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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

OR

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

For the transition period from _____ to _____

Commission file number 0-22705

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

33-0525145
(IRS Employer
Identification No.)

**12780 El Camino Real,
San Diego, California**
(Address of principal executive office)

92130
(Zip Code)

(858) 617-7600
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 85,417,797 as of April 24, 2015.

[Table of Contents](#)

NEUROCRINE BIOSCIENCES, INC.
FORM 10-Q INDEX

	<u>PAGE</u>
<u>PART I. FINANCIAL INFORMATION</u>	
ITEM 1: Financial Statements	3
Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014	3
Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2015 and 2014	4
Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014	5
Notes to the Condensed Consolidated Financial Statements	6
ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations	15
ITEM 3: Quantitative and Qualitative Disclosures About Market Risk	20
ITEM 4: Controls and Procedures	21
<u>PART II. OTHER INFORMATION</u>	
ITEM 1A: Risk Factors	21
ITEM 5: Other Information	30
ITEM 6: Exhibits	31
Signatures	32

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share information)
(unaudited)

	March 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 170,262	\$ 31,014
Short-term investments, available for sale	199,745	162,795
Receivables under collaboration agreements	30,030	—
Other current assets	4,916	4,394
Total current assets	404,953	198,203
Property and equipment, net	2,543	2,507
Long-term investments, available for sale	115,452	37,492
Restricted cash	4,831	4,831
Total assets	<u>\$ 527,779</u>	<u>\$ 243,033</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,270	\$ 246
Accrued liabilities	9,938	11,508
Current portion of cease-use liability	479	467
Current portion of deferred rent	152	119
Current portion of deferred gain on sale of real estate	3,348	3,324
Total current liabilities	15,187	15,664
Deferred gain on sale of real estate	13,468	14,322
Deferred revenue	10,231	—
Deferred rent	1,817	1,877
Cease-use liability	2,086	2,211
Other liabilities	260	260
Total liabilities	43,049	34,334
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.001 par value; 110,000,000 shares authorized; issued and outstanding shares were 85,372,303 as of March 31, 2015 and 76,465,942 as of December 31, 2014	85	76
Additional paid-in capital	1,312,321	1,035,205
Accumulated other comprehensive loss	(179)	(277)
Accumulated deficit	(827,497)	(826,305)
Total stockholders' equity	484,730	208,699
Total liabilities and stockholders' equity	<u>\$ 527,779</u>	<u>\$ 243,033</u>

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands, except per share data)
(unaudited)

	Three Months Ended	
	March 31,	
	2015	2014
Revenues:		
License fees	\$19,769	\$ —
Total revenues	19,769	—
Operating expenses:		
Research and development	16,575	8,572
General and administrative	5,482	4,153
Total operating expenses	22,057	12,725
Loss from operations	(2,288)	(12,725)
Other income:		
Gain (loss) on sale/disposal of assets	9	(10)
Deferred gain on real estate	830	804
Investment income, net	257	89
Total other income	1,096	883
Net loss	<u>\$ (1,192)</u>	<u>\$ (11,842)</u>
Net loss per common share:		
Basic and diluted	<u>\$ (0.01)</u>	<u>\$ (0.17)</u>
Shares used in the calculation of net loss per common share:		
Basic and diluted	<u>80,349</u>	<u>70,260</u>
Other comprehensive loss:		
Net loss	\$ (1,192)	\$ (11,842)
Net unrealized gains/(losses) on available-for-sale securities	98	(199)
Comprehensive loss	<u>\$ (1,094)</u>	<u>\$ (12,041)</u>

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Three Months Ended	
	March 31,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (1,192)	\$ (11,842)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	244	178
Gain on sale of assets	(839)	(794)
Deferred revenues	10,231	—
Deferred rent	(27)	6
Amortization of premiums on investments	1,011	617
Non-cash share-based compensation expense	3,600	2,447
Change in operating assets and liabilities:		
Accounts receivable under collaboration agreements and other assets	(30,552)	850
Accounts payable and accrued liabilities	(546)	(1,127)
Cease-use liability	(113)	(102)
Net cash used in operating activities	(18,183)	(9,767)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(159,221)	(108,907)
Sales and maturities of investments	43,398	43,391
Proceeds from sales of property and equipment	9	40
Purchases of property and equipment	(280)	(255)
Net cash used in investing activities	(116,094)	(65,731)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	273,525	136,241
Net cash provided by financing activities	273,525	136,241
Net increase in cash and cash equivalents	139,248	60,743
Cash and cash equivalents at beginning of the period	31,014	44,789
Cash and cash equivalents at end of the period	<u>\$ 170,262</u>	<u>\$ 105,532</u>

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Description of Business. Neurocrine Biosciences, Inc. (the Company or Neurocrine) was incorporated in California in 1992 and reincorporated in Delaware in 1996. The Company discovers and develops innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through its novel research and development (R&D) platform, focused on neurological and endocrine based diseases and disorders. The Company's two lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone (GnRH) antagonist for women's health that is partnered with AbbVie Inc. (AbbVie), and a vesicular monoamine transporter 2 (VMAT2) inhibitor for the treatment of movement disorders.

Basis of Presentation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company's financial position and of the results of operations and cash flows for the periods presented. The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K filed with the SEC. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The balance sheet at December 31, 2014 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

Impact of Recently Issued Accounting Standards. In May 2014, the Financial Accounting Standards Board (FASB) amended the existing accounting standards for revenue recognition, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. The amended guidance defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The amended guidance as currently issued will be effective for the Company starting in 2017. On April 1, 2015, the FASB voted to propose a one-year deferral to the effective date, but to permit entities to adopt one year earlier if they choose (i.e., the original effective date). The proposal will be subject to the FASB's due process requirement, which includes a period for public comments. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. The Company is in the process of determining the adoption method as well as the effects the adoption will have on its consolidated financial statements.

Use of Estimates. The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

2. REVENUE RECOGNITION AND SIGNIFICANT COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Revenue Recognition Policy. The Company recognizes revenue for the performance of services when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) services are rendered or products are delivered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

Effective in 2011, the Company follows the Accounting Standards Codification (ASC) for Revenue Recognition - Multiple-Element Arrangements, if applicable, to determine the recognition of revenue under license and collaboration agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses to our intellectual property, (ii) materials and technology, (iii) pharmaceutical supply, (iv) participation on joint development or joint steering committees, and (v) development services. The payments the Company receives under these arrangements typically include one or more of the following: up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; manufacturing and royalties on future product sales.

[Table of Contents](#)

The ASC provides guidance relating to the separation of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. The selling prices of deliverables under an arrangement may be derived using vendor specific objective evidence (VSOE), third-party evidence, or a best estimate of selling price (BESP), if VSOE or third-party evidence is not available. For most pharmaceutical licensing and collaboration agreements, BESP is utilized. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the agreement. In validating the BESP, management considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

The Company typically receives up-front payments when licensing its intellectual property, which often occurs in conjunction with a research and development agreement. The Company recognizes revenue attributed to the license upon delivery, provided that the license has stand-alone value.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, the Company recognizes the portion of the payment allocable to delivered items as revenue when the specific milestone is achieved, and the contingency is removed.

Prior to the revised multiple element guidance, described above, adopted by the Company on January 1, 2011, upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned were classified as deferred revenue and recognized as income over the contract or development period. Revenues from development milestones are accounted for in accordance with the Revenue Recognition – Milestone Method Topic of the FASB ASC. Milestones are recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive. A milestone event is considered to be substantive if its achievability was not reasonably assured at the inception of the agreement and the Company's efforts led to the achievement of the milestone or the milestone was due upon the occurrence of a specific outcome resulting from the Company's performance. The Company assesses whether a milestone is substantive at the inception of each agreement.

Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe). On March 31, 2015, the Company entered into a collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of NBI-98854 for movement disorders in Japan and other select Asian markets. Payments to the Company under this agreement include an up-front license fee of \$30 million, up to \$85 million in development and commercialization event-based payments, payments for the manufacture of pharmaceutical products, and royalties on product sales in select territories in Asia. Under the terms of the agreement, Mitsubishi Tanabe is responsible for all third-party development, marketing and commercialization costs in Japan and other select Asian markets with the exception of a single Huntington's chorea clinical trial to be performed by the Company, at an estimated cost of approximately \$12 million, should Mitsubishi Tanabe request the clinical trial. The Company will be entitled to a percentage of sales of NBI-98854 in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights.

Under the terms of the Company's agreement with Mitsubishi Tanabe, the collaboration effort between the parties to advance NBI-98854 towards commercialization in Japan and other select Asian markets is governed by a joint steering committee and joint development committee with representatives from both the Company and Mitsubishi Tanabe. There are no performance, cancellation, termination or refund provisions in the agreement that would have a material financial consequence to the Company. The Company does not directly control when event-based payments will be achieved or when royalty payments will begin. Mitsubishi Tanabe may terminate the agreement at its discretion upon 180 days' written notice to the Company. In such event, all NBI-98854 product rights for Japan and other select Asian markets would revert to the Company.

The Company has identified the following deliverables associated with the Mitsubishi Tanabe agreement: NBI-98854 technology license and existing know-how, development activities to be performed as part of the collaboration, and the manufacture of pharmaceutical products. The respective standalone value from each of these deliverables has been determined by applying the BESP method and the revenue was allocated based on the relative selling price method with revenue recognition timing to be determined either by delivery or the provision of services.

[Table of Contents](#)

As discussed above, the BESP method required the use of significant estimates. The Company used an income approach to estimate the selling price for the technology license and an expense approach for estimating development activities and the manufacture of pharmaceutical products. The development activities and the manufacture of pharmaceutical products are expected to be delivered throughout the duration of the agreement. The technology license and existing know-how was delivered on the effective date of the agreement.

For the quarter ended March 31, 2015, the Company recognized revenue under this agreement of \$19.8 million associated with the delivery of a technology license and existing know-how. In accordance with the Company's continuing performance obligations, \$10.2 million of the \$30 million up-front payment is being deferred and recognized in future periods. Under the terms of the agreement, there is no general obligation to return the up-front payment for any non-contingent deliverable.

The Company evaluated the event-based payments under the Milestone Method and concluded only one immaterial event-based payment represents a substantive milestone. Event-based payments will be recognized when earned.

The Company is eligible to receive from Mitsubishi Tanabe tiered royalty payments based on product sales in Japan and other select Asian markets. Royalties will be recognized as earned in accordance with the terms of the agreement, when product sales are reported by Mitsubishi Tanabe, the amount can be reasonably estimated, and collectability is reasonably assured.

AbbVie Inc. (AbbVie). In June 2010, the Company announced an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively, GnRH Compounds) for women's and men's health. AbbVie made an upfront payment of \$75 million and has agreed to make additional development and regulatory event-based payments of up to \$480 million and up to an additional \$50 million in commercial event-based payments. The Company has assessed event-based payments under the revised authoritative guidance for research and development milestones and determined that event-based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (i) they are events that can only be achieved in part on the Company's past performance, (ii) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (iii) they result in additional payments being due to the Company. Development and regulatory event-based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of AbbVie. As of March 31, 2015, \$500 million remains outstanding in future event-based payments under the agreement. However, none of the remaining event-based payments meet the definition of a milestone in accordance with authoritative accounting guidance.

Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing and commercialization costs. The Company received funding for certain internal collaboration expenses, which included reimbursement from AbbVie for internal and external expenses related to the GnRH Compounds, through the end of 2012. The Company will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. Under the terms of the Company's agreement with AbbVie, the collaboration effort between the parties to advance GnRH Compounds towards commercialization was governed by a joint development committee with representatives from both the Company and AbbVie. The Company's participation in the joint development committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the term of the joint development committee, which was completed, as scheduled, in December 2012. AbbVie may terminate the collaboration at its discretion upon 180 days' written notice to the Company. In such event, the Company would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to the Company.

[Table of Contents](#)

3. INVESTMENTS

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

Investments consist of the following (*in thousands*):

	March 31, 2015	December 31, 2014
Certificates of deposit	\$ 16,521	\$ 17,438
Commercial paper	11,943	7,498
Corporate debt securities	280,573	174,323
Securities of government sponsored entities	6,160	1,028
Total investments	\$ 315,197	\$ 200,287

The following is a summary of investments classified as available-for-sale securities (*in thousands*):

	Contractual Maturity (in years)	Amortized Cost	Gross Unrealized Gains(1)	Gross Unrealized Losses(1)	Aggregate Estimated Fair Value
March 31, 2015:					
Classified as current assets:					
Certificates of deposit	Less than 1	\$ 9,320	\$ 2	\$ (2)	\$ 9,320
Commercial paper	Less than 1	11,948	6	(11)	11,943
Corporate debt securities	Less than 1	178,406	14	(91)	178,329
Securities of government-sponsored entities	Less than 1	153	—	—	153
Total short-term available-for-sale securities		\$ 199,827	\$ 22	\$ (104)	\$ 199,745
Classified as non-current assets:					
Certificates of deposit	1 to 2	\$ 7,200	\$ 2	\$ (1)	\$ 7,201
Corporate debt securities	1 to 2	102,345	14	(115)	102,244
Securities of government-sponsored entities	1 to 2	6,004	3	—	6,007
Total long-term available-for-sale securities		\$ 115,549	\$ 19	\$ (116)	\$ 115,452
December 31, 2014:					
Classified as current assets:					
Certificates of deposit	Less than 1	\$ 9,072	\$ —	\$ (6)	\$ 9,066
Commercial paper	Less than 1	7,497	1	—	7,498
Corporate debt securities	Less than 1	145,321	5	(123)	145,203
Securities of government-sponsored entities	Less than 1	1,029	—	(1)	1,028
Total short-term available-for-sale securities		\$ 162,919	\$ 6	\$ (130)	\$ 162,795
Classified as non-current assets:					
Certificates of deposit	1 to 2	\$ 8,400	\$ —	\$ (28)	\$ 8,372
Corporate debt securities	1 to 2	29,245	—	(125)	29,120
Total long-term available-for-sale securities		\$ 37,645	\$ —	\$ (153)	\$ 37,492

(1) Unrealized gains and losses are included in other comprehensive loss.

