g) none of Seller or any of its Subsidiaries that transfer assets pursuant to this Agreement is a party to any Contract with any Person under which Seller or such Subsidiary has agreed to share any Tax Liability, (h) no transaction contemplated by this Agreement is subject to withholding, (i) none of Seller or any of its Subsidiaries that transfer assets pursuant to this Agreement has any actual or potential Liability under Treasury Regulations Section 1.1502-6 (or any comparable or similar provision of federal, state, local or foreign Law), as a transferee or successor, pursuant to any contractual obligation, or otherwise for any Taxes of any Person, (j) Schedule 3.18(j) sets forth each jurisdiction in which Seller or its Subsidiaries files, is required to file or has been required to file a Tax Return or is or has been liable for any Taxes on a "nexus" basis, in each case with respect to the Purchased Assets, and (k) no claim has ever been made by a Tax authority in a jurisdiction other than those set forth on Schedule 3.18(j) asserting that any of Seller or any of its Subsidiaries is or may be subject to Taxes assessed by such jurisdiction with respect to the Purchased Assets.

# ARTICLE 4 REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser represents and warrants to Seller, that each of the following representations and warranties is true and correct as of the date of this Agreement and as of the Closing Date.

**4.1 Organization and Qualification.** Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate or other power and authority and all necessary governmental approvals to own, lease and operate its properties and to carry on its business as now being conducted.

- **4.2 Authority Relative to this Agreement.** Purchaser has all necessary corporate power and authority to execute and deliver this Agreement and the other Transaction Documents to which it is a party, to perform its obligations hereunder and to consummate the Acquisition. The execution and delivery of this Agreement and the other Transaction Documents by Purchaser and the consummation by Purchaser of the Acquisition have been duly and validly authorized by all necessary corporate action of the Purchaser and its board of directors, and no other corporate proceedings on the part of Purchaser are necessary to authorize this Agreement or to consummate the Acquisition. This Agreement and the other Transaction Documents have been or when executed and delivered will be duly executed and delivered by Purchaser and, assuming the due authorization, execution and delivery by the other Parties hereto, each such agreement constitutes a legal, valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with its terms, subject to the Bankruptcy Exception.
- **4.3 No Conflict.** The execution and delivery of this Agreement by Purchaser do not, and the performance by Purchaser of its obligations hereunder and the consummation of the Acquisition will not: (i) conflict with or violate any provision of the Purchaser's certificate of incorporation or bylaws, each as amended to date, or any resolutions adopted by the board of directors of Purchaser; or (ii) assuming that all filings and notifications described in Section 4.4 have been made, conflict with or violate any Law or Order applicable to Purchaser or by which Purchaser is bound or affected.
- **4.4 Required Filings and Consents.** Except for the filings, permits, authorizations, consents and approvals as may be required under, and other applicable requirements of, the Exchange Act, the execution and delivery of this Agreement by Purchaser do not, and the performance by Purchaser of its obligations hereunder and the consummation of the Acquisition will not, require any consent, approval, authorization or permit of, or filing by Purchaser with or notification by Purchaser to, any Governmental Authority or any Third Party.
- 4.5 Claims and Proceedings. To the Purchaser's Knowledge, there is no Claim (whether or not the defense thereof or Liabilities in respect thereof are covered by insurance), pending or threatened that could reasonably be expected to impair or delay the ability of Purchaser to effect the Closing, nor is there any Order of any Governmental Authority or arbitrator outstanding against, or, to the Purchaser's Knowledge, investigation by any Governmental Authority that could reasonably be expected to impair or delay the ability of Purchaser to effect the Closing.

### 4.6 Capitalization.

(a) As of the date of this Agreement, the authorized capital stock of Purchaser consists of (i) 113,000,000 shares of Purchaser Common Stock, (ii) 100,000 shares of Purchaser Preferred Stock. As of the close of business on the day immediately preceding the date of this Agreement, (i) 20,498,946 shares of Purchaser Common Stock are issued and outstanding, (ii) zero shares of Purchaser Common Stock are held in the treasury of Purchaser, (iii) 2,500,000 shares of Purchaser Common Stock are reserved for future issuance pursuant to stock options, of which 895,980 are subject to outstanding options, 1,604,020 shares have been reserved for future option or stock grants and zero shares have been issued upon the exercise of options, (iv) 5,623,772 shares of Purchaser Common Stock are reserved for future issuance pursuant to

warrants, (v) 1,000 shares of Purchaser Series A Convertible Preferred Stock are issued and outstanding, convertible into either 4,827,000 or 9,654,000 shares of the Purchaser common stock, and (vi) zero shares of Purchaser Series B Preferred Stock are issued and outstanding. Except as set forth in this Section 4.6, there are no options, warrants, convertible debt or other convertible instruments or other rights, agreements, arrangements or commitments of any character relating to the issued or unissued capital stock of Purchaser or obligating Purchaser to issue or sell any shares of capital stock of, or other equity interests in, Purchaser. All shares of Purchaser Common Stock, Purchaser Series A Preferred Stock and Purchaser Series B Preferred Stock issued and outstanding or subject to issuance as aforesaid, upon issuance on the terms and conditions specified in the instruments pursuant to which they are issuable, are or will (upon issuance) be duly authorized, validly issued, fully paid and non-assessable.

(b) The shares of Purchaser Common Stock to be issued pursuant to Section 2.5 or Section 2.6 will be duly authorized, validly issued, fully paid and non assessable and not subject to preemptive rights created by statute, Purchaser's certificate of incorporation or bylaws or any agreement to which Purchaser is a party or is bound. The shares of Purchaser Common Stock to be issued pursuant to Section 2.5 (i) will be issued in a transaction exempt from registration under the Securities Act as a private placement pursuant to either Section 4(2) of the Securities Act or such other exemption from the registration requirements of the Securities Act as may be available, (ii) will, when issued, be registered or exempt from registration under applicable Blue Sky Laws and (iii) will be approved for listing on the NASDAQ Capital Market, subject to official notice of issuance.

#### 4.7 SEC Filings; Financial Statements.

- (a) Purchaser has filed all forms, reports, statements, schedules and other documents required to be filed by it with the SEC since January 1, 2011 under the Securities Act or the Exchange Act (collectively, the "Purchaser SEC Reports"). The Purchaser SEC Reports (i) at the time they were filed and, if amended, as of the date of such amendment, complied in all material respects with all applicable requirements of the Securities Act or the Exchange Act, as the case may be, and the rules and regulations promulgated thereunder, and (ii) did not, at the time they were filed, and, if amended, as of the date of such amendment, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. No Affiliate or Subsidiary of Purchaser is required to file any form, report, statement, schedule or other document with the SEC under the Securities Act or the Exchange Act in connection with the Acquisition.
- (b) Each of the consolidated financial statements (including, in each case, any notes thereto) contained (or incorporated by reference) in the Purchaser SEC Reports was prepared in accordance with GAAP applied on a consistent basis throughout the periods indicated (except as may be indicated in the notes thereto or, in the case of unaudited statements, as permitted by Form 10-Q of the SEC) and each fairly presents, in all material respects, the consolidated financial position, results of operations and cash flows of Purchaser and its consolidated Subsidiaries as at the respective dates thereof and for the respective periods indicated therein, except as otherwise noted therein (subject, in the case of unaudited statements,

to normal and recurring year-end adjustments which are not, in the aggregate, material to Purchaser and its Subsidiaries, taken as a whole).

- (c) As of the date of this Agreement, there are no outstanding or unresolved comments in comment letters received from the SEC with respect to the Purchaser SEC Reports that would reasonably be expected to delay Purchaser's performance of its obligations under the Registration Rights Agreement. To the Knowledge of Purchaser, none of the Purchaser SEC Reports is the subject of ongoing SEC review that would reasonably be expected to delay Purchaser's performance of its obligations under the Registration Rights Agreement. There are no inquiries or investigations by the SEC or any Governmental Authority pending or threatened regarding any accounting practices of Purchaser or any of its Subsidiaries.
- (d) Purchaser maintains and has maintained a standard system of accounting established and administered in accordance with GAAP in all material respects. Purchaser and its Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets, (iii) access to assets is permitted only in accordance with management's general or specific authorizations, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.
- (e) Since January 1, 2011, neither Purchaser nor any of its Subsidiaries nor, to the Knowledge of Purchaser, any Representative of Purchaser or any of its Subsidiaries, has received or otherwise had or obtained knowledge of any complaint, allegation, assertion or claim, whether written or oral, regarding the accounting or auditing practices, procedures, methodologies or methods of Purchaser or any of its Subsidiaries or their respective internal accounting controls, including any complaint, allegation, assertion or claim that Purchaser or any of its Subsidiaries has engaged in questionable accounting or auditing practices.
- (f) For purposes of the representations and warranties in this Section 4.7, Novogen Limited, Purchaser's majority shareholder, shall not be deemed or considered an Affiliate of Purchaser.
- **4.8 No Finder.** Neither Purchaser nor any Person acting on behalf of Purchaser has agreed to pay to any broker, finder, investment banker or any other Person, a brokerage, finder's or other fee or commission in connection with this Agreement or any matter related hereto, nor has any broker, finder, investment banker or any other Person taken any action on which a Claim for any such payment could be based.
- **4.9** Access. Purchaser and its representatives have been given full access to the assets, books, records, Contracts and employees of Seller, and have been given the opportunity to meet with officers and other representatives of Seller for the purpose of investigating and obtaining information regarding Seller's business, operations and legal affairs, including, without limitation, the Program.

**4.10** No Implied Representations. Purchaser agrees that neither Seller nor any other Person acting on behalf of Seller has made or is making any representations or warranties, express or implied, except those representations set forth in Article 3 of this Agreement. Except in the case of fraud, neither Seller nor any other Person shall be subject to any liability to Purchaser or any other Person resulting from Seller's making available to Purchaser, or Purchaser's use of, any information, documents or material made available to Purchaser in the due diligence materials provided to Purchaser, including in any virtual or actual "data room," presentations (formal or informal) or in any other form in connection with this Agreement or the transactions contemplated hereby, unless any such information is expressly set forth herein in the representations set forth in Article 3 of this Agreement.

## ARTICLE 5 COVENANTS

- **5.1 Access and Information.** From the date hereof until the earlier of the Closing and the termination of this Agreement pursuant to Article 9, subject to applicable Laws, Seller shall: (i) afford Purchaser and its Representatives reasonable access, during regular business hours and subject to reasonable notice, to the Purchased Assets and consultants of Seller with knowledge of the Purchased Assets; provided, however, that Purchaser acknowledges that Seller has no employees and may have as few as one consultant available for such purpose, and such lack of personnel shall neither constitute a breach of this Agreement by Seller nor be a condition to Purchaser's obligation to effect the Closing; (ii) furnish Purchaser with copies of such documentation and information held by or under the control of Seller or any of its Subsidiaries and related to the Purchased Assets as Purchaser may reasonably request; and (iii) instruct the employees of Seller, and its counsel and financial advisors to cooperate with Purchaser in its investigation of the Purchased Assets. No investigation pursuant to this Section 5.1 shall alter any representation or warranty given hereunder by Seller. All information received pursuant to this Section 5.1 shall be governed by the terms of the Confidentiality Agreement. In the event that Purchaser requests any document or material pursuant to this Section 5.1 for which any attorney-client or other legal privilege is available, Seller's obligation to provide Purchaser with access to such document or material shall be conditioned upon execution by Seller and Purchaser of an appropriate common interest and confidentiality agreement in reasonable and customary form.
- **5.2 Conduct of Business.** During the period from the date hereof until the earlier of the Closing and the termination of this Agreement pursuant to Article 9, except as otherwise contemplated by this Agreement or as Purchaser otherwise agrees in writing in advance, Seller shall use its commercially reasonable efforts to preserve intact the Purchased Assets as in existence on the date of this Agreement. By way of amplification and not in any way limiting the prior sentence, during the period from the date hereof to the Closing, except as otherwise contemplated by this Agreement or as Purchaser shall otherwise consent (which consent shall not be unreasonably withheld or delayed), Seller shall not, and shall cause each of its Subsidiaries not to:
  - (a) incur, create or assume any Lien (other than Permitted Liens) on any of the Purchased Assets;

- **(b)** sell, lease, license, transfer or dispose of any Purchased Assets;
- (c) enter into any contract, arrangement or commitment related to the Purchased Assets;
- (d) dispose of or permit to lapse any rights in, to or for the use of any Program Technology, or disclose to any Person not an employee any Program Technology not heretofore a matter of public knowledge, except pursuant to judicial or administrative process;
- (e) settle any claims, actions, arbitrations, disputes or other Proceedings (i) that would impair the ability of Seller or any of its Subsidiaries to consummate the transactions contemplated by this Agreement and the Registration Rights Agreement, or (ii) affecting the Purchased Assets;
- (f) do any other act which would cause any representation or warranty of Seller in this Agreement to be or become untrue in any material respect or intentionally omit to take any action necessary to prevent any such representation or warranty from being untrue in any material respect at such time; and
  - (g) authorize or enter into any agreement or commitment with respect to any of the foregoing.

In addition, Seller shall continue to take commercially reasonable and customary measures and precautions to protect and maintain the confidentiality of the Program Know-How, consistent with Seller's past practice.

### 5.3 No Shop.

- (a) From the date of signing of this Agreement until the earlier of the Closing and the termination of this Agreement pursuant to Article 9, Seller shall not and shall cause its Subsidiaries and their respective Representatives not to, directly or indirectly, (i) solicit, initiate, encourage or entertain any inquiries or proposals, or discuss, negotiate with or enter into any understanding, arrangement or agreement, relating to the direct or indirect disposition, whether by sale, merger or otherwise, of all or any portion of the Purchased Assets to any Person other than Purchaser or its Affiliates, or (ii) disclose, directly or indirectly, to any Person (other than Purchaser and its Representatives) any confidential information concerning the Purchased Assets except as necessary to comply with its obligations pursuant to this Agreement.
- **(b)** The parties acknowledge that there may be no adequate remedy at Law for a breach of Section 5.3(a) and that money damages may not be an appropriate remedy for breach of such Section. Therefore, the parties agree that Purchaser has the right to injunctive relief and specific performance of Section 5.3(a) in the event of any breach of such Section in addition to any rights it may have for damages.
- **5.4** Commercially Reasonable Efforts. From the date of signing of this Agreement until the earlier of the Closing and the termination of this Agreement pursuant to Article 9, Seller and Purchaser shall cooperate and use their respective commercially reasonable efforts to fulfill as promptly as practicable the conditions precedent to the other party's obligations hereunder,

including securing as promptly as practicable any authorizations or consents required in connection with the transactions contemplated hereby. Notwithstanding anything to the contrary contained herein, neither Purchaser nor Seller shall be required to (i) agree to sell, divest, dispose of or hold separate any assets or businesses, or otherwise take or commit to take any action that could reasonably limit their freedom of action with respect to, or their ability to retain, one or more businesses, product lines or assets, or (ii) litigate, (or defend) against any Proceeding (including any proceeding seeking a temporary restraining order or preliminary injunction) challenging any of the transactions contemplated hereby as violative of any competition Law.

5.5 Ancillary Agreement. At the Closing, each of Seller and Purchaser shall execute and deliver the Registration Rights Agreement.

#### 5.6 Notification.

- (a) Between the date of this Agreement and the earlier of the Closing and the termination of this Agreement pursuant to Article 9, Seller shall promptly notify Purchaser in writing if it becomes aware of (i) any fact, circumstance, event or action the existence, occurrence or taking of which (A) has had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect, (B) has resulted in, or could reasonably be expected to cause, any representation or warranty made by Seller hereunder to be untrue or inaccurate in any material respect (without giving effect to any materiality or Material Adverse Effect qualification in such representation or warranty), or (C) has resulted in, or could reasonably be expected to result in, the failure of any of the conditions set forth in Article 6 to be satisfied; (ii) any notice or other communication from any Person alleging that the consent of such Person is or may be required in connection with the transactions contemplated by this Agreement and the Registration Rights Agreement; (iii) any notice or other communication from any Governmental Authority in connection with the transactions contemplated by this Agreement or the Registration Rights Agreement; and (iv) any Claim commenced or, to Seller's Knowledge, threatened against, relating to or involving or otherwise affecting the Purchased Assets or the Assumed Liabilities that, if pending on the date of this Agreement, would have been required to have been disclosed pursuant to Section 3.12 or that relates to the consummation of the transactions contemplated by this Agreement and the Registration Rights Agreement. No such notification shall affect the representations or warranties of Seller, or Purchaser's right to rely thereon, or the conditions to the obligations of Purchaser.
- **(b)** Purchaser's receipt of information pursuant to this Section 5.6 shall not operate as a waiver or otherwise affect any representation, warranty or agreement given or made by Seller in this Agreement or the Registration Rights Agreement and shall not be deemed to amend or supplement the Seller Disclosure Schedules. Should any such fact or condition require any change to the Seller Disclosure Schedule, Seller shall promptly deliver to Purchaser a supplement to the Seller Disclosure Schedule specifying such change. Such delivery shall not affect any rights of Purchaser under this Agreement; provided that to the extent such update relates to a matter that occurred after the execution of this Agreement (and that should not have otherwise been set forth on the Schedules as of the execution of this Agreement) that results in any breach of any representation or warranty of Seller that but for this Section 5.6 would entitle Purchaser to not consummate the Closing (a "Termination Update"), and, to the extent such breach is not cured by Seller prior to the Closing Date, Purchaser may terminate this Agreement

in accordance with Section 6.1(a). If Purchaser proceeds to consummate the Closing after receiving a Termination Update, Purchaser shall be deemed to have waived any and all rights or remedies against Seller to which Purchaser might otherwise be entitled in respect of a breach that would be cured by such Termination Update. For clarity, if Purchaser proceeds to consummate the Closing after receiving any update or information other than a Termination Update, Purchaser shall be entitled to exercise any rights or remedies pursuant to this Agreement in respect of a breach that would be cured by such update, including any rights or remedies under Article 8, and such update shall not be effective to cure and correct for any purpose any such breach of any representation, warranty or covenant which would have existed if Seller had not provided such update.

(c) Between the date of this Agreement and the Closing, Purchaser shall promptly notify Seller in writing if it becomes aware of any fact, circumstance, event or action the existence, occurrence or taking of which (i) has caused in, or would reasonably be expected to cause, any representation or warranty made by Purchaser hereunder to be untrue or inaccurate, or (ii) has caused, or would reasonably be expected to cause, any covenant or agreement of Purchaser hereunder not to be complied with. No such notification shall affect the representations or warranties of Purchaser, or Seller's right to rely thereon, or the conditions to the obligations of Seller.

# ARTICLE 6 CONDITIONS TO CLOSING

- **6.1 Conditions to the Obligations of Purchaser.** The obligation of Purchaser to effect the Closing is subject to the satisfaction (or waiver) on or prior to the Closing of the following conditions:
- (a) Representations and Warranties. No event or events shall have occurred since the date of this Agreement which, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect. The representations and warranties of Seller set forth in Article 3 (without giving effect to any supplement to the Seller Disclosure Schedule pursuant to Section 5.6(b)) shall be true and correct in all material respects as of the date of this Agreement to the extent such representations and warranties are not qualified by materiality or Material Adverse Effect and in all respects to the extent such representations and warranties are so qualified, and shall be true and correct in all material respects as of the date of Closing to the extent such representations and warranties are not qualified by materiality or Material Adverse Effect and in all respects to the extent such representations and warranties are so qualified, as though made on and as of the Closing (except to the extent expressly made as of an earlier date, in which case as of the earlier date).
- **(b)** <u>Covenants</u>. Seller shall have performed and complied in all material respects with all of its covenants contained in Article 5 at or before the Closing (to the extent that such covenants require performance by Seller at or before the Closing).
  - (c) Closing Deliverables. At the Closing, Seller shall have delivered to Purchaser the following:

- (i) A duly executed Assignment and Assumption Agreement, in the form attached hereto as Exhibit A;
- (ii) A duly executed Registration Rights Agreement, in the form attached hereto as Exhibit D;
- (iii) A duly executed Patent Assignment in the form attached hereto as Exhibit B;
- (iv) Letters addressed to KP Pharmaceutical Technology, Inc., Sai Advantium Pharma Limited and MPI Research, Inc. informing them that Purchaser is the new owner of the SB939 API, the histology slides and any information related to SB939; and
  - (v) The IND Letter, executed by a duly authorized officer of Seller.
- (d) <u>Consents</u>. Any consents, approvals or filings listed in Seller Disclosure Schedules with respect to the representations of Seller in Section 3.4, shall have been obtained and shall be in full force and effect, except to the extent the failure to obtain any such consent would not, in the reasonable judgment of Purchaser, be material to the Purchased Assets or Purchaser.
- (e) <u>Seller Shareholder Approval</u>. The Acquisition contemplated by this Agreement shall have received the requisite approval of the Seller's shareholders.
- (f) <u>Certificate</u>. Purchaser shall have received a certificate, signed by a duly authorized officer of Seller and dated the Closing Date, to the effect that the conditions set forth in Sections 6.1(a) and 6.1(b) have been satisfied.
- **(g)** No Prohibition. No temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Acquisition shall have been issued by any court of competent jurisdiction and remain in effect.
- **6.2 Conditions to the Obligations of Seller.** The obligation of Seller to effect the Closing is subject to the satisfaction (or waiver) prior to the Closing of the following conditions:
- (a) Representations and Warranties. The representations and warranties of Purchaser set forth in Article 4 shall be true and correct in all material respects as of the date of this Agreement to the extent such representations and warranties are not qualified by materiality or Material Adverse Effect and in all respects to the extent such representations and warranties are so qualified, and shall be true and correct in all material respects as of the date of Closing to the extent such representations and warranties are not qualified by materiality or Material Adverse Effect and in all respects to the extent such representations and warranties are so qualified, as though made on and as of the Closing (except to the extent expressly made as of an earlier date, in which case as of the earlier date).
- **(b)** Covenants. Purchaser shall have performed and complied with all of its covenants contained in Article 5 at or before the Closing (to the extent that such covenants require performance by Purchaser at or before the Closing).

- (c) <u>Closing Deliverables</u>. Purchaser shall have delivered to Seller the following:
  - (i) A duly executed Assignment and Assumption Agreement, in the form attached hereto as Exhibit A;
  - (ii) A duly executed Registration Rights Agreement, in the form attached hereto as Exhibit D;
  - (iii) The IND Acknowledgment Letter, executed by a duly authorized officer of Purchaser; and
  - (iv) Share certificates bearing appropriate legends representing the Closing Stock Payment.
- (d) <u>Consents</u>. Any consents or approvals required by Purchaser to consummate the Acquisition shall have been obtained and shall be in full force and effect, except to the extent the failure to obtain any such consent does not have a material adverse effect on the aggregate benefits to be derived by Seller from the transactions contemplated by this Agreement.
- (e) <u>Certificate</u>. Seller shall have received a certificate, signed by a duly authorized officer of Purchaser and dated the Closing Date, to the effect that the conditions set forth in Sections 6.2(a) and 6.2(b) have been satisfied.
- (f) No Prohibition. No temporary restraining order, preliminary or permanent injunction or other order preventing the consummation of the Acquisition shall have been issued by any court of competent jurisdiction and remain in effect.

# ARTICLE 7 ADDITIONAL COVENANTS

7.1 Further Assurances. Seller hereby agrees, without further consideration, to execute and deliver following the Closing such other instruments of transfer and take such other action as Purchaser or its counsel may reasonably request in order to put Purchaser in possession of, and to vest in Purchaser, good, valid and unencumbered title to, the Purchased Assets in accordance with this Agreement. In addition to the foregoing, Seller shall execute and deliver, and shall cause its Subsidiaries to execute and deliver as applicable, to Purchaser such documentation as shall be reasonably requested and approved by Purchaser, including preparing powers of attorney, the filing of assignments, agreements, documents and instruments, and preparing assignments in substantially the forms as approved by Purchaser, in order to transfer to Purchaser, and put Purchaser in possession of and to vest in Purchaser good, valid and unencumbered title to, any Program Patents in any jurisdiction.

#### 7.2 Seller's Non-Compete.

(a) Without the express prior written consent of Purchaser, neither Seller nor any of its Subsidiaries shall, at any time during the period commencing on the Closing Date and ending on the fourth (4th) anniversary thereof, directly or indirectly, itself, or with, through or on

behalf of a Third Party, Develop, manufacture, commercialize or otherwise Exploit any small molecule compound the primary mechanism of action of which is selective and specific inhibition of histone deacetylase (HDAC) (each such compound, a "Competing Compound," and such activities with respect to any Competing Compound, a "Competing Business"); provided, however, that this Section 7.2(a) shall not be construed to prohibit or restrict any Third Party acquiror of Seller (a "Third Party Acquiror"), whether by merger, sale of stock, sale of assets or otherwise (a "Change of Control Transaction"), or any of such Third Party Acquiror or any of its affiliated companies, from engaging in a Competing Business, if the applicable Competing Compound is: (i) controlled by the Third Party Acquiror or any of its affiliated companies prior to consummation of such Change of Control Transaction; (ii) acquired (whether by in-license or otherwise) by such Third Party Acquiror or any of its affiliated companies after consummation of such Change of Control Transaction; or (iii) developed internally by such Third Party Acquiror or any of its affiliated companies, either before or after consummation of such Change of Control Transaction, without the use of or reference to Confidential Information of Purchaser.