Table of Contents

The following table presents information about available-for-sale investments in an unrealized loss position (*in thousands*):

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
March 31, 2015:						
Certificates of deposit	\$ 6,437	\$ (3)	\$ 240	\$ —	\$ 6,677	\$ (3)
Commercial paper	4,974	(11)	—	—	4,974	(11)
Corporate debt securities	204,039	(192)	6,371	(14)	210,410	(206)
Total	<u>\$215,450</u>	<u>\$ (206)</u>	<u>\$ 6,611</u>	<u>\$ (14)</u>	<u>\$222,061</u>	<u>\$ (220)</u>
December 31, 2014:						
Certificates of deposit	\$ 16,957	\$ (34)	\$ —	\$ —	\$ 16,957	\$ (34)
Corporate debt securities	149,477	(248)	—	—	149,477	(248)
Securities of government-sponsored entities	1,028	(1)	—	—	1,028	(1)
Total	<u>\$167,462</u>	<u>\$ (283)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$167,462</u>	<u>\$ (283)</u>

The primary objective of the Company's investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. The Company's investment policy limits interest-bearing security investments to certain types of instruments issued by institutions with primarily investment grade credit ratings and places restrictions on maturities and concentration by asset class and issuer.

The Company reviews the available-for-sale investments for other-than-temporary declines in fair value below cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. This evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below the cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security, and the intent to sell, or whether the Company will more likely than not be required to sell the security before recovery of its amortized cost basis. The assessment of whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security. As of March 31, 2015 and December 31, 2014, the Company believes the cost bases for available-for-sale investments were recoverable in all material respects.

4. FAIR VALUE MEASUREMENTS

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs include quoted prices for similar instruments in active markets and/or quoted prices for identical or similar instruments in markets that are not active near the measurement date; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company classifies its cash equivalents and available for sale investments within Level 1 or Level 2. The fair value of the Company's high quality investment grade corporate debt securities is determined using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or prices for similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company did not reclassify any investments between levels in the fair value hierarchy during the three months ended March 31, 2015.

Table of Contents

The Company's assets which were measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014 were determined using the inputs described above and are as follows (*in millions*):

	Carrying Value	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
March 31, 2015:				
Classified as current assets:				
Cash and money market funds	\$ 136.4	\$ 136.4	\$ —	\$ —
Certificates of deposit	9.3	9.3	—	—
Commercial paper	17.4	—	17.4	—
Securities of government-sponsored entities	0.2	—	0.2	—
Corporate debt securities	206.7	—	206.7	—
Subtotal	370.0	145.7	224.3	—
Classified as long-term assets:				
Certificates of deposit	12.1	12.1	—	—
Corporate debt securities	102.2	—	102.2	—
Securities of government-sponsored entities	6.0	—	6.0	—
Total	490.3	157.8	332.5	—
Less cash, cash equivalents and restricted cash	(175.1)	(141.2)	(33.9)	—
Total investments	<u>\$ 315.2</u>	<u>\$ 16.6</u>	<u>\$ 298.6</u>	<u>\$ —</u>
December 31, 2014:				
Classified as current assets:				
Cash and money market funds	\$ 28.7	\$ 28.7	\$ —	\$ —
Certificates of deposit	9.1	9.1	—	—
Commercial paper	7.5	—	7.5	—
Securities of government-sponsored entities	1.5	—	1.5	—
Corporate debt securities	147.0	—	147.0	—
Subtotal	193.8	37.8	156.0	—
Classified as long-term assets:				
Certificates of deposit	13.2	13.2	—	—
Corporate debt securities	29.1	—	29.1	—
Total	236.1	51.0	185.1	—
Less cash, cash equivalents and restricted cash	(35.8)	(33.5)	(2.3)	—
Total investments	<u>\$ 200.3</u>	<u>\$ 17.5</u>	<u>\$ 182.8</u>	<u>\$ —</u>

5. SHARE-BASED COMPENSATION

The compensation expense related to the Company's share-based compensation arrangements has been included in the condensed consolidated statements of comprehensive loss as follows (*in millions*):

	Three Months Ended	
	March 31,	
	2015	2014
General and administrative	\$ 1.7	\$ 1.2
Research and development	1.9	1.2
Total share-based compensation expense	<u>\$ 3.6</u>	<u>\$ 2.4</u>

The fair value of equity instruments that vest based on continued employee service, net of estimated forfeitures, is recognized and amortized on a straight-line basis over the requisite service period. For restricted stock units (RSUs) with performance-based vesting requirements (PRSUs), no expense is recorded until the performance condition is probable of being achieved. The Company estimates forfeiture rates for equity awards based on past behavior for similar equity awards with further consideration given to the class of employees to whom the equity awards were granted.

[Table of Contents](#)

As of March 31, 2015, total unrecognized estimated compensation cost related to non-vested stock options and non-vested RSUs, that vest over a given service period, granted prior to that date was \$26.3 million and \$19.4 million, respectively, which is expected to be recognized over a weighted average period of approximately 3.2 years and 3.4 years, respectively. Additionally, the Company has approximately 0.5 million PRSUs outstanding. The total unrecognized estimated compensation cost related to these PRSUs is \$11.0 million and is expected to be recognized at the point when the performance conditions have been achieved, which is when these events will become probable.

During the three months ended March 31, 2015 and 2014, stock options to purchase approximately 0.7 million and 0.4 million shares of the Company's common stock were exercised, respectively. The cash received by the Company from stock option exercises during the three months ended March 31, 2015 and 2014 was approximately \$2.8 million and \$3.0 million, respectively. The Company also issued approximately 0.2 million and 0.1 million shares of common stock pursuant to the vesting of RSUs during the three months ended March 31, 2015 and 2014, respectively.

Stock Option Assumptions

The Company granted stock options to purchase approximately 0.7 million and 0.8 million shares of the Company's common stock during the three months ended March 31, 2015 and 2014, respectively. These stock options generally vest monthly over a four-year period. The exercise price of all stock options granted during the three months ended March 31, 2015 and 2014 was equal to the closing price of the Company's common stock on the date of grant. The estimated fair value of each stock option granted was determined on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions for the stock option grants:

	Three Months Ended March 31,	
	2015	2014
Risk-free interest rate	1.6%	2.3%
Expected volatility of common stock	66.6%	71.3%
Dividend yield	0.0%	0.0%
Expected option term	6.7 years	7.1 years

The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. The expected volatility is based on the historical volatility of the Company's common stock over the most recent period commensurate with the estimated expected term of the Company's stock options. The expected option term is estimated based on historical experience as well as the status of the employee. For example, directors and officers have a longer expected option term than all other employees. The risk-free rate for periods within the contractual life of the option is based upon observed interest rates appropriate for the expected term of the Company's employee stock options. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future. For the three months ended March 31, 2015 and 2014, share-based compensation expense related to stock options was \$2.4 million and \$1.9 million, respectively.

Restricted Stock Units

During the three months ended March 31, 2015, the Company granted approximately 0.4 million RSUs that vest annually over a four year period. Additionally, during the three months ended March 31, 2015 and 2014, the Company granted 50,000 and 475,000 PRSUs, respectively. These PRSUs vest based on the achievement of pre-defined Company-specific performance criteria and expire approximately five years from the grant date. As the performance based criteria for vesting for the PRSUs is not currently probable, no associated expense has been recorded for these PRSUs during the three months ended March 31, 2015. The fair value of RSUs is estimated based on the closing sale price of the Company's common stock on the date of the RSU grant. For the three months ended March 31, 2015 and 2014, share-based compensation expense related to RSUs was \$1.2 million and \$0.5 million, respectively.

6. STOCKHOLDERS' EQUITY

Equity Financing

In February 2015, the Company completed a public offering of common stock in which the Company sold 8.0 million shares of its common stock at an offering price of \$36.00 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$270.7 million.

In February 2014, the Company completed a public offering of common stock in which the Company sold 8.0 million shares of its common stock at an offering price of \$17.75 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$133.2 million.

Shelf Registration Statements

In February 2014, the Company filed an automatic shelf registration statement which immediately became effective by rule of the SEC. For so long as the Company continues to satisfy the requirements to be deemed a well-known seasoned issuer, this shelf registration statement allows the Company to issue an unlimited number of shares of its common stock from time to time. As of March 31, 2015, the Company had sold 16.0 million shares under this shelf registration statement.

In December 2012, the SEC declared effective a shelf registration statement filed by the Company in November 2012. The shelf registration statement allows the Company to issue shares of its common stock from time to time for an aggregate initial offering price of up to \$150 million. As of March 31, 2015, the Company had not sold any shares under this shelf registration statement.

The specific terms of future offerings, if any, under any of the shelf registration statements would be established at the time of such offerings.

7. REAL ESTATE

In December 2007, the Company closed the sale of its facility and associated real property for a purchase price of \$109 million. Concurrent with the sale, the Company retired the entire \$47.7 million in mortgage debt previously outstanding with respect to the facility and associated real property, and received cash of \$61.0 million net of transaction costs and debt retirement.

Upon the closing of the sale of the facility and associated real property, the Company entered into a lease agreement (Lease) with DMH Campus Investors, LLC (DMH) whereby it leased back for an initial term of 12 years its corporate headquarters comprised of two buildings located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California. The Company also entered into a series of lease amendments (Amendments), beginning in late 2008, through which it vacated the Front Building, but continues to occupy the Rear Building. The ultimate result of this real estate sale was a net gain of \$39.1 million which was deferred in accordance with authoritative guidance. The Company recognized \$0.8 million of the deferred gain during each of the three month periods ended March 31, 2015 and 2014, respectively, and will recognize the remaining \$16.8 million of the deferred gain over the initial Lease term which will expire at the end of 2019.

Under the terms of the Lease and the Amendments, the Company pays base annual rent (subject to an annual fixed percentage increase), plus a 3.5% annual management fee, property taxes and other normal and necessary expenses associated with the Lease such as utilities, repairs and maintenance. In lieu of a cash security deposit under the Lease, Wells Fargo Bank, N.A. issued on the Company's behalf a letter of credit in the amount of \$4.6 million, which is secured by a deposit of equal amount with the same bank. The Company also has the right to extend the Lease for two consecutive ten-year terms.

In December 2010, the Company entered into a sublease agreement (Sublease) for approximately 16,000 square feet of the Rear Building. The Sublease is expected to result in approximately \$0.6 million of rental income per year over the three year initial term of the Sublease and is recorded as an offset to rent expense. The Sublease provides an option to extend for two one-year renewal periods. The income generated under the Sublease is lower than the Company's financial obligation under the Lease for the Rear Building with DMH, as determined on a per square foot basis. Consequently, at December 31, 2010 the Company was required to record a cease-use liability for the net present value estimated difference between the expected income to be generated under the Sublease and future subleases and the Lease obligation over the remaining term of the Lease for the space that is occupied by the subtenant. This transaction resulted in \$2.5 million of gross cease-use expense, and a reversal of \$173,000 in associated deferred rent, each being recorded in December 2010. In August 2012, the Company extended the terms of the Sublease and increased the leased square footage to approximately 17,000 square feet. This transaction resulted in approximately \$150,000 of gross cease-use expense, and a reversal of \$15,000 in associated deferred rent, each being recorded in September 2012.

In September 2011, the Company entered into a second sublease agreement (Second Sublease) for approximately 3,300 square feet of space in the Rear Building. The Second Sublease is expected to result in approximately \$0.1 million in rental income per year over the three year term and is recorded as an offset to rent expense. The Second Sublease provides an option to extend for a one-year renewal period, and was extended for the one-year renewal period. Similar to the Sublease, the Second Sublease resulted in \$0.3 million of gross cease-use expense, and a reversal of \$47,000 in associated deferred rent, each being recorded in September 2011.

In November 2012, the Company entered into a third sublease agreement (Third Sublease) for approximately 14,000 square feet of space in the Rear Building. The Third Sublease is expected to result in approximately \$0.5 million in rental income per year over the three and a half year term and is recorded as an offset to rent expense. The Third Sublease provides the subtenant with an option to extend the term for two one-year renewal periods. Similar to the previous subleases, the Third Sublease resulted in \$1.2 million of gross cease-use expense, and a reversal of \$250,000 in associated deferred rent, each being recorded in December 2012.

[Table of Contents](#)

The following table sets forth changes to the accrued cease-use liability during the three months ended March 31, 2015 and 2014 (*in thousands*):

	Three Months Ended	
	March 31,	
	2015	2014
Beginning balance	\$ 2,678	\$ 3,096
Payments	(113)	(102)
Ending balance	<u>\$ 2,565</u>	<u>\$ 2,994</u>

8. LOSS PER COMMON SHARE

The Company computes basic net loss per share using the weighted average number of common shares outstanding during the period. In computing the diluted net loss, potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and warrants and the vesting of RSUs and PRSUs, are excluded from the diluted loss per share calculation because of their anti-dilutive effect.

For the three months ended March 31, 2015, the Company realized a net loss of \$1.2 million. Potentially dilutive securities totaled approximately 3.9 million for the three months ended March 31, 2015. Options to purchase approximately 0.1 million shares of common stock were outstanding during the three months ended March 31, 2015 with an exercise price greater than the average market price of the underlying common shares.

For the three months ended March 31, 2014, the Company realized a net loss of \$11.8 million. Potentially dilutive securities totaled approximately 3.0 million for the three months ended March 31, 2014. Options to purchase approximately 0.9 million shares of common stock were outstanding during the three months ended March 31, 2014 with an exercise price greater than the average market price of the underlying common shares.

9. RESEARCH AND DEVELOPMENT

Research and development (R&D) expenses consists primarily of salaries, payroll taxes, employee benefits, and share-based compensation charges, for those individuals involved in ongoing R&D efforts; as well as scientific contractor fees, preclinical and clinical trial costs, R&D facilities costs, laboratory supply costs, and depreciation of scientific equipment. All such costs are charged to R&D expense as incurred. These expenses result from the Company's independent R&D efforts as well as efforts associated with collaborations and in-licensing arrangements. In addition, the Company funds R&D at other companies and research institutions under agreements, which are generally cancelable. The Company reviews and accrues clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of patient studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations section contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in Part II, Item 1A under the caption "Risk Factors." The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Financial Statements and Notes thereto for the year ended December 31, 2014 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2014.

OVERVIEW

We discover and develop innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through our novel research and development (R&D) platform, focused on neurological and endocrine based diseases and disorders. Utilizing a portfolio approach to drug discovery, we have multiple small molecule drug candidates at various stages of pharmaceutical development. We develop proprietary pharmaceuticals for our pipeline, as well as collaborate with other pharmaceutical companies on our discoveries.

To date, we have not generated any revenues from the sale of products. We have funded our operations primarily through private and public offerings of our common stock and payments received under R&D collaboration agreements. While we independently develop many of our product candidates, we have entered into collaborations for several of our programs, and intend to rely on existing and future collaborators to meet funding requirements. We expect to generate future operating cash flow losses as product candidates are advanced through the various stages of clinical development. As of December 31, 2014, we had an accumulated deficit of \$826.3 million and expect to incur operating cash flow losses for the foreseeable future, which may be greater than losses in prior years.