- (b) Seller hereby acknowledges and agrees that in the event of any breach of Section 7.2(a) by Seller, Purchaser may suffer an irreparable injury such that no remedy at law would adequately protect or appropriately compensate Purchaser for such injury. Accordingly, Seller agrees that Purchaser may seek to enforce Section 7.2(a) by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that Purchaser may have for a breach of Section 7.2(a). In the event that the covenant set forth in Section 7.2(a) shall ever be deemed to exceed the time, geographic scope or other limitations permitted by applicable Law in any jurisdiction, then any court is expressly empowered to reform such covenant, and such covenant shall be deemed reformed, in such jurisdiction to the maximum time, geographic, product or service or other limitations permitted by applicable Law. Notwithstanding anything to the contrary in this Agreement, nothing in this Agreement shall be construed so as to preclude Seller or any of its Subsidiaries from holding, purchasing or otherwise acquiring up to (but not more than) five percent (5%) of any class of securities of any Person engaged in the development or commercialization of Competing Compounds or products containing the same if such securities are listed on any national or regional securities exchange or have been registered under Section 12(g) of the Exchange Act.
- **7.3 Patent Assignment.** Promptly following the Closing, Purchaser shall file such patent assignments with the U.S. Patent and Trademark Office and with foreign patent offices as are necessary to record the assignment of the Program Patents to Purchaser, at Purchaser's expense.
- **7.4 Public Announcements.** Notwithstanding anything to the contrary contained herein, except as may be required to comply with the requirements of any applicable Law and the rules and regulations of any stock exchange upon which the securities of one of the parties is listed, from and after the date hereof, no press release or similar public announcement or communication shall be made or caused to be made by either party and/or any of such party's Affiliates relating to this Agreement or the transactions contemplated hereby unless specifically approved in advance by the other party, such consent not to be unreasonably withheld; provided, however, that: (a) the parties may jointly issue one or more press release(s) announcing the consummation of the transactions contemplated by this Agreement; (b) either party may issue such press releases, public announcements or communications or make such SEC filings as it

determines are reasonably necessary to comply with applicable Law (including disclosure requirements of the SEC) or with the requirements of any stock exchange on which securities issued by a party or its Affiliates are traded; and (c) Seller may communicate with its shareholders regarding this Agreement and the transactions contemplated hereby as may be required by applicable Law or Seller's organizational documents or with respect to payments hereunder or Article 8.

7.5 Confidentiality. The provisions of that certain Confidentiality Agreement dated February 29, 2012, by and between Purchaser and Seller (the "Confidentiality Agreement") are hereby incorporated herein and shall remain binding and in full force and effect; provided, however, that all obligations of the Purchaser under the Confidentiality Agreement with respect to the Purchased Assets shall terminate simultaneously with the Closing. Except as otherwise provided herein or in the other Transaction Documents, Seller shall treat after the date hereof as strictly confidential all nonpublic, confidential or proprietary information concerning the Purchased Assets ("Confidential Information") and such shall be the Confidential Information of Purchaser; provided, however, that the publication of those pending or in-process publications set forth on Schedule 7.5 and relating to the Seller Compounds of which Seller notified Purchaser prior to the date of this Agreement shall not constitute a breach of this Section 7.5; and provided, further, that the foregoing obligations shall not apply to (a) any information which was or comes into the public domain through no breach of this Agreement by Seller, (b) any information in the possession of any Third Party Acquiror prior to a Change of Control Transaction, other than as a result of disclosure by Seller, (c) any information that is independently developed or discovered by any Third Party Acquiror without reference to information concerning the Purchased Assets that was in Seller's possession on the Closing Date, (d) is rightfully communicated to any Third Party Acquiror by another Third Party, free and clear of any obligation of confidence, or (e) is or was communicated by the Purchaser to an unaffiliated Third Party free of any obligation of confidence. In addition, Seller shall not be prohibited from disclosing any portion of the Confidential Information that Seller is required to disclose by judicial or administrative process or, in the opinion of legal counsel, by other

**7.6 Expenses.** Each of the Parties shall bear its own expenses incurred in connection with the preparation, execution and performance of this Agreement and the Acquisition, including all fees and expenses of its Representatives.

#### 7.7 Transfer of Purchased Assets.

(a) With respect to (i) documented Clinical Data and Program Know-How in Seller's possession and control, (ii) Patent Files and (iii) Inventory, Seller shall transfer and deliver all of the aforementioned items, promptly following the Closing Date, as may be requested by Purchaser and at Purchaser's expense for shipping and handling, to the locations, and in accordance with the instructions, specified by Purchaser. Purchaser acknowledges that all Clinical Data and Program Know-How will be provided as paper files that Seller has Provided Purchaser with electronic courtesy copies of Clinical Data and that Seller is not obligated to provide any additional electronic documents to Purchaser relating to Clinical Data or Program Know-How.

- (b) Promptly after the Closing Date, Seller shall (i) send letters (in form and substance satisfactory to Purchaser) to the FDA and other Regulatory Authorities indicating that the Regulatory Materials are transferred to Purchaser and that Purchaser is the new owner of the Regulatory Materials as of the Closing Date, and (ii) provide to Purchaser a copy of said letters. Promptly after the Closing Date, the parties will cooperate in transferring the Regulatory Materials to Purchaser. The target date for the transfer shall be agreed upon by the parties. Within twenty (20) days after the Closing Date, Seller will forward to Purchaser a complete copy of the Regulatory Materials for the Program Compounds, as well as copies of all correspondence with, and periodic and other reports (including adverse event reports and the underlying data) to, Regulatory Authorities with respect to the Program Compounds or Regulatory Materials. Until the Regulatory Materials have been transferred to Purchaser, Seller shall be responsible for maintaining them. After such transfer, Purchaser will assume all responsibility for the Regulatory Materials, at Purchaser's sole cost and expense.
- (c) Prior to the Closing, each party shall cooperate with the other in making and maintaining all regulatory filings that may be necessary in connection with the execution, delivery and performance of this Agreement or the Transaction Documents.
- 7.8 Communication With Agencies. Until the Regulatory Materials are transferred to Purchaser, Seller shall have responsibility for all communications with the FDA relating to the Program Compounds, and Seller will promptly provide Purchaser with copies of all communications to or from the FDA with respect to the Program Compounds and/or the manufacture thereof. After such transfer has been completed, Purchaser shall have responsibility for all such communications. Seller shall promptly provide Purchaser with copies of any communications or contacts it sends to or receives from any other Governmental Authority concerning the Program Compounds.

### 7.9 Adverse Experience Reporting.

- (a) Until the Regulatory Materials are transferred to Purchaser, Seller shall be responsible for the adverse experience and safety reporting for the Products in compliance with the requirements of applicable Law (including Healthcare Laws). After the Regulatory Materials are transferred to Purchaser, Purchaser shall assume such responsibility.
- **(b)** Until the Regulatory Materials are transferred to Purchaser, Seller shall be responsible for (i) maintaining the global safety database for the Program Compounds, (ii) monitoring of all clinical experiences for the Program Compounds and (iii) safety monitoring, pharmacovigilance surveillance, compliance and filing of all required safety reports to Regulatory Authorities, including without limitation annual safety reports, as and to the extent required by applicable Law (including Healthcare Laws) for any study conducted by or for Seller with respect to the Program Compounds.
- **7.10 Assistance in Proceedings.** For a period of forty-five (45) days after the Closing Date, Seller will cooperate with Purchaser and its counsel in the contest or defense of, and make available its personnel and provide any testimony and access to its Books and Records in connection with, any proceeding involving or relating to (a) any contemplated transaction or (b) any action, activity, circumstance, condition, conduct, event, fact, failure to act, incident,

occurrence, plan, practice, situation, status or transaction on or before the Closing Date involving Seller or the Purchased Assets; in each case, at Purchaser's sole expense, except to the extent that Seller is expressly obligated to provide any such requested cooperation or assistance by the express terms of this Agreement (other than this Section 7.10).

# ARTICLE 8 SURVIVAL; INDEMNIFICATION

#### 8.1 Survival.

- (a) The representations, warranties, pre-Closing covenants and pre-Closing agreements of Seller and Purchaser contained in this Agreement, the Seller Disclosure Schedule, the certificates delivered pursuant to Section 6.1(f) and Section 6.2(e) and the Transaction Documents, and the parties' indemnification obligations pursuant to Section 8.2(a) and Section 8.3(a) shall survive the Closing and shall expire upon the expiration of twelve (12) months after the Closing Date, except that the representations and warranties contained in Section 3.1 (Organization and Qualification), Section 3.2 (Corporate Authorization), Section 3.14 (No Finder), Section 3.18 (Taxes), Section 4.1 (Organization and Qualification) and Section 4.2 (Corporate Authorization) (collectively, the "Fundamental Representations") and the parties' indemnification obligations pursuant to Section 8.2(a) and Section 8.3(a) with respect to the Fundamental Representations, shall expire on the expiration of twenty-four (24) months after the Closing Date; *provided, however*; that such indemnification obligations shall not terminate with respect to any item as to which an Indemnified Party shall have, before the termination of such applicable period, made a Claim by delivering a Notice of Claim in accordance with this Agreement to the Indemnifying Party, which obligations with respect to such Notice of Claim shall survive until all such Claims have been resolved. The right to indemnification based upon the representations and warranties, covenants and obligations contained in this Agreement shall not be affected by any investigation (including any environmental investigation or assessment) conducted with respect to, or any Knowledge acquired (or capable of being acquired) at any time (except as set forth in this Agreement, the Seller Disclosure Schedules), whether before or after the execution and delivery of this Agreement or the Closing Date.
- (b) All post-Closing covenants and post-Closing agreements made by Seller or Purchaser in or pursuant to this Agreement or any other Transaction Document shall survive the Closing and remain in full force and effect to give effect to their respective terms, unless otherwise expressly provided for by their terms.
- **8.2 Indemnification by Seller.** Subject to the limitations set forth in Section 8.5(a), Seller shall indemnify, defend, save and hold Purchaser and its Affiliates and their respective Representatives (collectively, "Purchaser Indemnitees") harmless from and against all Damages (but net of the amount of (x) any insurance proceeds realized by such Purchaser Indemnitees from insurance policies with respect to such matters and (y) any recoveries by any Purchaser Indemnitees from any Third Party, without duplication) imposed on, sustained, incurred or suffered by, or asserted against, any of the Purchaser Indemnitees, whether in respect of Third Party Claims, claims between the parties hereto, resulting or arising from:

- (a) Seller's breach of any representation or warranty contained in this Agreement or the Transaction Documents to which Seller is a party;
- (b) Seller's breach or nonfulfillment of any covenant, obligation or agreement made by Seller in or pursuant to this Agreement or in any Transaction Document to which Seller is a party; and
  - (c) Seller's failure to satisfy any Liabilities relating to any Excluded Asset and any of its obligations relating to any of the Retained Liabilities.
- **8.3 Indemnification by Purchaser.** Subject to the limitations set forth in Section 8.5(b), Purchaser shall indemnify, defend, save and hold Seller and its Representatives (collectively, "Seller Indemnitees") harmless from and against any and all Damages (but net of the amount of (x) any insurance proceeds realized by such Seller Indemnitees from insurance policies with respect to such matters and (y) any recoveries by any Seller Indemnitees from any third party, without duplication) imposed on, sustained, incurred or suffered by, or asserted against, any of the Seller Indemnitees, whether in respect of Third Party Claims or claims between the parties hereto, resulting or arising from:
  - (a) Purchaser's breach of any representation or warranty contained in this Agreement, the Transaction Documents to which Purchaser is a party;
- **(b)** Purchaser's breach or nonfulfillment of any covenant, obligation or agreement made by Purchaser in or pursuant to this Agreement or in any Transaction Document to which Purchaser is a party; or
- (c) Purchaser's failure to fully assume and discharge any Liabilities relating to any Assumed Liabilities and any of its obligations relating to any of the Assumed Liabilities.