Our two lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone (GnRH) antagonist in Phase III development for the treatment of endometriosis and Phase II clinical studies for the treatment of uterine fibroids that is partnered with AbbVie Inc. (AbbVie), and a vesicular monoamine transporter 2 (VMAT2) inhibitor for the treatment of movement disorders, currently in Phase III development. Additionally, in 2014 we advanced a third drug candidate into clinical development, our corticotropin releasing factor (CRF) receptor antagonist for the treatment of classic congenital adrenal hyperplasia (CAH). We intend to maintain certain commercial rights to our VMAT2 inhibitor and CRF antagonist programs to evolve into a fully-integrated pharmaceutical company.

AbbVie Inc. (AbbVie). In June 2010, we announced an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation GnRH antagonists (collectively, GnRH Compounds) for women's and men's health. The goal of the agreement is to develop and commercialize GnRH Compounds. AbbVie made an upfront payment of \$75 million and has agreed to make additional development and regulatory event-based payments of up to \$480 million and up to an additional \$50 million in commercial event-based payments. We have assessed event-based payments under the revised authoritative guidance for R&D milestones and determined that event-based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (1) they are events that can only be achieved in part on our past performance, (2) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (3) they result in additional payments being due to us. Development and regulatory event-based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of AbbVie. As of March 31, 2015, \$500 million remains outstanding in future event-based payments under the agreement. However, none of the remaining event-based payments meet the definition of a milestone in accordance with authoritative accounting guidance.

Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing and commercialization costs. We received funding for certain internal collaboration expenses which included reimbursement from AbbVie for internal and external expenses related to the GnRH Compounds through the end of 2012. We will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. Under the terms of our agreement with AbbVie, the collaboration effort between the parties to advance GnRH Compounds towards commercialization was governed by a joint development committee with representatives from both us and AbbVie. The collaborative development portion of the agreement concluded, as scheduled, on December 31, 2012. Our participation in the joint development committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the term of the joint development committee, which was completed in December 2012. AbbVie may terminate the collaboration at its discretion upon 180 days' written notice to us. In such event, we would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to us. Since the inception of the agreement, we have recorded revenues of \$75.0 million related to the amortization of up-front license fees, \$30.0 million in milestone revenue, and \$37.0 million in sponsored development revenue.

[Table of Contents](#)

Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe). On March 31, 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of NBI-98854 for movement disorders in Japan and other select Asian markets. Payments from Mitsubishi Tanabe under this agreement include an up-front license fee of \$30 million, up to \$85 million in development and commercialization event-based payments, payments for the manufacture of pharmaceutical products, and royalties on product sales in select territories in Asia. Under the terms of the agreement, Mitsubishi Tanabe is responsible for all third-party development, marketing and commercialization costs in Japan and other select Asian markets with the exception of a single Huntington's chorea clinical trial to be performed by us, at a cost of approximately \$12 million, should Mitsubishi Tanabe request the clinical trial. We will be entitled to a percentage of sales of NBI-98854 in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights. Under the terms of the agreement with Mitsubishi Tanabe, the collaboration effort between the parties to advance NBI-98854 towards commercialization is governed by a joint steering committee and joint development committee with representatives from both Neurocrine and Mitsubishi Tanabe. Mitsubishi Tanabe may terminate the agreement at its discretion upon 180 days' written notice to us. In such event, all NBI-98854 product rights in Japan and other select Asian markets would revert to us. During the first quarter of 2015, we have recorded revenues of \$19.8 million related to the up-front license fee. In accordance with our continuing performance obligations, \$10.2 million of the \$30 million upfront payment is being deferred and recognized in future periods.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenues under collaborative research agreements and grants, clinical trial accruals (R&D expense), share-based compensation, lease related activities, investments, and fixed assets. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The items in our financial statements requiring significant estimates and judgments are as follows:

Revenue Recognition. We recognize revenue for the performance of services when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) services are rendered or products are delivered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

Effective in 2011, we follow the Accounting Standards Codification (ASC) for Revenue Recognition - Multiple-Element Arrangements and the ASC for Collaborative Arrangements, if applicable, to determine the recognition of revenue under our license and collaboration agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses to our intellectual property, (ii) materials and technology, (iii) pharmaceutical supply, (iv) participation on joint development or joint steering committees, and (v) development services. The payments we receive under these arrangements typically include one or more of the following: up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; manufacturing and royalties on future product sales.

The ASC provides guidance relating to the separation of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, we evaluate certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. The selling prices of deliverables under an arrangement may be derived using vendor specific objective evidence (VSOE), third-party evidence, or a best estimate of selling price (BESP), if VSOE or third-party evidence is not available. For most pharmaceutical licensing and collaboration agreements, BESP is utilized. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the agreement. In validating the BESP, we consider whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

[Table of Contents](#)

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

We typically receive up-front payments when licensing our intellectual property, which often occurs in conjunction with a research and development agreement. We recognize revenue attributed to the license upon delivery, provided that the license has stand-alone value.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, we recognize the portion of the payment allocable to delivered items as revenue when the specific milestone is achieved, and the contingency is removed.

Prior to the revised multiple element guidance, described above, adopted by us on January 1, 2011, upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned were classified as deferred revenue and recognized as income over the contract or development period. Revenues from development milestones are accounted for in accordance with the Revenue Recognition – Milestone Method Topic of the FASB ASC. Milestones are recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive. A milestone event is considered to be substantive if its achievability was not reasonably assured at the inception of the agreement and our efforts led to the achievement of the milestone or the milestone was due upon the occurrence of a specific outcome resulting from our performance. We assess whether a milestone is substantive at the inception of each agreement.

Research and Development Expense. Our R&D expenditures include costs related to preclinical and clinical trials, scientific personnel, equipment, consultants, sponsored research, share-based compensation and allocated facility costs. We do not track fully burdened R&D costs separately for each of our drug candidates. We review our R&D expenses by focusing on four categories: external development, personnel, facility and depreciation, and other. External development expenses consist of costs associated with our external preclinical and clinical trials, including pharmaceutical development and manufacturing. Personnel expenses include salaries and wages, share-based compensation, payroll taxes and benefits for those individuals involved in ongoing R&D efforts. Other R&D expenses mainly represent laboratory supply expenses, scientific consulting expenses and other expenses.

Share-based Compensation. We grant stock options to purchase our common stock to our employees and directors under our 2011 Equity Incentive Plan, as amended (the 2011 Plan), and grant stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements. We also grant certain employees stock bonuses and restricted stock units (RSUs) under the 2011 Plan. Additionally, we have outstanding stock options that were granted under previous option plans from which we no longer make grants. Share-based compensation expense recognized in accordance with authoritative guidance for the three months ended March 31, 2015 and 2014 was \$3.6 million and \$2.4 million, respectively.

For purposes of calculating share-based compensation, we estimate the fair value of stock option awards using a Black-Scholes option-pricing model. The determination of the fair value of share-based compensation awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including but not limited to expected stock price volatility over the term of the awards and the expected term of stock options. Our stock options have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates. The fair value of RSUs is estimated based on the closing sale price of our common stock on the date of issuance.

Stock option awards and RSUs generally vest over a three to four year period and the corresponding expense is ratably recognized over those same time periods. For RSUs with performance-based vesting requirements (PRSUs), no expense is recorded until the performance condition is probable of being achieved.

If factors change and we employ different assumptions, share-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining share-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining share-based compensation expense for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made. If actual forfeitures vary from our estimates, we will recognize the difference in compensation expense in the period the actual forfeitures occur or at the time of vesting.

THREE MONTHS ENDED MARCH 31, 2015 AND 2014**License Fee Revenues**

As discussed above, during the first quarter of 2015, we entered into collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of our VMAT2 inhibitor NBI-98854 for movement disorders in Japan and other select Asian markets. Payments from Mitsubishi Tanabe under this agreement include an up-front license fee of \$30 million. During the first quarter of 2015, we have recorded revenues of \$19.8 million related to the up-front license fee.

Operating Expenses*Research and Development*

The following table presents our total R&D expenses by category during the periods presented:

	Three Months Ended	
	March 31,	
	2015	2014
	(In millions)	
External development expense:		
VMAT2	\$ 5.2	\$ 0.6
CRF	1.5	0.3
Other	0.3	0.2
Total external development expense	7.0	1.1
R&D personnel expense	6.6	4.7
R&D facility and depreciation expense	1.5	1.3
Other R&D expense	1.5	1.5
Total R&D expense	<u>\$ 16.6</u>	<u>\$ 8.6</u>

R&D expense increased by \$8.0 million; from \$8.6 million in the first quarter of 2014 to \$16.6 million in the first quarter of 2015. The majority of this increase in R&D expense is due to a \$5.9 million increase in external development expenses from 2014 to 2015. Our VMAT2 Phase III clinical program, which was initiated during the second half of 2014, is responsible for \$4.6 million of the increase in external development expenses. Additionally, in late 2014 we announced a new program, our CRF antagonist for congenital adrenal hyperplasia which increased external development expenses by approximately \$1.2 million. Approximately \$1.9 million of the increase in R&D expense was due to higher R&D personnel related expense, primarily due to an increase in headcount coupled with a \$0.7 million increase in share-based compensation.

General and Administrative

General and administrative expense increased to \$5.5 million in the first quarter of 2015 compared with \$4.2 million during the same period in 2014. The \$1.3 million increase in general and administrative expense is primarily due to higher personnel related costs (increased by \$1.0 million), with share-based compensation costs accounting for half of this increase. Additionally, external costs related to market research and other professional services were \$0.1 million higher for the first quarter of 2015 when compared to the same period in 2014.

Net Loss

Our net loss for the first quarter of 2015 was \$1.2 million, or a net loss of \$0.01 per share, compared to a net loss of \$11.8 million, or a net loss of \$0.17 per share, during the same period in 2014. The decrease in our net loss from 2014 to 2015 was primarily a result of \$19.8 million in revenue recognized from the up-front license fee from Mitsubishi Tanabe. This license fee revenue was offset by an increase in operating expenses of \$9.3 million.

LIQUIDITY AND CAPITAL RESOURCES

Net cash used in operating activities during the first three months of 2015 was \$18.2 million compared to \$9.8 million during the same period in 2014. The \$8.4 million increase is primarily due to an increase in operating expenses of \$9.3 million.

Net cash used in investing activities during the first three months of 2015 was \$116.1 million compared to \$65.7 million during the same period in 2014. The fluctuation in net cash used in investing activities resulted primarily from the timing differences in investment purchases, sales and maturities of investments, and the fluctuation of our portfolio mix between cash equivalents and short-term and long-term investment holdings.

[Table of Contents](#)

Net cash provided by financing activities during the first three months of 2015 was \$273.5 million compared to \$136.2 million during the same period in 2014. The increase in cash provided by financing activities was primarily due to net proceeds of approximately \$270.7 million from our public offering of common stock in February 2015, compared to net proceeds of approximately \$133.2 million from our public offering of common stock in February 2014. Stock option exercises yielded approximately \$2.8 million and \$3.0 million in cash proceeds during the first three months of 2015 and 2014, respectively.

At March 31, 2015, our cash, cash equivalents, and investments totaled \$485.5 million compared with \$231.3 million at December 31, 2014.

Equity Financing. In February 2015, we completed a public offering of common stock in which we sold 8.0 million shares of our common stock at an offering price of \$36.00 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$270.7 million.

In February 2014, we completed a public offering of common stock in which we sold 8.0 million shares of our common stock at an offering price of \$17.75 per share. The net proceeds generated from this transaction, after underwriting discounts and commissions and offering costs, were approximately \$133.2 million.

Shelf Registration Statements. In February 2014, we filed an automatic shelf registration statement which immediately became effective by rule of the SEC. For so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, this shelf registration statement allows us to issue an unlimited number of shares of our common stock from time to time. As of March 31, 2015, we had sold 16.0 million shares under this shelf registration statement.

In December 2012, the SEC declared effective a shelf registration statement filed by us in November 2012. The shelf registration statement allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to \$150 million. As of March 31, 2015, we had not sold any shares under this shelf registration statement.

We believe that our existing capital resources, together with interest income and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, we cannot guarantee that these capital resources and payments will be sufficient to conduct all of our R&D programs as planned. The amount and timing of expenditures will vary depending upon a number of factors, including progress of our R&D programs.

We may require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, the cost of product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We may seek to access the public or private equity markets whenever conditions are favorable. For example, we have an effective shelf registration statement on file with the SEC which allows us to issue an unlimited number of shares of our common stock from time to time. We may also seek additional funding through strategic alliances or other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt may involve operating covenants that may restrict our business. If adequate funds are not available through these means, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies or product candidates. To the extent that we are unable to obtain third-party funding for such expenses, we expect that increased expenses will result in increased cash flow losses from operations. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

OFF-BALANCE SHEET ARRANGEMENTS

As of March 31, 2015, we did not have any off-balance sheet arrangements.

INTEREST RATE RISK

We are exposed to interest rate risk on our short and long term investments. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum average maturity of our investments does not exceed 12 months. If a 10% change in interest rates had occurred on March 31, 2015, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments and the nature of our investments, we have concluded that we do not have a material financial market risk exposure.

NEW ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU), “Revenue from Contracts with Customers,” which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. The ASU defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The ASU as currently issued will be effective for us starting in 2017. On April 1, 2015, the FASB voted to propose a one-year deferral to the effective date, but to permit entities to adopt one year earlier if they choose (i.e., the original effective date). The proposal will be subject to the FASB’s due process requirement, which includes a period for public comments. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. We are in the process of determining the adoption method as well as the effects the adoption will have on our consolidated financial statements.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as “believes,” “expects,” “hopes,” “may,” “will,” “plan,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “proforma,” or “anticipates,” or other similar words (including their use in the negative), or by discussions of future matters such as the development or regulatory approval of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading in Part II titled “Item 1A. Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

A discussion of our exposure to, and management of, market risk appears in Part I, Item 2 of this Quarterly Report on Form 10-Q under the heading “Interest Rate Risk.”

ITEM 4. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports required by the Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officers, of any change to our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. In connection with the collaboration and license agreement entered into with Mitsubishi Tanabe in March 2015, we have developed additional internal controls over our process for accounting for revenue generating contracts. Except for these additional controls, our evaluation did not identify significant changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the quarter ended March 31, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1A. RISK FACTORS

The following Risk Factors do not reflect any material changes to the Risk Factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, other than the revisions to the risk factors set forth below with an asterisk (*) next to the title. The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations.

Risks Related to Our Company

Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.

Before obtaining regulatory approval for the sale of any of our potential products, we must subject these product candidates to extensive preclinical and clinical testing to demonstrate their safety and efficacy for humans. Clinical trials are expensive, time-consuming and may take years to complete.

In connection with the clinical trials of our product candidates, we face the risks that:

- the U.S. Food and Drug Administration (FDA) or similar foreign regulatory authority may not approve an Investigational New Drug (IND) Application or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA may require additional preclinical or clinical studies as a condition of the initiation of Phase I clinical studies, progression from Phase I to Phase II, or Phase II to Phase III, or for New Drug Application (NDA) approval;
- the product candidate may not prove to be effective or as effective as other competing product candidates;
- we may discover that a product candidate may cause harmful side effects or results of required toxicology studies may not be acceptable to the FDA;
- the results may not replicate the results of earlier, smaller trials;
- the FDA or similar foreign regulatory authorities may require use of new or experimental endpoints that may prove insensitive to treatment effects;

Table of Contents

- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- the results may not be statistically significant;
- patient recruitment may be slower than expected;
- patients may drop out of the trials; and
- regulatory requirements may change.

These risks and uncertainties impact all of our clinical programs. Specifically, with respect to our gonadotropin-releasing hormone (GnRH) program with AbbVie Inc. (AbbVie), any of the clinical, regulatory or operational events described above could delay timelines for the completion of the Phase III endometriosis program or the Phase II uterine fibroids program, require suspension of these programs and/or obviate filings for regulatory approvals. Similarly, our VMAT2 inhibitor program will be impacted if any of the events above lead to delayed timelines for the enrollment in, or completion of, the Phase III tardive dyskinesia or the Phase I Tourette syndrome clinical trials of NBI-98854.

In addition, late stage clinical trials are often conducted with patients having the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested but which can nevertheless adversely affect clinical trial results. Any failure or substantial delay in completing clinical trials for our product candidates may severely harm our business.

****We depend on our current collaborators, and may need to enter into future collaborations to develop and commercialize certain of our product candidates.***

Our strategy for fully developing and commercializing elagolix is dependent upon maintaining our current collaboration agreement with AbbVie. This collaboration agreement provides for significant future payments should certain development, regulatory and commercial milestones be achieved, and royalties on future sales of elagolix. Under this agreement, AbbVie is responsible for, among other things, conducting clinical trials and obtaining required regulatory approvals for elagolix; as well as manufacturing and commercialization of elagolix in the event it receives regulatory approval.

Because of our reliance on AbbVie, the development and commercialization of elagolix could be substantially delayed, and our ability to receive future funding could be substantially impaired, if AbbVie:

- failed to gain the requisite regulatory approval of elagolix;
- did not successfully launch and commercialize elagolix;
- did not conduct its collaborative activities in a timely manner;
- did not devote sufficient time and resources to our partnered program;
- terminated its agreement with us;
- developed, either alone or with others, products that may compete with elagolix;
- disputed our respective allocations of rights to any products or technology developed during our collaboration; or
- merged with a third party that wants to terminate our agreement.

In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe to develop and commercialize NBI-98854 in Japan and other select Asian markets. We will rely on Mitsubishi Tanabe to achieve certain development, regulatory and commercial milestones which, if achieved, could generate significant future revenue for us. Our collaboration with Mitsubishi Tanabe is subject to risks and uncertainties similar to those described above. In addition, we may need to enter into other collaborations to assist in the development and commercialization of other product candidates we are developing now or may develop in the future, and any such future collaborations would be subject to similar risks and uncertainties.

These issues and possible disagreements with AbbVie, Mitsubishi Tanabe or any future corporate collaborators could lead to delays in the collaborative research, development or commercialization of our product candidates. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization of drug candidates and, ultimately, our generation of product revenues.

Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.

All of our product candidates are currently in research or clinical development. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;

[Table of Contents](#)

- fail to receive necessary regulatory approvals on a timely basis or at all;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical to commercialize or fail to achieve market acceptance.

If any of our products encounters any of these potential problems, we may never successfully market that product.

We do not and will not have access to all information regarding the product candidates we licensed to AbbVie.

We do not and will not have access to all information regarding the products being developed and potentially commercialized by AbbVie, including potentially material information about clinical trial design and execution, safety reports from clinical trials, spontaneous safety reports if a product candidate is later approved and marketed, regulatory affairs, process development, manufacturing, marketing and other areas known by AbbVie. In addition, we have confidentiality obligations under our agreement with AbbVie. Thus, our ability to keep our shareholders informed about the status of product candidates under our collaboration with AbbVie will be limited by the degree to which AbbVie keeps us informed and allows us to disclose such information to the public. If AbbVie fails to keep us informed about the clinical development and regulatory approval of our collaboration and product candidates licensed to it, we may make operational and investment decisions that we would not have made had we been fully informed, which may materially and adversely affect our business and operations.

We have a history of losses and expect to incur negative operating cash flows for the foreseeable future, and we may never achieve sustained profitability.

Since our inception, we have incurred significant net losses and negative cash flow from operations. As a result of historical operating losses, we had an accumulated deficit of \$826.3 million as of December 31, 2014. We do not expect to be profitable, or generate positive cash flows from operations, for the year ending December 31, 2015.

We have not yet obtained regulatory approvals of any products and, consequently, have not generated revenues from the sale of products. Even if we succeed in developing and commercializing one or more of our drugs, we may not be profitable. We also expect to continue to incur significant operating and capital expenditures as we:

- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our product candidates;
- in-license or acquire new product development opportunities;
- implement additional internal systems and infrastructure; and
- hire additional clinical, scientific and marketing personnel.

We expect to experience negative cash flow in the coming years as we fund our operations, in-licensing or acquisition opportunities, and capital expenditures. We will need to generate significant revenues to achieve and maintain profitability and positive cash flow on an annual basis. We may not be able to generate these revenues, and we may never achieve profitability on an annual basis in the future. Our failure to achieve or maintain profitability on an annual basis could negatively impact the market price of our common stock. Even if we become profitable on an annual basis, we cannot assure you that we would be able to sustain or increase profitability on an annual basis.

****The price of our common stock is volatile.***

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the course of the last 12 months, the price of our common stock has ranged from approximately \$12.00 per share to approximately \$45.00 per share. The market price of our common stock may fluctuate in response to many factors, including:

- the results of our clinical trials;
- developments concerning new and existing collaboration agreements;
- announcements of technological innovations or new therapeutic products by us or others;
- general economic and market conditions;
- developments in patent or other proprietary rights;
- developments related to the FDA;
- future sales of our common stock by us or our stockholders;
- comments by securities analysts;

[Table of Contents](#)

- fluctuations in our operating results;
- government regulation;
- health care reimbursement;
- failure of any of our product candidates, if approved, to achieve commercial success; and
- public concern as to the safety of our drugs.

Because our operating results may vary significantly in future periods, our stock price may decline.

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our revenues are unpredictable and may fluctuate, among other reasons, due to our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing and contract research payments. A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect operating results in a quarter. Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline.

We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, we could lose our rights to those technologies and drug candidates.

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. For example, we license some of the core technologies used in our research and development activities and collaborations from third parties, including the GnRH receptor which we license from The Mount Sinai School of Medicine of the City University of New York for use in the elagolix program. If we were to default on our obligations under any of our licenses, we could lose some or all of our rights to develop, market and sell products covered by these licenses. Likewise, if we were to lose our rights under a license to use proprietary research tools, it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations. We also face the risk that our licensors could, for a number of reasons, lose patent protection or lose their rights to the technologies we have licensed, thereby impairing or extinguishing our rights under our licenses with them.

We have limited marketing experience, and no sales force or distribution capabilities, and if our products are approved, we may not be able to commercialize them successfully.

Although we do not currently have any marketable products, our ability to produce revenues ultimately depends on our ability to sell our products if and when they are approved by the FDA. We currently have limited experience in marketing and selling pharmaceutical products. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues will suffer.

The independent clinical investigators and contract research organizations that we rely upon to conduct our clinical trials may not be diligent, careful or timely, and may make mistakes, in the conduct of our trials.

We depend on independent clinical investigators and contract research organizations (CROs) to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, or not in compliance with Good Clinical Practices, it may delay or prevent the approval of our FDA applications and our introduction of new drugs. The CROs we contract with for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position.

We have no manufacturing capabilities. If third-party manufacturers of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may rise.

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the potential commercialization of our future products. We have no experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations, including current Good Manufacturing Practice regulations. Our third-party manufacturers might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. Our reliance on contract manufacturers also exposes us to the following risks:

[Table of Contents](#)

- contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance, and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical schedules or adequately manufacture our products in commercial quantities when required;
- switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all;
- our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store or distribute our products; and
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration, and other agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

Our current dependence upon third parties for the manufacture of our products may harm our profit margin, if any, on the sale of our future products and our ability to develop and deliver products on a timely and competitive basis.

If we cannot raise additional funding, we may be unable to complete development of our product candidates.

We may require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses and to pursue regulatory approvals for product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources, together with investment income, and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, these resources might be insufficient to conduct research and development programs to the full extent currently planned. If we cannot obtain adequate funds, we may be required to curtail significantly one or more of our research and development programs or obtain funds through additional arrangements with corporate collaborators or others that may require us to relinquish rights to some of our technologies or product candidates.

Our future capital requirements will depend on many factors, including:

- continued scientific progress in our research and development programs;
- the magnitude and complexity of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- competing technological and market developments;
- the establishment of additional strategic alliances;
- the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and
- the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. For example, we have an effective shelf registration statement on file with the Securities and Exchange Commission (SEC) which, for so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, allows us to issue an unlimited number of shares of our common stock from time to time. We also have an effective shelf registration statement on file with the SEC which allows us to issue shares of our common stock from time to time for an aggregate initial offering price of up to \$150 million. In the event that we fail to satisfy the requirements to be deemed a well-known seasoned issuer, we would be limited to using this shelf registration statement which may be used for the issuance of shares of our common stock for an aggregate initial offering price of up to only \$150 million. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

[Table of Contents](#)

If we are unable to retain and recruit qualified scientists or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts.

We are highly dependent on the principal members of our management and scientific staff. The loss of any of these people could impede the achievement of our objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to our success. We may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is commonplace in the biotechnology industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage or reimbursement for our products that could limit our product revenues and delay sustained profitability.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means may reduce our potential revenues. These payors' efforts could decrease the price that we receive for any products we may develop and sell in the future. In addition, third-party insurance coverage and adequate reimbursement levels may not be available to patients for any products we develop. Coverage and reimbursement levels may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If government and third-party payors do not provide adequate coverage and reimbursement levels for our products, or if price controls are enacted, our product revenues will suffer.

If physicians and patients do not accept our products, we may not recover our investment.

The commercial success of our products, if they are approved for marketing, will depend upon the acceptance of our products as safe and effective by the medical community and patients.

The market acceptance of our products could be affected by a number of factors, including:

- the timing of receipt of marketing approvals;
- the safety and efficacy of the products;
- the success of existing products addressing our target markets or the emergence of equivalent or superior products; and
- the cost-effectiveness of the products.

In addition, market acceptance depends on the effectiveness of our marketing strategy, and, to date, we have very limited sales and marketing experience or capabilities. If the medical community and patients do not ultimately accept our products as being safe, effective, superior and/or cost-effective, we may not recover our investment.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and NASDAQ rules, are creating uncertainty for companies such as ours. These laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. If we fail to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

Risks Related to Our Industry

We may not receive regulatory approvals for our product candidates or approvals may be delayed.

Regulation by government authorities in the United States and foreign countries is a significant factor in the development, manufacture and marketing of our proposed products and in our ongoing research and product development activities. Any failure to receive the regulatory approvals necessary to commercialize our product candidates would harm our business. The process of obtaining these approvals and the subsequent compliance with federal and state statutes and regulations require spending substantial time and financial resources. If we fail or our collaborators or licensees fail to obtain or maintain, or encounter delays in obtaining or maintaining, regulatory approvals, it could adversely affect the marketing of any products we develop, our ability to receive product or royalty revenues, our recovery of prepaid royalties, and our liquidity and capital resources. All of our products are in research and development, and we have not yet received regulatory approval to commercialize any product from the FDA or any other regulatory body. In addition, we have limited experience in filing and pursuing applications necessary to gain regulatory approvals, which may impede our ability to obtain such approvals.

In particular, human therapeutic products are subject to rigorous preclinical testing and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of biopharmaceutical products. Securing FDA approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA for each indication to establish the product candidate's safety and efficacy. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies. Any FDA or other regulatory approval of our product candidates, once obtained, may be withdrawn. If our potential products are marketed abroad, they will also be subject to extensive ongoing regulation by foreign governments.

Health care reform measures and other recent legislative initiatives could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of health care. In the United States, comprehensive health care reform legislation was enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the United States will continue to put pressure on the rate of adoption and pricing of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. Additionally, other recent federal legislation imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers are required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding distribution of the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, notification and purchaser license verification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted Federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our programs and products.

We face intense competition, and if we are unable to compete effectively, the demand for our products, if any, may be reduced.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies.

Competition may also arise from, among other things:

- other drug development technologies;
- methods of preventing or reducing the incidence of disease, including vaccines; and
- new small molecule or other classes of therapeutic agents.

Developments by others may render our product candidates or technologies obsolete or noncompetitive.

[Table of Contents](#)

We are performing research on or developing products for the treatment of several disorders including endometriosis, tardive dyskinesia, uterine fibroids, Tourette syndrome, classic congenital adrenal hyperplasia, stress-related disorders, pain, and other neurological and endocrine-related diseases and disorders, and there are a number of competitors to products in our research pipeline. If one or more of our competitors' products or programs are successful, the market for our products may be reduced or eliminated.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing and marketing experience; and
- production facilities.

If we are unable to protect our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

Our success will depend on our ability to, among other things:

- obtain patent protection for our products;
- preserve our trade secrets;
- prevent third parties from infringing upon our proprietary rights; and
- operate without infringing upon the proprietary rights of others, both in the United States and internationally.

Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Accordingly, we intend to seek patent protection for our proprietary technology and compounds. However, we face the risk that we may not obtain any of these patents and that the breadth of claims we obtain, if any, may not provide adequate protection of our proprietary technology or compounds.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our commercial collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our commercial collaborators and consultants. However, if our employees, commercial collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors.