#### 8.4 Notice of Claims.

- (a) If (i) any Purchaser Indemnitee or Seller Indemnitee (an "Indemnified Party.") believes that it has suffered or incurred or will suffer or incur any Damages for which it is entitled to indemnification under this Article 8, or (ii) any Claim is instituted by or against a third party with respect to which any Indemnified Party intends to claim any Damages, such Indemnified Party shall so notify the party or parties from whom indemnification is being claimed (the "Indemnifying Party.") with reasonable promptness and reasonable particularity in light of the circumstances then existing (the "Notice of Claim"). The Notice of Claim delivered pursuant to this Section 8.4 shall describe the Damages and/or Claim in reasonable detail and shall indicate the amount of the Damages that have been or may be suffered by the Indemnified Party. The failure of an Indemnified Party to give any notice required by this Section shall not affect any of such Party's rights under this Article 8 or otherwise except and to the extent that such failure is prejudicial to the rights or obligations of the Indemnifying Party.
- **(b)** Should any Claim be made or suit or proceeding be instituted against any Purchaser Indemnitee, which, if prosecuted successfully, would be a matter for which such Purchaser Indemnitee is entitled to indemnification pursuant to Section 8.2 (a "Third Party Claim"), Purchaser shall notify Seller within twenty (20) Business Days after Purchaser's receipt

of notification of the Third Party Claim, including a description of the factual basis of the Third Party Claim and shall indicate the amount of the Damages. Thereafter, Purchaser shall promptly deliver to Seller copies of all notices and documents (including court papers) received by Purchaser relating to the Third Party Claim. Seller shall be entitled to participate in the defense of the Third-Party Claim and, if it so chooses, to assume the defense thereof at its own expense with counsel selected by such Seller and reasonably acceptable to Purchaser, if Seller gives written notice to Purchaser of its election to assume the defense of such Third Party Claim within ten (10) Business Days after Seller receives notice of such claim from Purchaser; provided, however, that Seller shall not be entitled to assume the defense of any Claim related to, either directly or indirectly, (i) the Program Technology or any intellectual property acquired by Purchaser in connection with this Agreement, (ii) criminal liability, (iii) in which equitable relief is sought against a Purchaser Indemnitee or (iv) with respect to which the potential Damages could be reasonably expected to exceed the Indemnification Cap. If Seller assumes the defense of a Third-Party Claim, Seller may not consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim without the prior written consent of the Purchaser Indemnitee (not to be unreasonably withheld or delayed) if (i) such judgment or settlement does not include as an unconditional term thereof the giving by each claimant or plaintiff to each Purchaser Indemnitee of a full release from all liability in respect to such Third Party Claim, (ii) such judgment or settlement would result in the finding or admission of any violation of Law by Purchaser or the rights of any person, (iii) the sole relief provided is anything other than monetary damages or (iv) as a result of such consent or settlement, injunctive or other equitable relief would be imposed against the Purchaser Indemnitee. Purchaser will cooperate, at the expense of Seller, as Seller may reasonably request in investigating, defending and, subject to the terms set forth above, settling such Third Party Claim. If Seller elects not to defend a Third-Party Claim, is not permitted to defend such Third Party Claim or fails to notify Purchaser of its election as herein provided, Purchaser may pay, compromise, settle or defend such Third-Party Claim at the sole cost and expense of Seller if Seller is determined to be liable to Purchaser hereunder, provided, however, that no such payment in compromise or settlement of, or other compromise or settlement of, may be effected by Purchaser without Seller's consent (which shall not be unreasonably withheld or delayed). In any event, Seller shall be entitled, at its expense, to participate in any defense of such Third Party Claim with the consent of Purchaser which shall not be unreasonably withheld.

#### 8.5 Limitation of Claims.

(a) The Liability of Seller for indemnifiable Damages pursuant to Section 8.2(a) shall not be payable unless and until the aggregate amount of all Damages suffered or incurred by the Purchaser Indemnitees collectively exceeds one hundred thousand U.S. dollars (\$100,000); thereafter, a Purchaser Indemnitee shall be entitled to seek compensation for Damages, and Seller shall be responsible for the payment of Damages to the extent in excess of one hundred thousand U.S. dollars (\$100,000). The aggregate liability of Seller for indemnifiable Damages pursuant to Section 8.2(a) and Section 8.2(b) hereof shall in no event exceed ten percent (10%) of the Transaction Value of the Closing Stock Payment and all Milestone Payments and Contingent Earnouts actually made to Seller pursuant to Section 2.6 (with the Milestone Stock Payment valued based upon the Transaction Value of the Milestone Stock Payment) as of the date of the final non-appealable determination of such Damages (the "Indemnification Cap"). Notwithstanding the foregoing, the limitations on Damages set forth in

this Section 8.5 shall not apply to any Damages arising from any fraud by Seller or from Seller's breach of Section 7.2. Purchaser shall have the right to withhold and subject to resolution of any claim for indemnification in accordance with this Agreement, set off, against any unpaid Milestone Payment or Contingent Earnouts, Damages up to the Indemnification Cap (with any set-off against the Milestone Stock Payment valued based upon the Transaction Value of the Milestone Stock Payment) (the "Set-Off Right"). In the event that Seller delivers a Notice of Claim seeking Damages in excess of the Indemnification Cap and the Indemnification Cap subsequently increases to a greater value as a result of the occurrence of a Milestone and the related obligation of a Milestone Payment or Contingent Earnouts, Purchaser shall thereafter be entitled to received additional Damages or set off Damages in the amount of the subsequently increased Indemnification Cap.

- **(b)** The aggregate liability of Purchaser for indemnifiable Damages pursuant to Section 8.3(a) hereof shall in no event exceed the Transaction Value of the Closing Stock Payment and any Milestone Stock Payment if actually paid and delivered.
- (c) The right to indemnification under this Article 8 and the Set-Off Right shall constitute the sole and exclusive monetary remedy of the Purchaser Indemnitees and the Seller Indemnitees for Damages or otherwise arising from or in connection with this Agreement, including pursuant to Section 8.2 and the Transaction Documents or otherwise with respect to any of the transactions contemplated hereby.
- **8.6 Objections to Claims.** In case Seller shall object in writing to any claim or claims by a Purchaser Indemnitee made in any Notice of Claim, Purchaser Indemnitee shall have twenty (20) Business Days following the receipt of such written objection to respond in a written statement to the objection of Seller. If after such twenty (20) Business Day period there remains a dispute as to any claims, Seller and Purchaser shall attempt in good faith for thirty (30) Business Days to agree upon the rights of the respective parties with respect to each of such claims. If Seller and Purchaser should so agree, a memorandum setting forth such agreement shall be prepared by Purchaser and signed by Purchaser and Seller.
- **8.7 Resolution of Conflicts.** If no agreement can be reached after good faith negotiation between the parties pursuant to Section 8.6, Purchaser or Seller may initiate formal legal action pursuant to Section 10.6 of this Agreement to resolve such dispute.
  - 8.8 Survival of Indemnification Claims. The indemnification obligations set forth in this Article 8 shall survive the Closing.
- **8.9** Tax Effect of Indemnification Payments. All indemnity payments made by Seller to Purchaser Indemnitees, or by Purchaser to Seller Indemnitees, pursuant to this Agreement shall be treated for all Tax purposes as adjustments to the Purchase Price.

# ARTICLE 9 TERMINATION

**9.1 Termination.** This Agreement may be terminated at any time prior to the Closing:

- (a) by Purchaser by written notice to Seller if Purchaser is not then in material breach of any provision of this Agreement and:
- (i) there has been a breach, inaccuracy in or failure to perform any representation, warranty, covenant or agreement made by Seller pursuant to this Agreement that would give rise to the failure of any of the conditions specified in Section 6.1(a) or Section 6.1(b) and such breach, inaccuracy or failure has not been cured by Seller within twenty (20) days of Seller's receipt of written notice of such breach from Purchaser; or
- (ii) any of the conditions set forth in Sections 6.1(c)(i), 6.1(e), 6.1(f) or 6.1(g) shall not have been fulfilled within one (1) month after the date of this Agreement;
  - (b) by Seller by written notice to Purchaser if:
- (i) Seller is not then in material breach of any provision of this Agreement and there has been a breach, inaccuracy in or failure to perform any representation, warranty, covenant or agreement made by Purchaser pursuant to this Agreement that would give rise to the failure of any of the conditions specified in Section 6.2(a) or Section 6.2(b) and such breach, inaccuracy or failure has not been cured by Purchaser within twenty (20) days of Purchaser's receipt of written notice of such breach from Seller; or
- (ii) any of the conditions set forth in Section 6.2(c)(i), 6.2(e) or 6.2(f) shall not have been fulfilled within one (1) month after the date of this Agreement; or
- (c) by Purchaser or Seller if the Transaction has not been consummated within two (2) months after the date of this Agreement; provided, however, that a party shall not be permitted to terminate this Agreement pursuant to this Section 9.1(c) if the failure to consummate the Transaction within such period is attributable to a failure on the part of such party to perform any covenant in this Agreement required to be performed by such party at or prior to the Closing; or
- (d) by Purchaser or Seller in the event that a court of competent jurisdiction shall have issued a final and nonappealable Order having the effect of permanently restraining, enjoining or otherwise prohibiting the Transaction.
- **9.2 Effect of Termination.** In the event of the termination of this Agreement in accordance with Section 9.1, this Agreement shall thereafter become void and have no effect, and no party hereto shall have any liability to the other party hereto or their respective Affiliates, or their respective directors, officers or employees, except for the obligations of the parties hereto contained in this Section 9.2 and in Article 10 (and any related definitional provisions set forth in Article 1), and except that nothing in this Section 9.2 shall relieve any party from liability for any breach of this Agreement that arose prior to such termination, for which liability the provisions of Article 8 shall remain in effect in accordance with the provisions and limitations of such Article.

#### ARTICLE 10 GENERAL

10.1 Notices. All notices or other communications required or permitted to be given hereunder shall be in writing and shall be delivered by hand or sent by facsimile or sent, postage prepaid, by registered, certified or express mail or overnight courier service and shall be deemed given when so delivered by hand or facsimile, or if mailed, three (3) Business Days after mailing (one Business Day in the case of express mail or overnight courier service), to the parties at the following addresses or facsimiles (or at such other address or facsimile for a party as shall be specified in a notice given in accordance with this Section 10.1):

#### (a) If to Purchaser:

MEI Pharma, Inc. 11975 El Camino Real, Suite 101 San Diego, California 92130 Attention: Chief Executive Officer Telephone: +1 (858) 792-6300 Fax: +1 (858) 792-5406

With a simultaneous copy to:

Morgan, Lewis & Bockius LLP 101 Park Avenue, 40th Floor New York, NY 10178 Attention: Steven A. Navarro Telephone: +1 (212) 309-6147 Fax: +1 (212) 309-6001

### (b) If to Seller:

S\*Bio Pte Ltd. c/o EDBI 250 North Bridge Rd #28-00 Raffles City Tower Singapore 179101 Attention: Heng Tong Choo Telephone: +65 6832 6326 Fax: +65 6832 6838

With a simultaneous copy to:

Cooley LLP 4401 Eastgate Mall San Diego, CA 92121-1909 Attention: Jane K. Adams Telephone: +1 (858) 550-6000 Fax: +1 (858) 550-6420

- **10.2** Severability. If any provision of this Agreement for any reason shall be held to be illegal, invalid or unenforceable, such illegality shall not affect any other provision of this Agreement, but this Agreement shall be construed as if such illegal, invalid or unenforceable provision had never been included herein.
- 10.3 Assignment; Binding Effect. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be transferred, conveyed or assigned, in whole or in part, by operation of Law or otherwise, by either party without the prior written consent of the other party, except that: (a) Purchaser may assign, in its sole discretion, (i) any or all of its rights, interests and obligations under this Agreement to any of its Subsidiaries or Affiliates, but no such assignment shall relieve Purchaser of any of its obligations hereunder, or (ii) provided that the terms and conditions of Section 2.8(b), if applicable, are satisfied, this Agreement in whole to a single third party in connection with the transfer or sale of all or substantially all of Purchaser's business related to the Purchased Assets to such third party, whether by merger, sale of stock, sale of assets or otherwise; and (b) Seller may assign, in its sole discretion, this Agreement in whole to a single third party in connection with the transfer or sale of all or substantially all of Seller's business related to the Excluded Assets to such third party, whether by merger, sale of stock, sale of assets or otherwise. Any assignment not in accordance with the foregoing shall be void. Subject to the preceding sentences, this Agreement will be binding upon, inure to the benefit of and be enforceable by, the parties and their respective permitted successors and assigns.
- **10.4** No Third-Party Beneficiaries. This Agreement is for the sole benefit of the Parties and their successors and permitted assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the Parties and such successors and assigns, any legal or equitable rights hereunder.
- 10.5 Incorporation of Exhibits. All Exhibits and Schedules attached hereto and referred to herein are hereby incorporated herein and made a part of this Agreement for all purposes as if fully set forth herein.
- 10.6 Governing Law. THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF CALIFORNIA OTHER THAN CONFLICT OF LAWS PRINCIPLES THEREOF DIRECTING THE APPLICATION OF ANY LAW OTHER THAN THAT OF CALIFORNIA. COURTS WITHIN THE STATE OF CALIFORNIA (LOCATED WITHIN SAN DIEGO COUNTY) WILL HAVE JURISDICTION OVER ALL DISPUTES BETWEEN THE PARTIES HERETO ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE AGREEMENTS, INSTRUMENTS AND DOCUMENTS CONTEMPLATED HEREBY. THE PARTIES HEREBY CONSENT TO AND AGREE TO SUBMIT TO THE JURISDICTION OF SUCH COURTS. EACH OF THE PARTIES HERETO WAIVES, AND AGREES NOT TO ASSERT IN ANY SUCH DISPUTE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY CLAIM THAT (I) SUCH PARTY IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF SUCH COURTS, (II) SUCH PARTY AND SUCH PARTY'S PROPERTY IS IMMUNE FROM ANY LEGAL PROCESS ISSUED BY SUCH COURTS OR (III) ANY LITIGATION COMMENCED IN SUCH COURTS IS BROUGHT IN AN INCONVENIENT FORUM.