In addition, although we own a number of patents, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In addition, in an infringement proceeding a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. Interference proceedings declared by the United States Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to management. We cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

The technologies we use in our research as well as the drug targets we select may infringe the patents or violate the proprietary rights of third parties.

We cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us or our collaborators with respect to technologies used in potential products. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party's intellectual property unless that party grants us or our collaborators rights to use its intellectual property. In such cases, we could be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if our collaborators or we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

[Table of Contents](#)

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners and vendors, could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

Any relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Our business operations and activities may be directly, or indirectly, subject to various federal and state healthcare laws, including without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may restrict or prohibit a wide range of business activities, including, but not limited to, research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

In addition, any sales of our product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We face potential product liability exposure far in excess of our limited insurance coverage.

The use of any of our potential products in clinical trials, and the sale of any approved products, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of \$10 million per occurrence and \$10 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us would decrease our cash reserves and could cause our stock price to fall.

[Table of Contents](#)

Our activities involve hazardous materials, and we may be liable for any resulting contamination or injuries.

Our research activities involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. If an accident occurs, a court may hold us liable for any resulting damages, which may harm our results of operations and cause us to use a substantial portion of our cash reserves, which would force us to seek additional financing.

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

In the ordinary course of our business, we collect and store confidential and sensitive information on our networks and in our data centers. This information includes, among other things, our intellectual property and proprietary information, the confidential information of our collaborators and licensees, and the personally identifiable information of our employees. It is important to our operations and business strategy that this information remains secure and is perceived to be secure. Despite security measures, however, our information technology and network infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. Any such attack or breach could compromise our networks and data centers and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, delays and impediments to our discovery and development efforts, and damage to our reputation.

ITEM 5: Other Information

Not applicable.

[Table of Contents](#)

ITEM 6. EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
3.1	Certificate of Incorporation(1)
3.2	Certificate of Amendment to Certificate of Incorporation(1)
3.3	Bylaws, as amended(1)
4.1	Form of Common Stock Certificate(2)
10.1**	Collaboration and License Agreement dated March 31, 2015 between Mitsubishi Tanabe Pharma Corporation and the Company
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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.

(1) Incorporated by reference to the Company's Annual Report on Form 10-K filed on February 8, 2013

(2) Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-03172)

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Neurocrine Biosciences, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

** Confidential treatment has been requested with respect to certain parts of the exhibit.

Except as specifically noted above, the Company's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K have a Commission File Number of 000-22705.

SIGNATURES

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

NEUROCRINE BIOSCIENCES, INC.
(Registrant)

Dated: April 30, 2015

/s/ TIMOTHY P. COUGHLIN

Timothy P. Coughlin
Chief Financial Officer
(Duly authorized officer and Principal Financial Officer)

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (the “*Agreement*”) is entered into as of March 31, 2015 (the “*Effective Date*”), by and between NEUROCRINE BIOSCIENCES, INC., a Delaware corporation (“*Neurocrine*”), having an address of 12780 El Camino Real, San Diego, CA 92130, U.S., and MITSUBISHI TANABE PHARMA CORPORATION, a corporation organized under the laws of Japan (“*MTPC*”), having an address of 6-18, Kitahama 2-chome, Chuo-ku, Osaka 541-8505, Japan. Neurocrine and MTPC may be referred to herein individually as a “*Party*” or collectively as the “*Parties*”.

RECITALS

WHEREAS, Neurocrine is developing its proprietary compound referred to as NBI-98854 and owns or controls certain patents, know-how and other intellectual property relating to such compound;

WHEREAS, MTPC is engaged in the research, development and commercialization of pharmaceutical products; and

WHEREAS, MTPC desires to obtain from Neurocrine, and Neurocrine desires to grant to MTPC, an exclusive license to develop, register, import, manufacture and commercialize products containing NBI-98854 in Japan, China and other Asian countries, all subject to the terms and conditions of this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Neurocrine and MTPC hereby agree as follows:

1. DEFINITIONS

1.1 “*Affiliate*” means, with respect to any party, any entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such party, but for only so long as such control exists. As used in this Section 1.1, “control” means (a) to possess, directly or indirectly, the power to direct the management or policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of more than fifty percent (50%) of the voting share capital or other equity interest in such entity.

1.2 “**Alliance Manager**” has the meaning set forth in Section 3.8.

1.3 “**Applicable Laws**” means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including MAAs) of or from any court, arbitrator, Regulatory Authority or governmental agency or authority having jurisdiction over or related to the subject item.

1.4 “**Calendar Quarter**” means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, or December 31.

1.5 “**Calendar Year**” means each respective period of twelve (12) consecutive months ending on December 31.

1.6 “**CMC**” means chemistry, manufacturing, and control.

1.7 “**CMO**” means contract manufacturing organization.

1.8 “**Commercialization**” means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Products to customers) of Products in the Field in or outside of the MTPC Territory, including: (i) sales force efforts, detailing, advertising, medical education, planning, marketing, sales force training, and sales and distribution; (ii) scientific and medical affairs; and (iii) post-approval clinical trials. “**Commercialize**” and “**Commercializing**” have correlative meanings.

1.9 “**Commercialization Plan**” has the meaning set forth in Section 6.2.

1.10 “**Commercialization Strategy**” has the meaning set forth in Section 6.1.

1.11 “**Commercially Reasonable Efforts**” means, with respect to MTPC’s obligations under this Agreement with respect to Compounds and Products, those efforts and resources that are consistent with the exercise of customary scientific and business practices, as applied in the pharmaceutical industry for development, regulatory and commercialization activities conducted with respect to products at a similar stage of development or commercialization and having similar commercial potential, taking into account relative safety and efficacy, product profile, the competitiveness of the marketplace and the market potential of such products, the nature and extent of market exclusivity, including patent coverage and regulatory data protection, and price and reimbursement status. Commercially Reasonable Efforts requires that MTPC: (i) promptly assign responsibility for each such obligation to specific employee(s) who are held accountable for progress and monitor such progress on an ongoing basis, (ii) set and seek to achieve specific and meaningful objectives for carrying out such obligation, and (iii) make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

1.12 “Committee” means the JSC, JDC or any subcommittee established by the JSC, as applicable.

1.13 “Compound” means (a) valbenazine (referred to by Neurocrine as NBI-98854), having the chemical structure set forth in the Letter Agreement, or (b) any other compound or derivative of valbenazine that is claimed in a Patent existing on the Effective Date and included in the list of Patents attached to the Letter Agreement.

1.14 “Compound Invention” has the meaning set forth in Section 10.1(b)(i).

1.15 “Confidential Disclosure Agreement” means that certain Confidential Disclosure Agreement between Neurocrine and MTPC dated as of March 13, 2014.

1.16 “Confidential Information” means all Know-How and other proprietary scientific, marketing, financial or commercial information or data that is generated by or on behalf of a Party or its Affiliates or which one Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, whether made available orally, in writing, or in electronic form, including information comprising or relating to concepts, discoveries, inventions, data, designs or formulae in relation to this Agreement; provided that all Neurocrine Technology will be deemed Neurocrine’s Confidential Information, all MTPC Technology will be deemed MTPC’s Confidential Information, and all Joint Inventions and Joint Patents will be deemed both Parties’ Confidential Information.

1.17 “CMO” means a third-party company who has contracted with either Party to Manufacture, or engage in Manufacturing activities, of Compound or the Product.

1.18 “Control” or “Controlled” means, with respect to any Know-How, Patents or other intellectual property rights, the legal authority or right (whether by ownership, license or otherwise but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant access, a license or a sublicense of or under such Know-How, Patents or other intellectual property rights to another Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.19 “Cost of Goods” means, with respect to any Compound or Product, the fully burdened cost and expense to manufacture or supply such Compound or Product, which means: (a) in the case of products and services acquired from Third Parties, including quality control and quality assurance services, payments made to such Third Parties; and (b) in the case of manufacturing services performed by a Party or its Affiliates, including manufacturing services to support products and services acquired from Third Parties as contemplated in subsection (a), the actual unit costs of manufacture, plus the variances and other costs specifically provided for herein. Actual unit costs shall consist of [...***...], all calculated in accordance with GAAP. Direct material costs shall include the costs incurred in [...***...]. Direct

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labor costs shall include the cost of: (i) [...***...]; (ii) [...***...]; and (iii) [...***...]. Manufacturing overhead attributable to such Compound or Product shall include [...***...].

1.20 “Data” means any and all scientific, technical, test, marketing or sales data pertaining to any Compound or Product that is generated by or on behalf of MTPC or its Affiliates or Sublicensees, or by or on behalf of Neurocrine or its Affiliates or, to the extent Controlled by Neurocrine, Neurocrine Collaborators, including research data, clinical pharmacology data, CMC data (including analytical, manufacturing and quality control data and stability data), pre-clinical data, clinical data or submissions made in association with an IND or MAA with respect to any Compound or Product.

1.21 “Develop” means to develop (including clinical, non-clinical and CMC development), analyze, test and conduct preclinical, clinical and all other regulatory trials for a Compound or Product, as well as all related regulatory activities and any and all activities pertaining to new indications, pharmacokinetic studies and all related activities including work on new formulations, new methods of treatment and CMC activities including new manufacturing methods. **“Developing”** and **“Development”** have correlative meanings.

1.22 “Development Plan” has the meaning set forth in Section 4.2. The initial Development Plan is attached to the Letter Agreement.

1.23 “Drug Product” has the meaning set forth in Section 7.1(a).

1.24 “EU” means the European Union.

1.25 “Excluded Claim” has the meaning set forth in Section 15.3(f).

1.26 “Executive Officers” has the meaning set forth in Section 3.5.

1.27 “Export Control Laws” means all applicable U.S. laws and regulations relating to (a) sanctions and embargoes imposed by the Office of Foreign Assets Control of the U.S. Department of Treasury or (b) the export or re-export of commodities, technologies, or services, including the Export Administration Act of 1979, 24 U.S.C. §§ 2401-2420, the International Emergency Economic Powers Act, 50 U.S.C. §§ 1701-1706, the Trading with the Enemy Act, 50 U.S.C. §§ 1 et. seq., the Arms Export Control Act, 22 U.S.C. §§ 2778 and 2779, and the International Boycott Provisions of Section 999 of the U.S. Internal Revenue Code of 1986 (as amended).

1.28 “FCPA” means the U.S. Foreign Corrupt Practices Act (15 U.S.C. Section 78dd-1, et. seq.), as amended; the UK Anti-Bribery Act, and all applicable local anti-bribery laws and regulations.

***Confidential Treatment Requested

1.29 “**Field**” means the treatment, management, prophylaxis or diagnosis of any diseases in humans.

1.30 “**First Commercial Sale**” means, on a Product-by-Product and country-by-country basis, the first sale by MTPC or any of its Affiliates or Sublicensees, or Neurocrine or any of its Affiliates or Neurocrine Collaborators, as the case may be, to a Third Party for end use or consumption of a Product in a given country in or outside of the MTPC Territory, respectively, after Regulatory Approval has been granted with respect to such Product in such country. Any sale of Product by a Party to its Affiliate or sublicensee or licensee shall not constitute a First Commercial Sale unless there is no subsequent resale of such Product by such Affiliate or sublicensee or licensee.

1.31 “**GAAP**” means the generally accepted accounting principles of the applicable country or jurisdiction, consistently applied, and means the international financial reporting standards (“**IFRS**”) at such time as IFRS becomes the generally accepted accounting standard and Applicable Laws require that a Party use IFRS.

1.32 “**Generic Product**” means, with respect to a Product in a particular regulatory jurisdiction, any pharmaceutical product that (a) (i) contains the same active pharmaceutical ingredients as such Product, in the same formulation and dosage form as such Product and for the same route of administration as such Product and is approved by the Regulatory Authority in such country (for an indication for which such Product obtained Regulatory Approval from the applicable Regulatory Authority in such jurisdiction); or (ii) is approved by the Regulatory Authority in such country as a substitutable generic for such Product (for an indication for which such Product obtained Regulatory Approval from the applicable Regulatory Authority in such jurisdiction) on an expedited or abbreviated basis in a manner that relied on or incorporated data submitted by MTPC or its Affiliate or Sublicensee in connection with the Regulatory Approval for the Product in such jurisdiction; and (b) is sold in such jurisdiction by a Third Party that is not a Sublicensee and did not purchase such product in a chain of distribution that included any of MTPC or its Affiliates or Sublicensees.

1.33 “**Global Trial**” means a clinical trial designed to obtain data to be used to support filing for and obtaining Regulatory Approval of a Product in the Field in both (a) Japan and either (b) the U.S. or EU. For the avoidance of doubt, a Global Trial does not include the HD Trial.

1.34 “**Governmental Authority**” means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization 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).

1.35 “**HD**” means chorea associated with Huntington’s Disease.

1.36 “**HD Trial**” means the clinical trial of a Product for HD to be conducted by Neurocrine and/or Neurocrine Collaborator to support filing for and obtaining Regulatory Approval of a Product for HD [...***...] as set forth in Section 4.3 (a).

1.37 “**ICC**” has the meaning set forth in Section 15.3(a).

1.38 “**ICC Rules**” has the meaning set forth in Section 15.3(a).

1.39 “**ICH**” means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.40 “**IND**” means an investigational new drug application or equivalent application filed with the applicable Regulatory Authority, which application is required to commence human clinical trials in the applicable country.

1.41 “**Initiation**” means, with respect to a clinical trial, the first dosing of the first subject in such clinical trial.

1.42 “**Inventions**” means all inventions, whether or not patentable, discovered, made, conceived, or conceived and reduced to practice, in the course of activities contemplated by this Agreement.

1.43 “**JCC**” has the meaning set forth in Section 3.3

1.44 “**JDC**” has the meaning set forth in Section 3.2.

1.45 “**JMC**” has the meaning set forth in Section 3.1(g)

1.46 “**Joint Compound Improvement Invention**” means any Invention discovered, made, conceived, or conceived and reduced to practice after the Effective Date and during the Term of this Agreement jointly by one (1) or more employees or contractors of MTPC or its Affiliates and one (1) or more employees or contractors of Neurocrine which relate to the manufacture, use, formulation or composition of any Compound.

1.47 “**Joint Inventions**” means all Inventions discovered, made, conceived, or conceived and reduced to practice jointly by one (1) or more employees or contractors of MTPC or its Affiliates and one (1) or more employees or contractors of Neurocrine, but excluding Compound Inventions, MTPC Compound Improvement Inventions or Joint Compound Improvement Inventions, after the Effective Date and during the Term of this Agreement.

1.48 “**Joint Patent**” means any Patent to the extent it claims any Joint Invention.

1.49 “**JSC**” has the meaning set forth in Section 3.1.

1.50 “**Know-How**” means all technical information, know-how and data, including inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, compositions of matter, cells, cell lines, assays, animal models and other physical, biological, or chemical materials, expertise and other technology applicable to formulations, compositions or

***Confidential Treatment Requested

products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, nonclinical and clinical data, regulatory documents, data and filings, instructions, processes, formulae, expertise and information, relevant to the research, development, manufacture, use, importation, offering for sale or sale of, or which may be useful in studying, testing, developing, producing or formulating, products, or intermediates for the synthesis thereof. Know-How excludes Patents.

1.51 “Letter Agreement” means that certain letter agreement of even date herewith by and between Neurocrine and MTPC, including all exhibits thereto.

1.52 “Losses” has the meaning set forth in Section 12.1.

1.53 “MAA” means a marketing authorization application or equivalent application, and all amendments and supplements thereto, filed with the applicable Regulatory Authority in any country or jurisdiction.

1.54 “Manufacture” or “Manufacturing” shall mean the activities required to manufacture Compounds or Products by Neurocrine, itself or through its Affiliate or CMO, including test method development and stability testing, formulation development, process development, manufacturing scale up, process validation, the manufacturing of the starting material and quality assurance/quality control.

1.55 “Materials” has the meaning set forth in Section 4.8.

1.56 “MHLW” means the Ministry of Health, Labour and Welfare, or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products in Japan.

1.57 “Milestone Event” means any event identified in Section 8.2.

1.58 “Milestone Payment” means any payment identified in Section 8.2 to be made by MTPC to Neurocrine on the occurrence of a Milestone Event.

1.59 “MTPC Compound Improvement Invention” means any Invention discovered, made, conceived, or conceived and reduced to practice after the Effective Date and during the Term of this Agreement solely by one (1) or more employees or contractors of MTPC or its Affiliates which relate to the manufacture, use, formulation or composition of any Compound.

1.60 “MTPC Data” has the meaning set forth in Section 10.1(a).

1.61 “MTPC Indemnitee” has the meaning set forth in Section 12.1.

1.62 “**MTPC Know-How**” means all Know-How that MTPC or its Affiliate Controls as of the Effective Date or during the Term, including the Joint Inventions, that is necessary or reasonably useful for the research, Development, manufacture, use, importation, offer for sale or sale of any Compound or Product in the Field. The MTPC Know-How includes the MTPC Data.

1.63 “**MTPC Patents**” means all Patents that MTPC or its Affiliate Controls as of the Effective Date or during the Term that would be infringed, absent a license or other right to practice granted under such Patents, by the research, Development, manufacture, use, importation, offer for sale or sale of any Compound or Product in the Field (considering patent applications to be issued with the then-pending claims).

1.64 “**MTPC Technology**” means the MTPC Know-How and the MTPC Patents, including MTPC’s interest in the Joint Inventions and Joint Patents.

1.65 “**MTPC Territory**” means Japan, South Korea, Taiwan, China, Indonesia, Singapore, Malaysia, Sri Lanka, Thailand, Vietnam, Hong Kong, Pakistan, Philippines, Myanmar and Brunei.

1.66 “**Net Sales**” means, with respect to any Product, [...***...], less the following deductions [...***...], with respect to the sale or other disposition of such Product:

- (a) [...***...];
- (b) [...***...];
- (c) [...***...];
- (d) [...***...]; and
- (e) [...***...].

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

Upon any sale or other disposition of any Product that should be included within Net Sales for any consideration other than exclusively monetary consideration on bona fide arms’-

***Confidential Treatment Requested

length terms, then for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at [...***...].

In no event will any particular amount identified above be deducted more than once in calculating Net Sales. Sales of a Product between MTPC and its Affiliates or Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party that is not Sublicensee shall be included within the computation of Net Sales.

MTPC and its Affiliates and Sublicensees shall not sell any Product in combination with or as part of a bundle with other products, or offer packaged arrangements to customers that include a Product, in such a manner as to disproportionately discount the selling price of the Product as compared with the weighted-average discount applied to the other products, as a percent of the respective list prices (or if not available, a good faith estimate thereof) of such products and the Product prior to applying the discount.

In the event a Product is sold as a part of a Combination Product (as defined below), the Net Sales from the Combination Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product, during the applicable royalty reporting period, by the fraction, [...***...]. In case [...***...].

1.67 “Neurocrine Collaborator” means any Third Party licensee of Neurocrine with respect to the Development and Commercialization of Compounds and Products in any country outside the MTPC Territory.

1.68 “Neurocrine Data” has the meaning set forth in Section 10.1(a).

1.69 “Neurocrine Indemnitee” has the meaning set forth in Section 12.2.

1.70 “Neurocrine Know-How” means all Know-How that Neurocrine Controls as of the Effective Date or during the Term, including the Joint Inventions, that is necessary or reasonably useful for the research, Development, manufacture, testing, use, importation, offer for sale or sale of any Compound or Product in the Field in the MTPC Territory. The Neurocrine Know-How includes the Neurocrine Data. For clarity, the Neurocrine Know-How includes the know-how and data of Neurocrine’s CMO that is necessary or reasonably useful for the manufacture of any Compound or Product; provided such Know-How is in Neurocrine’s possession and Neurocrine has the legal right to transfer such Know-How.

1.71 “Neurocrine Patents” means all Patents in the MTPC Territory that Neurocrine Controls as of the Effective Date or during the Term that would be infringed, absent a license or other right to practice granted under such Patents, by the research, Development, manufacture,

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use, importation, offer for sale or sale of any Compound or Product in the Field in the MTPC Territory (considering patent applications to be issued with the then-pending claims). The Neurocrine Patents existing as of the Effective Date are set forth in a list attached to the Letter Agreement.

1.72 “Neurocrine Technology” means the Neurocrine Know-How, information on Manufacturing, the Neurocrine Patents, including Neurocrine’s interest in the Joint Inventions and Joint Patents, and the MTPC Compound Improvement Inventions and Joint Compound Improvement Invention.

1.73 “Patents” means (a) all national, regional and international patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, and (b) any renewals, divisions, continuations (in whole or in part), or requests for continued examination of any of such patents, certificates of invention and patent applications, and any all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.74 “Phase 1 Clinical Trial” means a clinical trial in any country conducted in a small number of human volunteers designed or intended to establish an initial safety profile, pharmacodynamics, or pharmacokinetics of a Compound or Product.

1.75 “Phase 2 Clinical Trial” means a clinical trial of a Compound or Product in human patients in any country to determine initial efficacy and dose range finding before embarking on a Phase 3 Clinical Trial.

1.76 “Phase 3 Clinical Trial” means a pivotal clinical trial of a Compound or Product in human patients in any country with a defined dose or a set of defined doses of a Product designed to ascertain efficacy and safety of such Compound or Product for the purpose of submitting applications for Regulatory Approval to the competent Regulatory Authority.

1.77 “PMDA” means the Pharmaceuticals and Medical Devices Agency or any successor thereto.

1.78 “Pricing and Reimbursement Approval” means, with respect to a Product, the approval, agreement, determination or decision of any Regulatory Authority establishing the price or level of reimbursement for such Product, as required in a given country or jurisdiction prior to sale of such Product in such jurisdiction.

1.79 “Product” means any pharmaceutical product containing a Compound as an active ingredient, alone or in combination with one (1) or more other active pharmaceutical ingredients (“**Combination Product**”), in any dosage form or formulation.

1.80 “Public Official or Entity” means (a) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international governmental organization, including any ministry or department of health or any state-owned or affiliated company or hospital, or (b) any candidate for political office, any political party or any official of a political party.

1.81 “Regulatory Approval” means any and all approvals, licenses, registrations, permits, notifications and authorizations (or waivers) of any Regulatory Authority that are necessary for the manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of a Product in any country or jurisdiction.

1.82 “Regulatory Authority” means any Governmental Authority that has responsibility in its applicable jurisdiction over the testing, development, manufacture, use, storage, import, transport, promotion, marketing, distribution, offer for sale, sale or other commercialization of pharmaceutical products in a given jurisdiction, including the MHLW and PMDA in Japan. For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical product to be reimbursed by national health insurance (or its local equivalent), Regulatory Authority shall also include any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

1.83 “Regulatory Filing” means all applications, filings, submissions, approvals, licenses, registrations, permits, notifications and authorizations (or waivers) with respect to the testing, Development, manufacture or Commercialization of any Compound or Product made to or received from any Regulatory Authority in a given country, including any INDs and MAAs.

1.84 “Royalty Term” has the meaning set forth in Section 8.3(b).

1.85 “Safety Data” means Data related solely to any adverse drug experiences and serious adverse drug experience as such information is reportable to Regulatory Authorities in or outside the MTPC Territory. Safety Data also includes “adverse events”, “adverse drug reactions” and “unexpected adverse drug reactions” as defined in the ICH Harmonised Tripartite Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting.

1.86 “SEC” means the U.S. Securities and Exchange Commission, or any successor entity.

1.87 “Sublicensee” means a Third Party to whom MTPC grants a sublicense to research, Develop, make, have made, use, import, promote, offer for sale or sell any Compound or Product in the Field in the MTPC Territory (either independently from or in cooperation with MTPC), beyond the mere right to purchase Products from MTPC and its Affiliates. In no event shall Neurocrine or any of its Affiliates be deemed a Sublicensee.

- 1.88 “**Supply Agreement**” has the meaning set forth in Section 7.2(a).
- 1.89 “**Tax Withholding Avoidance Documents**” has the meaning set forth in Section 8.1.
- 1.90 “**TD**” means neuroleptic-induced or dopamine receptor antagonist-induced tardive dyskinesia.
- 1.91 “**Term**” has the meaning set forth in Section 14.1.
- 1.92 “**Third Party**” means any entity other than Neurocrine or MTPC or an Affiliate of Neurocrine or MTPC.
- 1.93 “**U.S.**” means the United States of America, including its territories and possessions and the District of Columbia.
- 1.94 “**Valid Claim**” means (a) a claim of an issued and unexpired patent that has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a claim of a pending patent application that has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

2. GRANT OF LICENSES

2.1 **Licenses Granted to MTPC.** Subject to the terms and conditions of this Agreement, Neurocrine hereby grants to MTPC, during the Term:

(a) an exclusive (even as to Neurocrine, except as expressly set forth herein), royalty-bearing license, with the right to grant sublicenses as provided in Section 2.2, under the Neurocrine Technology to research, Develop, make, have made, use and import Compounds and Products in the Field and in the MTPC Territory and to promote, offer for sale and sell Products in the Field and in the MTPC Territory, which license includes the rights (i) to incorporate Neurocrine Data in Regulatory Filings with Regulatory Authorities in the MTPC Territory or in commercialization materials and (ii) to cross-reference Regulatory Filings Controlled by Neurocrine outside the MTPC Territory, in each case (i) and (ii) solely for the purposes of (A) obtaining Regulatory Approval for Products in the Field in the MTPC Territory or (B) supporting commercialization activities; and

(b) a non-exclusive, royalty-bearing license, with the right to grant sublicenses as provided in Section 2.2, under the Neurocrine Technology to make and have made Compounds

and Products outside the MTPC Territory solely for the purpose of exercising the license granted in Section 2.1(a).

2.2 Sublicenses. MTPC shall have the right to grant sublicenses under the licenses granted in Section 2.1 (i) to any Affiliate with the prior written notice to Neurocrine, and (ii) to any Third Party in the MTPC Territory with the prior written consent of Neurocrine, which consent shall be made or denied by Neurocrine within [...***...] of MTPC's written request, otherwise such consent shall be deemed to have been given, solely for the purpose of exercising the license granted in Section 2.1. All sublicenses granted under the licenses granted in Section 2.1 shall be in writing and shall be subject to, and consistent with, the terms and conditions of this Agreement. MTPC shall ensure that each agreement with a Sublicensee grants Neurocrine all rights with respect to Data, Inventions and Regulatory Filings made or generated by such Sublicensee as if such Data, Inventions and Regulatory Filings were made or generated by MTPC. MTPC shall be responsible for the compliance of its Affiliates and Sublicensees with the terms and conditions of this Agreement. When MTPC requests Neurocrine's consent to any sublicense, MTPC shall provide Neurocrine with a full and complete copy of such sublicense agreement. MTPC may redact from the copy of the sublicense agreement any financial terms and other conditions therein which shall not be necessary to verify the compliance with the terms and conditions of this Agreement. Within [...***...] after entering into any such sublicense, MTPC shall deliver a fully executed and redacted copy of the agreement to Neurocrine.

2.3 Licenses Granted to Neurocrine. Subject to the terms and conditions of this Agreement, MTPC hereby grants to Neurocrine:

(a) An exclusive (even as to MTPC, except as expressly set forth herein and to the extent permitted by the law of any country in the MTPC Territory other than Japan), royalty-free, fully-paid, irrevocable, perpetual license, with the right to sublicense through multiple tiers, under the MTPC Technology to research, Develop, make, have made, use and import Compounds and Products in the Field outside the MTPC Territory and to promote, sell and offer for sale Products in the Field outside the MTPC Territory, which license includes the rights (i) to incorporate MTPC Data in Regulatory Filings with Regulatory Authorities outside the MTPC Territory and (ii) to cross-reference Regulatory Filings Controlled by MTPC in the MTPC Territory, in each case solely for the purpose of obtaining Regulatory Approval for Products in the Field outside the MTPC Territory; and

(b) a non-exclusive, royalty-free, fully-paid, irrevocable, perpetual license, with the right to sublicense through multiple tiers, under the MTPC Technology to make and have made Compounds and Products in the MTPC Territory solely for the purpose of exercising the license granted in Section 2.3(a) and the reserved rights in Section 2.4

2.4 Reserved Rights. Neurocrine hereby expressly reserves (a) all rights to practice, and to grant licenses under, the Neurocrine Technology outside of the scope of the licenses granted in Section 2.1, for any and all purposes, (b) the right to conduct all activities to be conducted by Neurocrine as contemplated by this Agreement, including activities (if any) under the Development Plan, and as contemplated by the Supply Agreement and (c) the non-exclusive right to make and have made Compounds and Products in the MTPC Territory for the purpose of researching, Developing, making, having made, using and exporting Compounds and Products in

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the Field outside the MTPC Territory and promoting, selling and offering for sale Products in the Field outside the MTPC Territory. Subject only to the rights expressly granted under Section 2.3, MTPC hereby expressly reserves all rights to practice, and to grant licenses under, the MTPC Technology for any and all purposes.