- **10.7 Headings; Interpretation.** The descriptive headings contained in this Agreement are included for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement.
- 10.8 Counterparts; Facsimiles. This Agreement may be executed and delivered (including by electronic or facsimile transmission) in two or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.
- 10.9 Entire Agreement. This Agreement (including the Schedules and Exhibits attached hereto), the Transaction Documents executed in connection with the consummation of the Acquisition, and the Confidentiality Agreement (as amended by this Agreement), contain the entire agreement between the Parties with respect to the subject matter hereof and related transactions and supersede all prior agreements, written or oral, with respect thereto.
- 10.10 Disclosure Schedules. The representations and warranties contained in Article 3 of this Agreement are subject to (a) the exceptions and disclosures set forth in the part of the Seller Disclosure Schedule corresponding to the particular Section of Article 3 in which such representation and warranty appears; (b) any exceptions or disclosures explicitly cross-referenced in such part of the Seller Disclosure Schedule by reference to another part of the Seller Disclosure Schedule; and (c) any exception or disclosure set forth in any other part of the Seller Disclosure Schedule to the extent it is reasonably apparent on its face and without further inquiry that such exception or disclosure is intended to qualify such representation and warranty. No reference to or disclosure of any item or other matter in the Seller Disclosure Schedule shall be construed as an admission or indication that such item or other matter is material (nor shall it establish a standard of materiality for any purpose whatsoever) or that such item or other matter is required to be referred to or disclosed in the Seller Disclosure Schedule. The information set forth in the Seller Disclosure Schedule is disclosed solely for the purposes of this Agreement, and no information set forth therein shall be deemed to be an admission by any party hereto to any third party of any matter whatsoever, including of any violation of Law or breach of any agreement. The Seller Disclosure Schedule and the information and disclosures contained therein are intended only to qualify and limit the representations, warranties and covenants of Seller contained in this Agreement. Nothing in the Seller Disclosure Schedule is intended to create any covenant. Matters reflected in the Seller Disclosure Schedule. Such additional matters are set forth for informational purposes and do not necessarily include other matters of a similar nature.
- 10.11 Specific Enforcement. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached or threatened to be breached and that an award of money damages would be inadequate in such event. Accordingly, it is acknowledged that the

Parties shall be entitled to equitable relief, without proof of actual damages, to enforce performance of this Agreement in accordance with its terms, including an Order for specific performance, to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, in addition to any other remedy under this Agreement. Each party further agrees that neither the other party nor any other Person shall be required to obtain, furnish or post any bond or similar instrument in connection with or as a condition to obtaining any remedy referred to in this Section 10.11, and each Party hereto irrevocably waives any right it may have to require the obtaining, furnishing or posting of any such bond or similar instrument.

10.12 Waivers and Amendments; Non-Contractual Remedies; Preservation of Remedies. This Agreement may be amended, superseded, canceled, renewed or extended only by a written instrument signed by all of the Parties. The provisions hereof may be waived only in writing signed by all of the Parties. No delay on the part of any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any waiver on the part of any Party of any such right, power or privilege, preclude any further exercise thereof or the exercise of any other such right, power or privilege. Except as otherwise provided herein, the rights and remedies herein provided are cumulative and are not exclusive of any rights or remedies that any Party may otherwise have at Law or in equity.

[Signatures appear on next page]

IN WITNESS WHEREOF, intending to be legally bound hereby, the Parties have caused this Agreement to be signed in their respective names by their duly authorized representatives as of the date first above written.

MEI PHARMA, INC.

By: /s/ Daniel P. Gold

Daniel P. Gold Name:

President & Chief Executive Officer Title:

S\*BIO PTE LTD.

By: /s/ Choo Heng Tong

Name: Choo Heng Tong SBIO Director

Title:

[SIGNATURE PAGE TO ASSET PURCHASE AGREEMENT]

## EXHIBIT A

## FORM OF ASSIGNMENT AND ASSUMPTION AGREEMENT

## **EXHIBIT B**

## FORM OF PATENT ASSIGNMENT

## EXHIBIT C

## PROGRAM PATENTS

## EXHIBIT D

# FORM OF REGISTRATION RIGHTS AGREEMENT

1.

**EXHIBIT E** 

## **EXHIBIT F**

## IND ACKNOWLEDGMENT LETTER

**EXHIBIT G** 

IND LETTER

Schedule 2.1(c)

## REGULATORY MATERIALS

Schedule 2.1(d)

INVENTORY

Schedule 2.9

Schedule 7.5

# S\*BIO PTE LTD.

# DISCLOSURE SCHEDULE

### Schedule 2.5: Technology Transfer Plan

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#### [\*CONFIDENTIAL\*]

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### Schedule 4.3.2: Essential Development Elements

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### Schedule 7.1: Existing Product and Compound Available for Transfer to Licensee

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# Schedule 7.3: Existing Product and Compound to be Retained by Licensor

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#### COMMON STOCK PURCHASE AGREEMENT

THIS COMMON STOCK PURCHASE AGREEMENT (this "Agreement") is entered into as of August 5, 2016, by and among MEI Pharma, Inc., a Delaware corporation (the "Company"), and Helsinn Investment Fund SA, a limited liability company organized under the laws of Luxembourg ("Purchaser").

WHEREAS, the Company desires to issue and sell to Purchaser up to Five Million Dollars (\$5,000,000) worth of shares (the "Shares") of common stock, par value \$0.00000002 per share, of the Company (the "Common Stock"), which Shares shall be authorized and issued in accordance with the terms of this Agreement (the "Common Stock Financing"); and

WHEREAS, subject to the terms and conditions set forth in this Agreement, Purchaser desires to purchase from the Company the Shares.

NOW, THEREFORE, in consideration of the mutual promises, representations, warranties, covenants and conditions set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

### 1. PURCHASE AND SALE

- 1.1 Sale and Issuance of Shares. In consideration of the representations, warranties and covenants set forth herein, and subject to the terms and conditions set forth in this Agreement, the Company shall issue and sell to Purchaser, and Purchaser shall purchase from the Company, the Shares free and clear of any liens, claims or encumbrances of any nature whatsoever other than limitations on the ability to freely resell the Shares as a result of the offering of such Shares hereunder not being registered under applicable securities laws.
- 1.2 Closing. The purchase and sale of the Shares shall take place remotely via the exchange of documents and signatures at 10:00 a.m. on August 16, 2016, or at such other time as the Company and Purchaser shall mutually agree (which time, date and place are referred to in this Agreement as the "Closing"). At the Closing, the Company shall instruct Computershare Trust Company, N.A. (the "Transfer Agent") to register the issuance of the Shares (as defined below) via book entry, against delivery to the Company by Purchaser at the Closing of Five Million Dollars (\$5,000,000) (the "Closing Consideration"), payable in immediately available funds by wire transfer to an account or accounts designated by the Company. The "Closing Shares" shall mean that number of shares of Common Stock equal to Five Million (\$5,000,000) divided by the Bloomberg volume-weighted average price for a share of Common Stock on the NASDAQ Global Select Market during the ten trading day period beginning four trading days preceding the date hereof and ending on the fifth trading day hereafter, rounded to the nearest whole share.

#### 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

As of the date of the Closing (the "Closing Date"), the Company represents and warrants to Purchaser that, subject to exceptions and disclosures set forth in any part or subpart of the Company Disclosure Schedule corresponding to the particular Section or subsection of this Section 2, or any exceptions or disclosures set forth in any other part or subpart of the Company Disclosure Schedule to the extent it is reasonably apparent from the wording or any such exception or disclosure that such exception or disclosure is applicable to qualify such representation or warranty, and to the extent specifically referenced in the applicable representation or warranty, disclosures in the SEC Filings (as defined below) and the statements contained in this Section 2 are true, complete and correct (except that those statements which address matters only as of a particular date are true, correct and complete as of such date). The Company shall deliver an updated and current Company Disclosure Schedule prior to the Closing.

2.1 Organization and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as now conducted and as it is described in the SEC Filings. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would or would be reasonably expected to have, individually or in the aggregate, a material adverse effect on (i) the business, properties or financial condition of the Company, (ii) the Shares or (iii) the enforceability of this Agreement (a "Material Adverse Effect"); provided that none of the following shall be taken into account in determining whether there is a Material Adverse Effect: (a) any change in the market price or trading volume of the Company's stock; (b) any event, circumstance, change or effect in the industries in which the Company or its subsidiaries operates generally or the United States or European economy generally, financial markets or political conditions generally; (c) any act of terrorism, military action or war (whether or not declared), national or international calamity or similar event or any escalation or worsening thereof; (d) any event, circumstance, change or effect arising from or relating to any change in legal requirements or generally accepted accounting principles ("GAAP") (or interpretations of any legal requirements or GAAP); or (e) any change or effect attributable to the consummation of the transactions contemplated hereby, or the public announcement of the execution of, this Agreement (provided any such public announcement is not in breach of this Agreement); provided, in each case, that such effects do not, individually or in the aggregate, have a materially disproportionate adverse impact on the Company, taken as a whole, relative to any other "person" as such term is defined under Section 3

2.2 <u>Certificate of Incorporation and Bylaws</u>. The certificate of incorporation, bylaws and documents of similar substance (the "Governing Documents") of the Company and its subsidiaries that are on file with the United States Securities and Exchange Commission (the "SEC") are current, complete and correct copies thereof as in effect on the date hereof. The Governing Documents of the Company and its subsidiaries are in full force and effect. The Company and each subsidiary of the Company are in compliance with the terms of their respective Governing Documents.

### 2.3 Capitalization.

- (a) The authorized capital stock of the Company consists of 113,100,000 shares of capital stock, of which 113,000,000 shares are designated as Common Stock and 100,000 shares are designated as preferred stock, \$0.01 par value per share ("**Preferred Stock**"). As of the close of business on the date that is two Trading Days prior to the date of this Agreement, (i) 34,155,997 shares of Common Stock were issued and outstanding, all of which were validly issued and fully paid, nonassessable and free of preemptive rights; (ii) 5,063,612 shares of Common Stock were issuable (and such number was reserved for issuance) upon exercise of options to purchase Common Stock or as restricted stock units payable in Common Stock (the "**Options**") outstanding as of such date; (iii) 3,761,407 shares of Common Stock were issuable (and such number was reserved for issuance) upon exercise of warrants to purchase Common Stock (the "**Warrants**") outstanding as of such date; and (iv) no shares of Preferred Stock were issued and outstanding.
- (b) As of the close of business on the last Trading Day immediately preceding the date of this Agreement, except for (i) the Options and (ii) the Warrants, there were no options, warrants or other rights to acquire capital stock or other equity interests from the Company, or securities convertible into or exchangeable for such capital stock or other equity interests. Other than (A) shares of capital stock reserved for issuance as provided in this Section 2.3 and (B) options to purchase Common Stock or other equity awards issued in accordance with the Company's Amended and Restated 2008 Omnibus Equity Compensation Plan (the "Awards"), the Company has not issued any shares of its capital stock or other equity interests, or securities convertible into or exchangeable for such capital stock or other equity

interests except as set forth in its filings under the Securities Act of 1933, as amended ("Securities Act") and the Exchange Act. All outstanding shares of Common Stock and all shares of Common Stock subject to issuance upon exercise of the Options, the Awards and the Warrants, upon issuance prior to the Closing on the terms and conditions specified in the instruments pursuant to which they are issuable, will be duly authorized, validly issued, fully paid, nonassessable and free of preemptive rights. The Shares to be issued in connection with the Agreement, when issued as contemplated herein, will be duly authorized, validly issued, fully paid and nonassessable, will not be in violation of any preemptive rights and will be free and clear of all liens, charges, restrictions, claims, rights of first refusal and encumbrances except as set forth in this Agreement and the Company's Governing Documents. The issuance and sale of the Shares will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Purchaser) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities.

#### 2.4 Authorization; Enforceability.

- (a) The Company has all requisite corporate power and authority to execute, deliver and perform, as applicable, this Agreement and to issue and sell the Shares in accordance with the terms hereof.
- (b) All corporate action on the part of the Company and its officers and directors necessary for (i) the authorization, execution, delivery and performance of all obligations of the Company under this Agreement, (ii) the issuance and sale by the Company of the Shares hereunder and (iii) the listing of the Shares on the NASDAQ Global market, in each case have been taken. This Agreement constitutes a valid and legally binding obligation of the Company, enforceable in accordance with its terms, except as limited by applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally or by equitable principles (the "Equitable Exceptions"). No action on the part of the Company's stockholders is necessary for the authorization, execution, delivery or performance of the Company's obligations hereunder.