2.5 No Implied Licenses; Negative Covenant. Except as set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under or to any Patents, Know-How or other intellectual property owned or controlled by the other Party. Neither Party shall, nor shall it permit any of its Affiliates or sublicensees to, practice any Patents or Know-How licensed to it by the other Party outside the scope of the licenses granted to it under this Agreement.

2.6 Disclosure of Know-How. Neurocrine shall, without additional compensation, disclose and make available to MTPC, in whatever form MTPC may reasonably request (including by providing copies thereof), all Neurocrine Know-How (i) that is in existence as of the Effective Date, promptly after the Effective Date and (ii) that comes into existence after the Effective Date and that was not previously provided to MTPC, promptly after the earlier of the development, making, conception or reduction to practice of such Neurocrine Know-How. MTPC shall and shall cause its Affiliates to, without additional compensation, disclose and make available to Neurocrine, in whatever form Neurocrine may reasonably request (including by providing copies thereof), any MTPC Know-How not previously provided to Neurocrine, promptly after the earlier of the development, making, conception or reduction to practice of such MTPC Know-How.

2.7 Data Access. In any agreement entered into by Neurocrine after the Effective Date with a Neurocrine Collaborator, if such Neurocrine Collaborator is involved in generation of Data, Neurocrine shall use commercially reasonable efforts to require that such Neurocrine Collaborator allow Neurocrine to provide MTPC access to and the right to use all such Data generated by such Neurocrine Collaborator, without additional compensation, to the extent that such Data is reasonably useful for Development or Commercialization of Compounds and Products in the Field for the MTPC Territory, including preparation and filing of MAAs for a Product with the applicable Regulatory Authorities in the MTPC Territory, in accordance with this Agreement. If Neurocrine is unable, after using commercially reasonable efforts, to require that any such Neurocrine Collaborator allow Neurocrine to provide MTPC access to all such Data generated by such Neurocrine Collaborator, then notwithstanding Section 2.3, Neurocrine shall not have the right to provide and to grant a sublicense with respect to all MTPC Data to such Neurocrine Collaborator. Notwithstanding the foregoing, Neurocrine shall require each Neurocrine Collaborator to allow Neurocrine to provide to MTPC access and the right to use all Data related to Compounds and Products that is (i) Safety Data or (ii) otherwise necessary to be provided to any Regulatory Authority in the MTPC Territory in connection with the Development and Commercialization of Compounds and Products in the Field in the MTPC Territory and shall only provide to such Neurocrine Collaborator that MTPC Data that is either (a) Safety Data or (b) otherwise necessary to be provided to any Regulatory Authority outside

the MTPC Territory in connection with the Development and Commercialization of Compounds and Products in the Field outside the MTPC Territory.

3. GOVERNANCE

3.1 Joint Steering Committee. Promptly after the Effective Date, the Parties shall establish a joint steering committee (the “*Joint Steering Committee*” or the “*JSC*”), composed of an equal number of senior officers of each Party (initially three (3)) to oversee and guide the strategic direction of the collaboration of the Parties under this Agreement. The JSC shall in particular:

- (a) [...***...];
- (b) [...***...];
- (c) [...***...];
- (d) [...***...];
- (e) [...***...];
- (f) [...***...];
- (g) [...***...]; and
- (h) [...***...].

3.2 Joint Development Committee. Promptly after the Effective Date, the Parties shall establish a joint development committee (the “*Joint Development Committee*” or the “*JDC*”), composed of three (3) representatives of each Party, to review and discuss the Development of Compounds and Products in the Field in the MTPC Territory (and if applicable pursuant to Section 4.3, outside the MTPC Territory for the purpose of Regulatory Approval in the MTPC Territory), at the operational level. Each JDC representative shall have knowledge and expertise in the clinical development of products similar to Products. The JDC shall in particular:

- (a) [...***...]

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[...***...];

- (b) [...***...];
- (c) [...***...];
- (d) [...***...];
- (e) [...***...]; and
- (f) [...***...].

3.3 Joint Commercialization Committee. At a time to be determined by the JSC but in no event later than the commencement of the first filing of an MAA in the MTPC Territory, the Parties shall establish a joint commercialization committee (the “*Joint Commercialization Committee*” or the “*JCC*”), composed of three (3) representatives of each Party, to monitor and discuss the Commercialization of Products in the Field at the operational level. Each JCC representative shall have knowledge and expertise in the commercialization of products similar to Products. The JCC shall in particular:

- (a) [...***...];
- (b) [...***...];
- (c) [...***...];
- (d) [...***...]; and
- (e) [...***...].

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3.4 Committee Membership and Meetings.

(a) **Committee Members.** Each Committee representative shall have appropriate knowledge and expertise and sufficient seniority within the applicable Party to make decisions arising within the scope of the applicable Committee's responsibilities. Each Party may replace its representatives on any Committee on written notice to the other Party, but each Party shall strive to maintain continuity in the representation of its Committee members. Each Party shall appoint one (1) of its representatives on each Committee to act as a co-chairperson of such Committee. The co-chairpersons shall jointly prepare and circulate agendas to Committee members at least [...***...] before each Committee meeting and shall direct the preparation of reasonably detailed minutes for each Committee meeting, which shall be approved by the co-chairpersons and circulated to Committee members within [...***...] of such meeting.

(b) **Meetings.** Each Committee shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every [...***...], unless otherwise agreed by the Parties. Upon reasonable written request by any Party to hold ad-hoc meetings, both Parties agree to schedule such ad-hoc meetings within a reasonable time frame. Meetings of any Committee may be held in person, or by audio or video teleconference; provided that unless otherwise agreed by both Parties, at least [...***...] for each Committee shall be held in person, and all in-person Committees shall be held at locations alternately selected by the Parties. Each Party shall be responsible for all of its own expenses of participating in any Committee meetings. No action taken at any meeting of a Committee shall be effective unless at least one representative of each Party is participating.

(c) **Non-Member Attendance.** Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend the Committee meetings in a non-voting capacity; provided that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide at least [...***...] prior written notice to the other Party and obtain the other Party's approval for such Third Party to attend such meeting, which approval shall not be unreasonably withheld or delayed. Such Party shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

3.5 Decision-Making. All decisions of each Committee shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JDC, JCC or another subcommittee of the JSC, the representatives of the Parties cannot reach an agreement as to such matter within [...***...] after such matter was brought to such Committee for resolution, such disagreement shall be referred to the JSC for resolution. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the representatives of the Parties cannot reach an agreement as to such matter within [...***...] after such matter was brought to the JSC for resolution or after such matter has been referred to the JSC, such disagreement shall be referred to the Chief Executive Officer of Neurocrine and the Chief Executive Officer of MTPC or its designee (collectively, the "Executive Officers") for resolution as follows:

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(a) If [...***...], then the Executive Officers shall discuss in good faith a resolution of the matter that addresses both MTPC's objectives and Neurocrine's concern for worldwide Development and Commercialization of Products, and if the Executive Officers cannot resolve such matter within [...***...] after such matter has been referred to them, the Chief Executive Officer of [...***...] shall be entitled to make the final decision; provided that such decision shall be made in good faith [...***...].

(b) If [...***...], then the Executive Officers shall discuss in good faith a resolution of the matter, and if the Executive Officers cannot resolve such matter within [...***...] after such matter has been referred to them, the Chief Executive Officer of [...***...] shall be entitled to make the final decision; provided that such decision shall be made in good faith [...***...].

3.6 Limitations on Authority. Each Committee shall have only such powers as are expressly assigned to it in this Agreement, and such powers shall be subject to the terms and conditions of this Agreement. Without limiting the generality of the foregoing, no Committee will have the power to amend this Agreement, and no decision of a Committee may be in contravention of any terms and conditions of this Agreement.

3.7 Withdrawal. At any time during the Term and for any reason, Neurocrine shall have the right to withdraw from participation in any Committee upon written notice to MTPC, which notice shall be effective immediately upon receipt ("**Withdrawal Notice**"). Following the issuance of a Withdrawal Notice and subject to this Section 3.7, Neurocrine's representatives to the applicable Committee shall not participate in any meetings of such Committee. If, at any time following the issuance of a Withdrawal Notice, Neurocrine wishes to resume participation in the applicable Committee, Neurocrine shall notify MTPC in writing, and thereafter, Neurocrine's representatives to such Committee shall be entitled to attend any subsequent meeting of such Committee and to participate in the activities of, and decision-making by, such Committees as provided in this Article 3 as if a Withdrawal Notice had not been issued by Neurocrine. Following Neurocrine's issuance of a Withdrawal Notice, unless and until Neurocrine resumes participation in the applicable Committee in accordance with this Section 3.7(a) all meetings of the applicable Committee will be held at MTPC's facilities; and (b) Neurocrine shall have the right to continue to receive the minutes of such Committee meetings, but shall not have the right to approve the minutes for any meeting of such Committee held after Neurocrine's issuance of a Withdrawal Notice.

3.8 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual to act as the alliance manager for such Party (the "**Alliance Manager**"). Each Alliance Manager shall be responsible for alliance management between the Parties on a day-to-day basis throughout the Term. Each Alliance Manager shall be permitted to attend meetings of the JSC and other Committees as appropriate as non-voting participants. The Alliance Managers

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shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JSC and its subcommittees.

4. DEVELOPMENT

4.1 Development Responsibilities.

(a) **Development in the MTPC Territory.** Subject to the terms and conditions of this Agreement, MTPC (itself and with its Affiliates and Sublicensees, as applicable) shall be responsible, at its sole cost and expense, for all Development of Compounds and Products, including all clinical trials, formulation studies and regulatory activities, that are necessary for or otherwise support obtaining and maintaining Regulatory Approval solely in the MTPC Territory. MTPC may reasonably request that Neurocrine conduct or assist MTPC with certain of such Development activities on MTPC's behalf. If Neurocrine agrees to conduct or assist with any such activities, the Parties shall amend the Development Plan accordingly, and MTPC shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by Neurocrine to conduct such activities in accordance with the Development Plan provided that items and costs of such Development activities shall be discussed and agreed upon in advance between the Parties. For clarity, such Development activities which MTPC may request Neurocrine, itself or through any Affiliate or CMO, to conduct shall include Manufacturing activities which may be required for Regulatory Approval solely in the MTPC Territory.

(b) **Development Outside the MTPC Territory.** Subject to Section 4.3, Neurocrine (itself and with its Affiliates and Neurocrine Collaborators, as applicable) shall be responsible, at its sole cost and expense, for all Development of Compounds and Products that support obtaining and maintaining Regulatory Approval outside the MTPC Territory. Neurocrine, itself or through an Affiliate or Neurocrine Collaborators, may conduct all such activities in its sole discretion.

4.2 **Development Plan.** MTPC shall conduct all Development of Compounds and Products in the Field in the MTPC Territory in accordance with a comprehensive development plan (as amended in accordance with this Agreement, the "**Development Plan**"), the initial version of which has been agreed by the Parties and is attached to the Letter Agreement. The Development Plan will include Development of a Product for HD and TD in the MTPC Territory (unless Development of either such indication is terminated in accordance with the terms of this Agreement). The Parties intend that the Development Plan will include detailed descriptions of each clinical trial described therein; including the design, enrollment criteria, endpoints and protocols thereof, as well as the regulatory strategy for Products throughout the MTPC Territory, and MTPC will include all such information in the Development Plan when available. From time to time, but at least [...***...], MTPC will update the Development Plan and submit such updated plan to the JDC for review and discussion. The JDC will then submit the Development Plan to the JSC for review, discussion and approval.

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4.3 Joint Development.

(a) HD Trial. The Parties acknowledge that patient recruitment for clinical trials necessary for Regulatory Approval of a Product for HD in Japan may be unreasonably difficult, and that it might be in the best interests of the Commercialization of a Product in the MTPC Territory to instead use data from a HD Trial to obtain such Regulatory Approval. Promptly after the Effective Date, MTPC shall consult with PMDA with respect to the design and enrollment criteria for any clinical trials necessary to obtain Regulatory Approval of a Product for HD in Japan. MTPC shall promptly notify Neurocrine of the outcome of such consultation. Neurocrine and MTPC shall discuss in good faith and mutually agree on the study design, protocol and cost of the HD Trial prior to the initiation of the HD Trial by Neurocrine. Neurocrine shall initiate the HD Trial no later than [...***...]. MTPC shall update the Development Plan to include the HD Trial according to consultation by Neurocrine. Neurocrine shall conduct, at its own cost and expense, the HD Trial in accordance with the Development Plan; provided that [...***...].

(b) Global Trials. If the Parties agree to conduct a Global Trial, then the Parties and, if applicable, the relevant Neurocrine Collaborators shall discuss in good faith and determine the terms under which the Parties will conduct such Global Trial, including the allocation between the Parties of costs and expenses, decision-making process and authority for trial design and protocols, management of budget overages, allocation of Development activities and responsibilities and data sharing procedures. Neurocrine shall determine, in its sole discretion, whether and to what extent it participates in any cost-sharing or other activities related to Global Trials. Upon agreement, the Parties shall enter into a written agreement setting forth all such agreed terms.

4.4 Conduct of Development Activities. MTPC shall Develop Compounds and Products in the Field in the MTPC Territory in compliance with all Applicable Laws, including the FCPA and good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted. Neurocrine shall perform its obligations under this Agreement in compliance with all Applicable Laws, including the FCPA and good scientific and clinical practices under the Applicable Laws of the country in which such activities are conducted.

4.5 Records and Updates. MTPC shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of MTPC in the performance of Development activities pursuant to this Agreement. MTPC shall keep the JSC regularly

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informed of the status of all Development activities with respect to Compounds and Products in the Field in the MTPC Territory conducted by it pursuant to this Agreement. Without limiting the foregoing, at least [...***...], MTPC shall provide the JSC with summaries in reasonable detail of all data and results generated or obtained in the course of MTPC's and its Affiliates' and Sublicensees' performance of activities with respect to Compounds and Products in the Field in the MTPC Territory. Neurocrine shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of Neurocrine in the performance of Development activities requested by MTPC pursuant to this Agreement. Neurocrine shall keep the JSC regularly informed of the status of all Development activities with respect to Compounds and Products outside the MTPC Territory conducted by it pursuant to this Agreement. Without limiting the foregoing, at least [...***...] Neurocrine shall provide the JSC with summaries in reasonable detail of all data and results generated or obtained in the course of Neurocrine's and its Affiliates' and Collaborators' performance of Development activities requested by MTPC pursuant to this Agreement with respect to Compounds and Products outside the MTPC Territory.