### 2.5 SEC Filings; Financial Statements.

- (a) The Company has timely filed with or furnished to the SEC all registration statements, prospectuses, forms, reports, definitive proxy statements, schedules and documents required to be filed by it under the Securities Act or the Exchange Act, as the case may be (collectively, the "SEC Filings"). Each SEC Filing, as amended or supplemented, if applicable, (i) as of its date, or, if amended, as of the date of the last such amendment, complied in all material respects with the applicable requirements of the Securities Act and the Exchange Act, as the case may be, and the rules and regulations of the SEC thereunder, applicable to such SEC Filing, and (ii) did not, at the time it was filed (or at the time it became effective in the case of registration statements), or, if amended, as of the date of the last such amendment, contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading.
- (b) Each of the consolidated financial statements (including, in each case, any notes thereto) contained in the SEC Filings, as amended, supplemented or restated, if applicable, was prepared in accordance with GAAP applied (except as may be indicated in the notes thereto and, in the case of unaudited quarterly financial statements, as permitted by the Form 10-Q under the Exchange Act) on a consistent basis throughout the periods indicated (except as may be indicated in the notes thereto), and each presented fairly, in all material respects, the consolidated financial position, results of operations and cash flows of the Company and the consolidated subsidiaries of the Company as of the respective dates

thereof and for the respective periods indicated therein (subject, in the case of unaudited quarterly financial statements, to normal year-end adjustments).

- (c) The Company and its subsidiaries have implemented and maintain a system of internal control over financial reporting (as required by Rule 13a-15(a) under the Exchange Act) that is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with GAAP for external purposes and includes policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP and to maintain accountability of assets, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company, and (iii) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on its financial statements, and such system of internal control over financial reporting is reasonably effective.
- (d) The Company has implemented and maintains disclosure controls and procedures (as defined in Rule 13a-15(d) of the Exchange Act) that are designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time frames specified by the SEC's rules and forms (and such disclosure controls and procedures are reasonably effective), and has disclosed, based on its most recent evaluation of its system of internal control over financial reporting prior to the date of this Agreement, to the Company's independent registered accountant and the audit committee of the Board of Directors (A) any significant deficiencies and material weaknesses to the Company's knowledge in the design or operation of its internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) and (B) to the Company's knowledge any fraud that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

## 2.6 No Conflict; Required Filings and Consents.

- (a) The execution and delivery of this Agreement by the Company does not, and the performance of this Agreement by the Company will not, (i) conflict with or violate any provision of the Governing Documents of the Company or its subsidiaries, (ii) materially conflict with or violate any law applicable to the Company or by which any property or asset of the Company is bound or affected or (iii) conflict with, or constitute a default (or an event which, with notice or lapse of time or both, would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any Material Contract (as defined below).
- (b) The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any federal, national, supranational, state, provincial, municipal, local or other government, governmental, regulatory or administrative authority, agency or commission or any court, tribunal, or judicial or arbitral body of competent jurisdiction ("Governmental Authority") or other Person in connection with the execution, delivery and performance by the Company of the issuance of the Shares, other than (i) (A) filings required by applicable Blue Sky Laws (as defined below), (B) the filing of a Notice of Sale of Securities on Form D with the SEC under Regulation D of the Securities Act, (C) the filing of any requisite notices and/or application(s) to the NASDAQ Global Select Market for the issuance and sale of the Shares and the listing of the Shares thereon in the time and manner required thereby, and (D) those that have been made or obtained prior to the date of this Agreement, or (ii) where failure to obtain such consents, approvals,

authorizations or permits, or to make such filings or notifications, would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect

- 2.7 Employees and Employee Matters. The Company has complied in all material respects with all federal, state and local laws relating to the hiring of employees, consultants and advisors and the employment of labor, including provisions thereof relating to wages, hours, equal opportunity, collective bargaining and the payment of social security and other taxes. The Company is not delinquent in material payments to any of its employees for any wages, salaries, commissions, bonuses or other direct compensation for any services performed by them to date or amounts required to be reimbursed to such employees or upon any termination of the employment of any such employees.
- 2.8 Material Contracts. Except as disclosed in the SEC Filings, neither the Company nor any of its assets, properties, businesses or operations is a party to, bound or affected by, or receives benefits under any contract which is a "material contract" (as such term is defined in Item 601(b)(10) of Regulation S-K of the SEC) (a "Material Contract"). Except as would not, individually or in the aggregate, be reasonably expected to have a Material Adverse Effect, (i) each Material Contract is valid and binding on the Company and, to the Company's knowledge, each other party thereto, and in full force and effect, (ii) each Material Contract is enforceable against the Company and, to the Company's knowledge, the other parties thereto in accordance with the terms thereof, except as such enforceability may be limited by the Equitable Exceptions and (iii) the Company has not received written notice of any violation or default under (or any condition which with the passage of time or the giving of notice would cause such a violation of or default under) any Material Contract.
- **2.9 <u>Litigation</u>**. There is no material action, suit or proceeding pending or, to the Company's knowledge, currently threatened against the Company or against any director, officer or employee of the Company. The Company is not a party to, or subject to the provisions of, any order, writ, injunction, judgment or decree of any court or government agency or instrumentality. There is no material action, suit, proceeding or investigation by the Company currently pending or that the Company intends to initiate.
- 2.10 Taxes. Except as would not reasonably be expected to have a Material Adverse Effect, (i) all federal, state and local tax returns, reports and declarations of the Company required by law to be filed have been duly filed, (ii) all taxes and other fees due thereon have been paid and (iii) the Company has set aside on its books provisions reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There is no tax lien, whether imposed by any federal, state, county or local taxing authority, outstanding against the assets, properties or business of the Company. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company know of no basis for any such claim.
- 2.11 Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. The Company is in compliance with the requirements of the NASDAQ Global Select Market for continued listing of the Common Stock thereon and has not received any notification that the NASDAQ Global Select Market is contemplating terminating such listing. The Company has no reason to believe that it will not upon issuance of the Shares continue to be in compliance with all such listing and maintenance requirements. The issuance of the Shares hereunder does not contravene the rules of the NASDAQ Global Select Market.

- 2.12 Offering Exemption. Based in part on the representations of Purchaser set forth in Section 3.2 below, the offer, sale and issuance of the Shares in conformity with the terms of this Agreement are exempt from the registration requirements of the Securities Act and are exempt from the qualification or registration requirements of applicable state securities laws (the "Blue Sky Laws"). Neither the Company nor its affiliates, nor any agent on its or their behalf, (i) has engaged in any form of general solicitation or general advertising (within the meaning of Regulation D under the Securities Act) in connection with the Common Stock Financing, (ii) has solicited or will solicit any offers to sell or has offered to sell or will offer to sell all or any part of the Shares to any Person or Persons so as to bring the sale of the Shares by the Company within the registration provisions of the Securities Act or any state securities laws or (iii) has issued any shares of Common Stock or shares of any series of Preferred Stock or other securities or instruments convertible into, exchangeable for or otherwise entitling the holder thereof to acquire shares of Common Stock which would be integrated with the sale of the Shares to Purchaser for purposes of the Securities Act or of any applicable shareholder approval provisions, including, without limitation, under the rules and regulations of any exchange or automated quotation system on which any of the Securities of the Company are listed or designated, nor will the Company or any of its subsidiaries or affiliates take any action or steps that would require registration of any of the Shares under the Securities Act.
- 2.13 Affiliate Transactions. No employee, officer, director or 10% or greater shareholder of the Company or member of his or her immediate family (each a "Covered Person") is currently indebted to the Company, nor is the Company indebted (or committed to make loans or extend or guarantee credit) to any Covered Person. Except as disclosed in the SEC Filings, as of the date hereof, no Covered Person has any direct or indirect ownership interest in any firm or corporation with which the Company is affiliated or with which the Company has a business relationship, or any firm or corporation that competes with the Company (except for ownership of stock not to exceed 1% of the outstanding capital stock of any publicly traded company that may compete with the Company).
- 2.14 Investment Company Act. The Company is not, and is not an Affiliate (as defined below) of, and after giving effect to the Common Stock Financing, will not be an Affiliate of, an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940. For purposes of this Agreement, "Affiliate" shall mean any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 under the Securities Act.
- **2.15** Brokers or Finders. The Company has not retained any brokers, consultants or advisors in connection with this Agreement, and has no agreements to pay any commission or compensation in the nature of a finder's or broker's fee arising out of this Agreement or the transactions contemplated hereby.
- 2.16 Compliance with Rule 506. None of the Company, any of its predecessors, any affiliated issuer, any director, executive officer, other officer of the Company participating in the offering contemplated hereby, any beneficial owner of 20% or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with the Company in any capacity at the time of sale is disqualified from relying on Rule 506 of Regulation D under the Securities Act ("Rule 506") for any of the reasons stated in Rule 506(d) in connection with the issuance and sale of the Shares to Purchaser pursuant to this Agreement. The Company has exercised reasonable care, including without limitation, conducting a factual inquiry that is appropriate in light of the circumstances, into whether any such disqualification under Rule 506(d) exists, but has assumed the accuracy of the Purchaser's representations and warranties.

- 2.17 Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Filings, except as specifically set forth in a subsequent SEC Filing filed at least three (3) Trading Days prior to the date hereof: (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (a) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (b) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to the holders of its Common Stock or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. The Company does not have pending before the SEC any request for confidential treatment of information. Except for the issuance of the Shares contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its business, properties, operations, assets or financial condition, that would be required to be disclosed by the Company under applicable securities laws if the Company were publicly offering securities pursuant to an effective registration statement under the Securities Act at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.
- 2.18 Environmental Matters. The Company is in compliance with and has not received notice of any actual or potential liability under or relating to, or actual or potential violation of, applicable federal, state and local laws, rules and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to its business (the "Environmental Laws"). The Company has not received notice of any actual or potential liability under or relating to, or actual or potential violation of, any Environmental Laws, including for the investigation or remediation of any release or threat of release of hazardous materials, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice. The Company is not conducting or paying for, in whole or in part, any investigation, remediation or other corrective action pursuant to any Environmental Law at any location, and is not a party to any order, decree or agreement that imposes any obligation or liability under any Environmental Law. There are no costs or liabilities associated with Environmental Laws of or relating to the Company, except for any such matter, as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company is not aware of any facts or issues regarding its compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws, that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect, and the Company does not anticipate material capital expenditures relating to any Environmental Laws.
- **2.19** Title to Assets. Except as set forth in the SEC Filings, the Company has good and marketable title in all personal property owned by the Company that is material to the business of the Company, in each case free and clear of all liens, except for liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and liens for the payment of federal, state or other taxes, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company are held by it under valid, subsisting and enforceable leases with which the Company are in compliance.
- **2.20 Insurance.** The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the business in which the Company is engaged, including, but not limited to, directors and officers insurance. The Company does not have any reason to believe that it will not be able to renew its existing insurance coverage as and

when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

- **2.21 Foreign Corrupt Practices.** Neither the Company, nor to the knowledge of the Company, any agent or other person acting on behalf of the Company, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.
- **2.22** Accountants. The Company's independent registered public accounting firm is BDO USA, LLP. To the knowledge and belief of the Company, such accounting firm: (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ending December 31, 2016.
- **2.23 Office of Foreign Assets Control.** Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or Person acting on behalf of the Company, is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.
- 2.24 Money Laundering. The operations of the Company are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened
- **2.25** Shareholder Rights Plan. In connection with the transaction contemplated by this Agreement only, the Company and its directors, officers and shareholders, to the extent applicable, have taken all action necessary so that the Purchaser is not an "Acquiring Person" under any applicable control share acquisition or business combination or similar anti-takeover laws. The Company has no poison pill or other anti-takeover arrangement.
- 2.26 Acknowledgement. The Company acknowledges and agrees that Purchaser is acting solely in the capacity of an arm's length purchaser with respect to this Agreement and the transactions contemplated hereby. The Company further acknowledges that Purchaser is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to this Agreement and the transactions contemplated hereby and any advice given by Purchaser or any of their respective representatives or agents in connection with this Agreement and the transactions contemplated hereby is merely incidental to Purchaser's purchase of the Shares. The Company further represents to Purchaser that the Company's decision to enter into this Agreement has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

#### 3. REPRESENTATIONS AND WARRANTIES OF PURCHASER

As a material inducement to the Company to enter into and perform its obligations under this Agreement, Purchaser represents and warrants to the Company as follows:

**3.1** <u>Authorization; Enforceability.</u> Purchaser has all requisite power and authority to execute, deliver and perform this Agreement. All action on the part of Purchaser and, as applicable, its directors, officers, members, partners and shareholders, necessary for the authorization, execution, delivery and performance of all obligations of Purchaser under this Agreement has been taken. This Agreement constitutes the valid and legally binding obligations of Purchaser, enforceable in accordance with their terms, except as limited by the Equitable Exceptions.

#### 3.2 Investor Representations.

- (a) The Shares acquired by Purchaser hereunder will be acquired by Purchaser for its own account for investment purposes and not with a view to distribution in violation of the Securities Act. Purchaser does not presently have any contract, undertaking or agreement with any Person to sell, transfer or grant participation rights to such Person or to any other Person with respect to any of the Shares acquired by Purchaser hereunder.
  - (b) Purchaser is an "accredited investor" within the meaning of Rule 501(a) promulgated under the Securities Act.
- (c) Purchaser understands that the Shares are characterized as "restricted securities" under the federal securities laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such laws and applicable regulations such securities may be resold without registration under the Securities Act only in certain limited circumstances. Purchaser acknowledges and agrees that the Shares must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available or the Company receives an opinion of counsel reasonably satisfactory to the Company that such registration is not required. Purchaser has been advised or is aware of the provisions of Rule 144 promulgated under the Securities Act as in effect from time to time ("Rule 144"), which permit limited resale of shares purchased in a private placement subject to the satisfaction of certain conditions.
- (d) Purchaser acknowledges and agrees that it can bear the economic risk of its investment in the Shares and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares. Purchaser believes that it has received all the information it considers necessary or appropriate for deciding whether to purchase the Shares acquired by Purchaser hereunder. Purchaser further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Shares.
- (e) Purchaser has not agreed to incur, directly or indirectly, any liability for brokerage or finders' fees, agents' commissions or other similar charges in connection with this Agreement or any of the transactions contemplated hereby.
- (f) Purchaser is not relying and has not relied on any representations or warranties whatsoever regarding the subject matter of this Agreement, express or implied, except for the representations and warranties in <u>Section 2</u>, including the Company Disclosure Schedule. Such representations and warranties by the Company constitute the sole and exclusive representations and warranties of the Company in connection with the transactions contemplated by this Agreement and

Purchaser understands, acknowledges and agrees that all other representations and warranties of any kind or nature whether express, implied or statutory are specifically disclaimed by the Company.

- (g) In connection with the due diligence investigation of the Company by Purchaser and its affiliates, stockholders, directors, officers, employees, agents, representatives or advisors, Purchaser and its affiliates, stockholders, directors, officers, employees, agents, representatives and advisors have received and may continue to receive after the date hereof from the Company and its affiliates, stockholders, directors, officers, employees, consultants, agents, representatives and advisors certain estimates, projections, forecasts and other forward-looking information, as well as certain business plan information, regarding the Company and its business and operations. Purchaser hereby acknowledges that there are uncertainties inherent in attempting to make such estimates, projections, forecasts and other forward-looking statements, as well as in such business plans, and that Purchaser will have no claim against the Company, or any of its affiliates, stockholders, directors, officers, employees, consultants, agents, representatives or advisors, or any other Person with respect thereto unless any such information is expressly addressed or included in a representation or warranty contained in this Agreement. Accordingly, Purchaser hereby acknowledges and agrees that neither the Company nor any of its respective affiliates, stockholders, directors, officers, employees, consultants, agents, representatives or advisors, nor any other Person, has made or is making any express or implied representation or warranty with respect to such estimates, projections, forecasts, forward-looking statements or business plans unless any such information is expressly addressed or included in a representation or warranty contained in this Agreement.
- 3.3 Compliance with Laws. Neither Purchaser nor, to Purchaser's knowledge, any director, officer, agent, employee or Person acting on behalf of Purchaser, is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department. Purchaser represents and warrants to the Company as of each Closing as follows: if Purchaser is not a United States person (as defined by Section 7701(a)(30) of the Code), Purchaser has satisfied itself as to the full observance of the laws of its jurisdiction in connection with any invitation to subscribe for the Shares or any use of this Agreement, including (i) the legal requirements within its jurisdiction for the purchase of the Shares, (ii) any foreign exchange restrictions applicable to such purchase, (iii) any governmental or other consents that may need to be obtained and (iv) the income tax and other tax consequences, if any, that may be relevant to the purchase, holding, redemption, sale or transfer of the Shares. Purchaser's subscription and payment for and continued beneficial ownership of the Shares will not violate any applicable securities or other laws of Purchaser's jurisdiction.

#### 4. CONDITIONS TO PURCHASER'S OBLIGATIONS AT CLOSING

The obligations of Purchaser under this Agreement to purchase and pay for the Shares being purchased by Purchaser at the Closing are subject to the satisfaction or waiver, at or prior to the Closing, of the following conditions:

- **4.1** Representations and Warranties. The representations and warranties of the Company contained in Section 2 of this Agreement shall be true, correct and complete in all material respects (except for any such representation and warranty that is qualified as to materiality or Material Adverse Effect, which shall be true and correct in all respects) on and as of the Closing with the same force and effect as if they had been made at that time (except that those representations and warranties which address matters only as of a particular date need only be measured as of the specific date).
- **4.2** <u>Performance</u>. The Company shall have performed and complied in all material respects with all other conditions, covenants and agreements contained in this Agreement required to be performed or complied with by it on or before the Closing.

- **4.3** Legal Investment. On the Closing Date, the sale and issuance of the Shares shall be legally permitted by all laws and regulations to which Purchaser and the Company are subject.
  - 4.4 No Suspension. Trading in the Common Stock shall not have been suspended by the SEC or the NASDAO Global Select Market.
- **4.5** Consents and Approvals. Any consent required for the consummation of the transactions contemplated by this Agreement, including without limitation, the issuance of the Shares, shall have been obtained (collectively, "Consents").
- **4.6 Qualifications.** All authorizations, approvals or permits, if any, of any Governmental Authority that are required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall have been duly obtained and shall be effective on and as of the Closing.
- **4.7 No Injunction.** No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any Governmental Authority of competent jurisdiction which prohibits the consummation of any of the transactions contemplated by this Agreement.
- **4.8** Compliance Certificate. Purchaser shall have received a compliance certificate, executed by the Chief Executive Officer or Chief Financial Officer of the Company, dated as of the date of the Closing, to the effect that the conditions specified in Sections 4.1 and 4.2 have been satisfied.

#### 5. CONDITIONS TO THE COMPANY'S OBLIGATIONS AT CLOSING

The obligations of the Company under this Agreement to sell and issue to Purchaser the Shares to be purchased by Purchaser at the Closing are subject to the satisfaction or waiver, at or prior to the Closing, of the following conditions:

- **5.1** Representations and Warranties. The representations and warranties of Purchaser contained in Section 3 shall be true, correct and complete in all material respects (except for any such representation and warranty that is qualified as to materiality or Material Adverse Effect, which shall be true and correct in all respects) on and as of the applicable Closing with the same force and effect as if they had been made at such time (except that those representations and warranties which address matters only as of a particular date need only be true, correct and complete in all material respects as of such date).
- **5.2** <u>Performance</u>. Purchaser shall have performed and complied with all other conditions, covenants and agreements contained in this Agreement required to be performed or complied with by Purchaser on or before the Closing.
- **5.3** Qualifications. All authorizations, approvals or permits, if any, of any Governmental Authority that are required in connection with the lawful issuance and sale of the Shares pursuant to this Agreement shall have been duly obtained and shall be effective on and as of the Closing.
- **5.4 No Injunction.** No statute, rule, regulation, executive order, decree, ruling or injunction shall have been enacted, entered, promulgated or endorsed by any Governmental Authority of competent jurisdiction which prohibits the consummation of any of the transactions contemplated by this Agreement.

- **5.5** Consents and Approvals. Any Consent required for the consummation of the transactions contemplated by this Agreement, including without limitation, the issuance of the Shares, shall have been obtained. If applicable, the waiting period (or any extension thereof) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, required in order for the Partnership Agreement to become effective shall have expired or been terminated.
- 5.6 <u>Partnering Agreement</u>. The License, Development and Commercialization Agreement of even date herewith (the "Partnering Agreement") shall not have been terminated.

#### 6. COVENANTS

- **6.1** Purchaser Lock-Up. Purchaser covenants and agrees as follows:
- (a) Purchaser will not, without the prior written consent of the Company, during the period commencing on the Closing Date and, subject to the terms set forth herein, ending 180 days after the Closing Date (the "Lock-Up Period"), (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any Shares purchased in the Closing or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Shares, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of the Shares purchased in the Closing, in cash or otherwise. Notwithstanding the foregoing, Purchaser may transfer the Shares to any of its shareholders or Affiliates; *provided* that in the case of any transfer or distribution pursuant to this subparagraph during the Lock-Up Period, each done or transferee shall sign and deliver a lock-up letter with terms substantially similar to the terms of this Section 6.1.
- (b) Notwithstanding anything to the contrary contained herein, Purchaser agrees that Purchaser shall not effect any sale, transfer or other disposition of any Shares unless: (a) such sale, transfer or other disposition is effected pursuant to an effective registration statement under the Securities Act; (b) such sale, transfer or other disposition is made in conformity with the requirements of Rule 144, as evidenced by a broker's letter and a representation letter executed by Purchaser (reasonably satisfactory in form and content to the Company) stating that such requirements have been met; or (c) counsel reasonably satisfactory to the Company (which may be counsel to the Company) shall have advised the Company in a written opinion letter (reasonably satisfactory in form and content to the Company), upon which the Company may rely, that such sale, transfer or other disposition will be exempt from the registration requirements of the Securities Act.
- (c) Notwithstanding any other provision of this Section 6.1, this Section 6.1 shall not prohibit or restrict any disposition of Common Stock by Purchaser in connection with (i) a bona fide tender offer by a Person other than Purchaser or the Company that is not opposed by the Board of Directors and involving a Change of Control of the Company (as defined below); or (ii) an issuer tender offer by the Company; provided, that in the event that the tender offer is not completed, the Shares shall remain subject to the restrictions contained in this Section 6.1. For the purposes of this Agreement, a "Change of Control" means the transfer, in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of capital stock of the Company if, after such transfer, the stockholders of the Company immediately prior to such transfer do not own at least fifty percent (50%) of the outstanding voting securities of the Company (or the surviving entity).
- (d) Purchaser acknowledges and agrees that stop transfer instructions will be given to the Company's transfer agent with respect to the Shares until the expiration of the Lock-Up Period.

#### 6.2 Notifications.

- (a) Prior to the Closing, the Company will promptly advise Purchaser in writing of any notice or other communication from any third Person alleging that the consent of a third Person is required in connection with the transactions contemplated by this Agreement.
- (b) Prior to the Closing, each party shall promptly notify the other of any action, suit or proceeding that is instituted or specifically threatened in writing against such party to restrain, prohibit or otherwise challenge the legality of any transaction contemplated by this Agreement.
- **6.3** <u>Standstill.</u> During the period commencing on the Closing Date and ending on the earliest of (i) three (3) years following the Closing Date, (ii) the date on which any third party unaffiliated with Purchaser commences a tender offer or exchange offer for more than fifty percent (50%) of the Company's outstanding Common Stock, and (iii) the date the Company publicly announces its intent to consummate a Change of Control (the "**Standstill Period**"), neither the Purchaser nor any of Purchaser's representatives or affiliates will, in any manner, directly or indirectly:
- (a) make, effect, initiate or cause (i) any acquisition of beneficial ownership of any securities of the Company or any securities of any subsidiary or other affiliate of the Company to the extent that such acquisition would result in Purchaser's beneficial ownership of the Company exceeding 15%, (ii) any acquisition of any assets of the Company or any assets of any subsidiary or other affiliate of the Company, (iii) any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving the Company or any subsidiary or other affiliate of the Company, or involving any securities or assets of the Company or any securities or assets of any subsidiary or other affiliate of the Company or involving any securities or assets of the Securities and Exchange Commission) or consents with respect to any securities of the Company; provided, however, that notwithstanding the provisions of this Section 6.3(a)(i), if the number of shares of then outstanding Common Stock of the Company is reduced or if the ownership percentage of Purchaser is increased as a result of a repurchase by the Company of shares of Common Stock, or a stock split, stock dividend or a recapitalization of the Company, Purchaser shall not be required to dispose of its holdings of shares of the Common Stock even though such action resulted in Purchaser's beneficial ownership increasing;
- (b) form, join or participate in a "group" (as defined in the Exchange Act and the rules promulgated thereunder) with respect to the beneficial ownership of any securities of the Company;
  - (c) act, alone or in concert with others, to seek to control or influence the management, Board of Directors or policies of the Company;
- (d) take any action that might require the Company to make a public announcement regarding any of the types of matters set forth in clause "(a)" of this Section 6.3;
- (e) agree or offer to take, or encourage or propose (publicly or otherwise) the taking of, any action referred to in clause "(a)", "(b)", "(c)" or "(d)" of this sentence;
  - (f) assist, induce or encourage any other Person to take any action of the type referred to in clause "(a)", "(b)", "(c)", "(d)" or "(e)" of this sentence;
  - (g) enter into any discussions, negotiations, arrangement or agreement with any other Person relating to any of the foregoing; or

(h) request or propose that the Company amend, waive or consider the amendment or waiver of any provision set forth in this Section 6.3.

Notwithstanding the foregoing, it is understood and agreed that Purchaser shall not be prohibited from entering into an agreement and having discussions with legal, accounting or financial advisors for the limited purposes of evaluating any of the transactions contemplated by this Section 6.3, and Purchaser may initiate private discussions with, and submit proposals confidentially to, the Chief Executive Officer of the Company regarding a transaction otherwise prohibited by this Section 6.3; provided, however, that any such proposal shall be expressly conditioned on approval of the Board of Directors and will not require public disclosure.

- **6.4** Commercial Reasonable Efforts. Each Party will use its commercially reasonable efforts to satisfy in a timely fashion each of the conditions to be satisfied by it under Section 4 and Section 5 of this Agreement. Without limiting the foregoing, the Company shall take all action necessary to (i) cause the lawful issuance of the Shares in accordance with this Agreement at Closing and (ii) make all filings with the Securities and Exchange Commission necessary to permit Purchaser to sell Shares in accordance with Rule 144.
- **6.5** Notice of Issuances. In the event the Company intends to issues shares of capital stock (other than in connection with the issuance of shares of capital stock upon the exercise of employee options), the Company shall notify Purchaser to the extent legally permitted to do so.
- 6.6 Securities Laws Disclosure; Publicity. The Company shall, by 9:00 a.m. (New York City time) on the Trading Day immediately following the date hereof, issue a press release disclosing the material terms of the transactions contemplated hereby, and shall, within four (4) Trading Days following the date hereof, file a Current Report on Form 8-K disclosing the material terms of the transactions contemplated hereby and including this Agreement as an exhibit thereto. The Company and Purchaser shall consult with each other regarding the substance of any public disclosure by either party regarding this Agreement (including the filing of the Agreement as an exhibit to a periodic filing with the SEC) and regarding the issuance of any other press releases with respect to the transactions contemplated hereby, and neither the Company nor Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of Purchaser, or without the prior consent of Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication.
- **6.7** Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that Purchaser is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar antitakeover plan or arrangement in effect or hereafter adopted by the Company, or that Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Shares under this Agreement or under any other agreement among the Company and Purchaser.
- **6.8** <u>Indemnification of Purchaser.</u> Subject to the provisions of this <u>Section 6.7</u>, the Company will indemnify and hold Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "**Purchaser Party**") harmless from any and all losses, liabilities, obligations, claims,

contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of the Company's breach of its representations, warranties or covenants under this Agreement (unless such action is based upon a breach of Purchaser's representation set forth in Section 3.2). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, provided that the failure to so notify the Company shall not prejudice the Purchaser Party's right to indemnification except to the extent the Company is materially prejudiced thereby), and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel for all Purchaser Parties entitled to indemnification hereunder. The Company will not be liable to any Purchaser Party under this Agreement (y) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (z) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in this Agreement. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company and any liabilities that the Company may be subject to pursuant to law. The Company will have the exclusive right to settle any claim or proceeding, provided that the Company will not settle any such claim, action or proceeding without the prior written consent of the Purchaser Party, which will not be unreasonably withheld or delayed; provided, however, that such consent shall not be required if the settlement includes a full and unconditional release satisfactory to the Purchaser Party from all liability arising or that may arise out of such claim or proceeding and does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any Purchaser Party. Notwithstanding the foregoing, in no event will the Company's liability under this Section 6.7 exceed (i) an aggregate of \$5,000,000 in connection with any claim based on a breach of the representations, warranties or covenants contained in Sections 1.1, 2.1, 2.2, 2.3, 2.4, 2.6, 2.11, 2.12, 2.16 or ARTICLE 6 or (ii) an aggregate of \$2,000,000 in connection with any claim based on the breach of any other provision of this Agreement.

**6.9** <u>Listing of Common Stock</u>. The Company hereby agrees to use commercially reasonable efforts to maintain the listing or quotation of the Common Stock on the NASDAQ Global Select Market.

**6.10 Form D; Blue Sky Filings.** The Company agrees to timely file a Form D with respect to the Shares as required under Regulation D and to provide a copy thereof, promptly upon request of Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Shares for, sale to Purchaser at each Closing under applicable Blue Sky Laws and shall provide evidence of such actions promptly upon request of Purchaser.

**6.11** <u>Book Entry Statement</u>. The Company hereby agrees to deliver to Purchaser a book entry statement from the Transfer Agent showing the Shares registered in the name of Purchaser within three (3) business days of the Closing.

#### 7. SURVIVAL OF REPRESENTATIONS

All representations, warranties, covenants and other agreements of the Company hereunder shall be deemed made on and as of the Closing as though such representations, warranties, covenants and other

agreements were made on and as of such date. All representations and warranties made by a party to this Agreement herein or pursuant hereto shall survive each Closing and the delivery of the Shares for a period of 15 months thereafter. All covenants and other agreements made by a party to this Agreement herein or pursuant hereto shall survive until all obligations set forth therein shall have been performed or satisfied or they shall have terminated in accordance with their terms

#### 8. TERMINATION

- **8.1 Termination.** This Agreement may be terminated at any time until the Closing:
  - (a) by the mutual written consent of Purchaser and the Company;
  - (b) by the Company or the Purchaser upon termination of the Partnering Agreement in accordance with its terms;
- (c) by the Company if (i) any of the representations and warranties of Purchaser contained in Section 3 of this Agreement shall fail to be true and correct or (ii) there shall be a breach by Purchaser of any covenant of Purchaser in this Agreement that, in either case, (A) would result in the failure of a condition set forth in Section 5, and (B) which is not curable or, if curable, is not cured upon the occurrence of the twentieth (20th) day after written notice thereof is given the Company to Purchaser;
- (d) by Purchaser if (i) any of the representations and warranties of the Company contained in Section 2 of this Agreement shall fail to be true and correct or (ii) there shall be a breach by the Company of any covenant of the Company in this Agreement that, in either case, (A) would result in the failure of a condition set forth in Section 4, and (B) which is not curable or, if curable, is not cured upon the occurrence of the twentieth (20th) day after written notice thereof is given by Purchaser to the Company; or
- (e) by either Purchaser or the Company in the event that any court of competent jurisdiction or Governmental Authority shall have issued an order, decree or ruling or taken any other action restraining, enjoining or otherwise prohibiting the actions contemplated hereby and such order, decree, ruling or other action shall have become final and nonappealable.
- **8.2** Effect of Termination. In the event of any termination of this Agreement as provided in Section 8.1, this Agreement (other than Section 9, which shall remain in full force and effect) shall forthwith become wholly void and of no further force and effect; provided that nothing herein shall relieve any party from liability for willful breach of this Agreement.

#### 9. GENERAL

- **9.1** Successors and Assigns. Except as otherwise provided herein, the terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and permitted assigns of the parties (including any permitted transferees of any Shares). Purchaser and the Company may not assign their respective rights or obligations under this Agreement, in whole or in part, except with the consent of the other party; provided, however, the rights and obligations of Purchaser may be assigned, without the prior written consent of the Company, to one or more of Purchaser's affiliates. Any attempted assignment made in contravention of this Agreement shall be null and void and of no force or effect.
- 9.2 Entire Agreement. This Agreement and the documents, schedules and exhibits referred to herein or therein constitute the entire agreement between the parties and supersede all prior

communications, representations, understandings and agreements of the parties with respect to the subject matter hereof and thereof. No party shall be liable or bound to any other party in any manner by any warranties, representations or covenants except as specifically set forth herein or therein. All schedules and exhibits hereto are hereby incorporated herein by reference. Nothing in this Agreement, express or implied, is intended to confer upon any third party any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

- **9.3** General Interpretation. The terms of this Agreement have been negotiated by the parties hereto and the language used in this Agreement shall be deemed to be the language chosen by the parties hereto to express their mutual intent. This Agreement shall be construed without regard to any presumption or rule requiring construction against the party causing such instrument or any portion thereof to be drafted, or in favor of the party receiving a particular benefit under this Agreement. No rule of strict construction will be applied against any Person.
- **9.4** Injunctive Relief. Purchaser and the Company acknowledge and agree that, in view of the uniqueness of the Shares, damages at law would be insufficient for any breach by Purchaser or the Company of any of their respective covenants in this Agreement. Accordingly, each party agrees that in the event of any breach or threatened breach by the other party of any provisions of this Agreement, the non-breaching party be entitled to seek equitable relief in the form of an order to specifically perform or an injunction to prevent irreparable injury.
- **9.5** Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the principles of conflicts of law thereof.
- **9.6 Jurisdiction.** The parties hereby irrevocably and unconditionally submit to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement.
- **9.7** <u>Counterparts</u>. This Agreement may be executed in any number of counterparts and by the parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement, and may be delivered to the other parties hereto by facsimile.
- 9.8 Section Headings and References. The section headings contained herein are for the convenience of the parties and in no way alter, modify, amend, limit or restrict the contractual obligations of the parties. When a reference is made in this Agreement to a Section or Exhibit, such reference is to a Section or Exhibit of or to this Agreement unless otherwise indicated. The words "hereof," "herein," "hereto" and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The terms defined in the singular has a comparable meaning when used in the plural, and vice versa. References to a Person are also to its successors and permitted assigns. References to an agreement are to such agreement as amended, restated, modified or otherwise supplemented, from time to time. The term "dollars" and "\$" means United States dollars. The word "including" means "including without limitation" and the words "include" and "includes" have corresponding meanings.
- 9.9 Severability. If any term of provision of this Agreement is determined to be illegal, unenforceable or invalid in whole or in part for any reason, such illegal, unenforceable or invalid provisions or party thereof shall be stricken from this Agreement, and such provision shall not affect the legality, enforceability or validity of the remainder of this Agreement. If any provision or part thereof of this Agreement is stricken in accordance with the provisions of this Section 9.9, then such stricken

provision shall be replaced, to extent possible, with a legal, enforceable and valid provision that is as similar in tenor to the stricken provision as is legally possible.

**9.10** Notices. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when received by facsimile or email (provided that the party providing such notice promptly confirms receipt of such transmission with the other party), (c) when received after having been sent by registered or certified mail, return receipt requested and postage prepaid or (d) when received after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company and to Purchaser at the address as set forth below or at such other address as Purchaser or the Company may designate by 10 days advance written notice to the Company (in the case of Purchaser) or Purchaser (in the case of the Company).

### if to the Company:

MEl Pharma, Inc. 11975 El Camino Real, Suite 101 San Diego, CA 90130 Attn: Chief Executive Officer Facsimile: +1 858-792-5406

Facsimile: +1 858-792-5406 Email: dgold@meipharma.com

with copies (which shall not constitute notice) to:

MEl Pharma, Inc. 11975 El Camino Real, Suite 101 San Diego, CA 92130 Attn: General Counsel Facsimile: +1 858-792-5406 Email: urso@meipharma.com

Morgan, Lewis & Bockius LLP 101 Park Avenue New York, NY 10178 Facsimile: (212) 309-6001

Email: steven.navarro@morganlewis.com

#### if to Purchaser:

Helsinn Investment Fund SA 412F, Route d'Esch L - 2086 Luxembourg

Attn: Mr Jean-Robert Bartolini Facsimile: ++352 47 1101

Email: JeanRobert.Bartolini@sgggroup.com

with copies (which shall not constitute notice) to:

Helsinn Healthcare SA Via Pian Scairolo 9, CH-6912 Lugano, Switzerland Attn: General Counsel

Facsimile: +41 (0)91 985 2121 Email: matteo.missaglia@helsinn.com

and:

Hogan Lovells US, LLP 100 International Drive Suite 2000 Baltimore, MD 21202

Baltimore, MD 21202 Facsimile: 401-659-2701

Email: david.gibbons@hoganlovells.com

- **9.11** Amendments and Waivers. Except as otherwise expressly set forth in this Agreement, any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of each party hereto (with respect to an amendment) and the written consent of each party from whom a waiver is sought (with respect to a waiver). No waiver of any provision or consent to any action shall constitute a waiver of any other provision or consent to any other action, whether or not similar. No waiver or consent shall constitute a continuing waiver or consent or commit a party to provide a waiver in the future except to the extent specifically set forth in writing.
  - 9.12 Expenses. Each party hereto will pay its own expenses in connection with the transactions contemplated hereby.
- **9.13** Persons Entitled to Benefits of Agreement. This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other person.
- **9.14** Further Assurances. The Company and Purchaser shall use their commercially reasonable efforts, in the most expeditious manner practicable, to satisfy or cause to be satisfied the intent and purposes of this Agreement by executing and delivering such instruments, documents and other writings as may be reasonably necessary or desirable.

IN WITNESS WHEREOF, the undersigned parties have duly executed this Common Stock Purchase Agreement effective as of the date first above written.

# **COMPANY:**

# MEI PHARMA, INC.

By: /s/ Daniel P. Gold

Daniel P. Gold, Chief Executive Officer

# **PURCHASER:**

# HELSINN INVESTMENT FUND SA

By: /s/ Riccardo Braglia

Riccardo Braglia, Group Vice Chairman and CEO

{Signature Page to Common Stock Purchase Agreement}

#### 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: November 9, 2016 /s/ Daniel P. Gold

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

#### CERTIFICATION

#### I, Thomas M. Zech, 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 Company'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: November 9, 2016

/s/ Thomas M. Zech
Thomas M. Zech

Chief Financial Officer (Principal Financial Officer)

#### 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 Thomas M. Zech, 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 September 30, 2016, (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: November 9, 2016

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

/s/ Thomas M. Zech

Thomas M. Zech Chief Financial Officer (Principal Financial Officer)