4.6 Development Diligence. MTPC shall use Commercially Reasonable Efforts to Develop, file MAAs and, as applicable, seek Pricing and Reimbursement Approval for and seek and maintain Regulatory Approval for Products in the Field throughout the MTPC Territory. MTPC shall conduct all such activities in accordance with the Development Plan.

4.7 Use of Subcontractors. MTPC may perform its Development activities under this Agreement through one or more subcontractors, provided that (a) MTPC will remain responsible for the work allocated to, and payment to, such subcontractors to the same extent it would if it had done such work itself; (b) each subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Article 13, and (c) each subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work. For clarity, any intellectual property owned, developed or licensed by, or on behalf of such subcontractor, prior to, or independent of, subcontractor's performance of any such work shall be subcontractor's property and shall not assign to MTPC. MTPC may also subcontract work on terms other than those set forth in this Section 4.7 with the prior approval of the JDC.

4.8 Materials Transfer. In order to facilitate the Development activities contemplated by this Agreement, either Party may provide to the other Party certain biological materials or chemical compounds Controlled by the supplying Party (collectively, "**Materials**") for use by the other Party in furtherance of such Development activities. Except as otherwise provided for under this Agreement, all such Materials delivered to the other Party will remain the sole property of the supplying Party, will be used only in furtherance of the Development activities conducted in accordance with this Agreement, will not be used or delivered to or for the benefit of any Third Party, except for subcontractors, without the prior written consent of the supplying Party, and will be used in compliance with all Applicable Laws. The Materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. Except as expressly set forth in this Agreement, THE MATERIALS ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT

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LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

5. REGULATORY ACTIVITIES

5.1 Conduct of Regulatory Activities. MTPC shall be solely responsible for formulating regulatory strategy and for preparing, filing, obtaining and maintaining Regulatory Approvals for Products in the Field in the MTPC Territory. MTPC, its Affiliate or Sublicensee shall be the holder of all Regulatory Approvals for Products in the Field in the MTPC Territory and shall have responsibility for interactions with Regulatory Authorities with respect to Products in the Field in the MTPC Territory. MTPC shall consult with Neurocrine through the JDC regarding, and keep Neurocrine regularly informed of, the preparation, Regulatory Authority review and approval of submissions and communications with Regulatory Authorities with respect to Products in the Field in the MTPC Territory. In addition, MTPC shall promptly provide Neurocrine with copies of any material documents, information and correspondence received from a Regulatory Authority with an English summary thereof and, upon reasonable request by Neurocrine, with copies of any other documents, reports and communications from or to any Regulatory Authority relating to Compounds, Products or activities under this Agreement, with an English summary thereof. Except as agreed otherwise by the Parties under Section 4.3, MTPC shall bear all expenses it incurs to conduct all regulatory activities in the MTPC Territory under this Agreement.

5.2 Neurocrine Activities. Neurocrine agrees to keep MTPC informed of the preparation, Regulatory Authority review and approval of submissions and communications with Regulatory Authorities with respect to Products in the Field outside the MTPC Territory. In addition, Neurocrine shall, upon reasonable request by MTPC, promptly provide MTPC with copies of any material documents, information and correspondence received from a Regulatory Authority outside the MTPC Territory in Neurocrine's possession and Neurocrine has the legal right to transfer. In the event that Neurocrine Data shall be incorporated in the Regulatory Filing to obtain Regulatory Approvals in MTPC Territory, Neurocrine shall promptly provide MTPC copies of any modification, correction and revision of such Neurocrine Data to fulfill MTPC's obligation in Development and Regulatory Approval in the MTPC Territory. In addition, in such case, Neurocrine shall retain any records relating to or supporting for such Neurocrine Data incorporated in the Regulatory Filing in the MTPC Territory as long as any Regulatory Agency in the MTPC Territory requires MTPC, its Affiliates or Sublicensees to keep such records. Upon MTPC's reasonable request, Neurocrine shall assist MTPC to fulfill the requirements of any Regulatory Agency in the MTPC Territory related to Neurocrine Data incorporated in the Regulatory Filing in the MTPC Territory, and MTPC shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by Neurocrine to conduct such activities, provided that items and costs of such activities shall be discussed and agreed upon in advance between the Parties.

5.3 Inspections and Audits.

(a) **By Regulatory Authorities.** In the event that MTPC receives any correspondence, inquiry or request for an inspection or audit from a Regulatory Authority which relates to Neurocrine Data, MTPC shall promptly notify Neurocrine of such correspondence, inquiry or request of any inspection or audit. Neurocrine shall cooperate with MTPC in responding to such correspondence, inquiry or any inspection or audit concerning any of Neurocrine Data, and MTPC shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by Neurocrine to conduct such activities.

(b) **By MTPC.** In the event that Neurocrine Data shall be incorporated in the Regulatory Filing to obtain Regulatory Approvals in MTPC Territory, Neurocrine shall permit MTPC's authorized representatives to conduct a reasonable examination or quality inspection of such Neurocrine Data.

5.4 Adverse Event Reporting; Pharmacovigilance Agreement. As between the Parties: (a) Neurocrine shall be responsible for the timely reporting of all quality, complaints and Safety Data relating to Compounds and Products to the appropriate Regulatory Authorities outside the MTPC Territory; and (b) except as otherwise agreed in writing by the Parties, MTPC shall be responsible for the timely reporting of all quality, complaints and Safety Data relating to Compounds and Products to the relevant Regulatory Authorities in the MTPC Territory, in each case in accordance with Applicable Laws of the relevant countries and Regulatory Authorities. The Parties shall cooperate with each other with respect to their respective pharmacovigilance responsibilities, and each Party shall be solely responsible for costs relating to its respective pharmacovigilance responsibilities, unless agreed otherwise by the Parties in writing. The Parties shall negotiate in good faith and enter into, in timely manner, a mutually acceptable pharmacovigilance agreement with respect to the Compound and Product. Unless otherwise mutually agreed, such pharmacovigilance agreement shall cover the exchange of safety information and appropriate management of pharmacovigilance activities to fulfill all legal and regulatory requirements both inside and outside of the MTPC Territory.

6. COMMERCIALIZATION

6.1 Commercialization. MTPC shall have the exclusive right to Commercialize Products in the Field in the MTPC Territory during the Term, subject to the terms and conditions of this Agreement. Without limiting the foregoing, during the Term, MTPC will have the exclusive right and responsibility for the following with respect to Products in the Field in the MTPC Territory: (a) establishing the Commercialization (including marketing) strategy and tactics (the "**Commercial Strategy**"); (b) establishing pricing and reimbursement; (c) managed care contracting; (d) receiving, accepting and filling orders; (e) distribution to customers; (f) controlling invoicing, order processing and collecting accounts receivable for sales; and (g) recording sales in its books of account for sales.

6.2 Commercialization Plan. [...***...], MTPC shall prepare a preliminary, non-binding commercialization plan for the marketing, promotion and pricing of Products in the Field in the MTPC Territory during the [...***...] after First Commercial

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Sale in the MTPC Territory. [...***...], MTPC shall prepare a non-binding plan for the marketing, promotion and pricing of Products in the Field in such country during the [...***...] after First Commercial Sale in such country, which plan shall be reasonable in scope and detail and may be amended by MTPC (the “**Commercialization Plan**” for such country). MTPC shall update each Commercialization Plan on a yearly basis in connection with royalty payments under Section 9.1 (to cover the subsequent [...***...]) and shall promptly provide each such update and any material amendments to each Commercialization Plan to Neurocrine through the JCC. Without limiting the provisions of this Section 6.2, through the JCC, MTPC shall regularly consult with and provide updates to Neurocrine regarding the Commercial Strategy and Commercialization of Products in the Field in the MTPC Territory.

6.3 Diligence. During the Term, MTPC shall use Commercially Reasonable Efforts to market, promote and otherwise Commercialize a Product in the Field throughout the MTPC Territory. Without limiting the foregoing, MTPC shall use Commercially Reasonable Efforts to achieve First Commercial Sale of a Product in each country in the MTPC Territory within a reasonable time [...***...].

7. MANUFACTURE AND SUPPLY

7.1 Development Supply.

(a) Obligations. Neurocrine, itself or through any Affiliate or CMO, shall supply all of MTPC’s, its Affiliates’ and Sublicensees’ requirements of Compounds and Products, including matched placebo, in the form of drug product (“**Drug Product**”), or in the form of bulk Compound (“API”) if MTPC requests, for all Development of Compounds and Products in the Field in the MTPC Territory, pursuant to a separate supply agreement to be entered into between the Parties (the “**Development Supply Agreement**”), along with a quality agreement, reasonably in advance of anticipated first development supply of API or Drug Product in the MTPC Territory. Unless agreed otherwise by the Parties, MTPC shall use all API or Drug Product supplied by Neurocrine under this Section 7.1 solely to conduct Development in the Field in the MTPC Territory in accordance with the terms of this Agreement. Notwithstanding anything in this Agreement to the contrary, at any time MTPC may elect to manufacture Compounds and Products itself for its Development use in the MTPC Territory, provided that MTPC shall remain responsible for payment for supply of all API or Drug Product under outstanding purchase orders submitted to Neurocrine.

(b) Price. All Drug Product supplied by Neurocrine for Development use will be supplied at a price of (i) [...***...] and (ii) [...***...] and (iii) a price corresponding to the above (i) and (ii) in case of Drug Product in strength other than [...***...]. Neurocrine will invoice MTPC within [...***...] after the acceptance of each shipment of Drug Product or API is notified by MTPC pursuant to the Section 7.1(e), and MTPC will pay each such invoice within [...***...] after receipt thereof. The price of such API and Drug Product may be changed due to an unexpected cost increase, such as a substantial increase of the raw materials costs. In such case,

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Neurocrine shall notify MTPC of the proposed changed price and reason for such change and the Parties shall agree in good faith to be supplied at the updated Neurocrine's Cost of Goods.

(c) Forecasting and Ordering. As soon as practicable after the Effective Date, MTPC shall provide Neurocrine with forecasts of MTPC's purchase orders for API and Drug Product for Development use, which may be placed for the initial [...***...] after the Effective Date, and thereafter, MTPC will provide Neurocrine with non-binding forecasts of MTPC's subsequent purchase orders for Drug Product and API for Development use [...***...] prior to the estimated date of placing each such purchase order. Upon receipt of MTPC's non-binding forecast above, Neurocrine shall confirm whether the stock of API which can be allocated for anticipated MTPC's purchase orders and shall provide the forecast of the stock of API for MTPC's use for the following [...***...], then notify of such availability or non-availability and forecast of such API stock to MTPC. The purchase orders for Development use shall be placed to allow no less than [...***...] in case of Drug Product and [...***...] in case of API lead time prior to the delivery dates specified in such purchase orders, and Neurocrine will use commercially reasonable efforts to comply with the requested delivery dates. In the event there is no API available to manufacture Drug Product, purchase orders for Drug Product for Development use shall be placed to allow no less than [...***...] lead time prior to the delivery dates in the purchase order. Purchase orders for Drug Product and API for Development use will be non-cancelable. The JDC or the JMC (if and when the JMC is formed) shall coordinate the forecasting, ordering and supply of API and Drug Product under this Section 7.1.

(d) Compliance. Neurocrine, itself or through its Affiliate or CMO, shall manufacture Drug Product or API in compliance with all Applicable Laws and in accordance with such appropriate quality, specifications and test methods, formula and manufacturing process as specified by mutual written agreement of Neurocrine and MTPC, which may not be changed by Neurocrine without prior written consent of MTPC, except as may be required by any Regulatory Authorities. MTPC shall not use Drug Product or API that to MTPC's knowledge does not meet the then-prevailing quality, specifications and test methods, formula and manufacturing process.

(e) Acceptance. MTPC shall confirm the quality of the Drug Product or API delivered by Neurocrine's CMOs conforms to the specifications and shall use the testing method specified by mutual agreement of Neurocrine and MTPC. In case that any quantity of Drug Product or API supplied by Neurocrine's CMOs hereunder does not, at the time of delivery, conform to the then-prevailing specifications, Neurocrine shall at its own cost replace such quantity of the Drug Product or API with material of the quality specified in such specifications, and MTPC shall at Neurocrine's option and expense return to Neurocrine or its CMO or dispose of such quantity of the Drug Product or API that failed to meet such specifications; provided, however, that MTPC shall have notified Neurocrine, within [...***...] from receipt of the applicable Drug Product or API of the failure of such quantity to meet the specifications and in any event before MTPC uses such Drug Product or API for any purpose. If MTPC notifies Neurocrine within such [...***...] that the Drug Product or API does not conform to the specifications, Neurocrine may have the relevant Drug Product or API tested by an appropriate independent laboratory reasonably acceptable to MTPC to determine finally whether or not the Drug Product or API conforms to its specifications. The results of such test

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carried out by the laboratory shall be binding upon the Parties. The expenses of the laboratory will be borne by the Party against which the laboratory rules. ALL OTHER EXPRESS AND IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE SPECIFICALLY DISCLAIMED BY NEUROCRINE AND EXCLUDED FROM THE TERMS OF SALE OF THE DRUG PRODUCT OR API.

(f) Responsibility of Quality. Neurocrine shall perform and have sole responsibility for all quality tests on API and Drug Product manufactured by Neurocrine or Neurocrine's CMO. Neurocrine shall prepare, maintain and retain all required documents, data and retained sample including batch record, certificate of analysis, GMP statement and TSE statement, relating to the Manufacturing of API and Drug Product in accordance with the Applicable Law and regulations and shall, upon request of MTPC, furnish MTPC with copies of those documents and data. For avoidance of doubt, MTPC may perform, in its sole discretion, such quality tests on API and Drug Product Manufactured by Neurocrine or Neurocrine's CMO upon its receipt according to the test methods to be transferred by Neurocrine.

7.2 Commercial Supply.

(a) Supply Agreement. Unless and until elected otherwise by MTPC, Neurocrine, itself or through its Affiliate or CMO, shall manufacture and supply MTPC's, its Affiliates' and Sublicensees' requirements for Compounds and Products, either as (i) API or (ii) Drug Product, for commercial use in the MTPC Territory, pursuant to a separate supply agreement to be entered into between the Parties (the "**Supply Agreement**"), along with a quality agreement, reasonably in advance of anticipated First Commercial Sale of Product in the MTPC Territory. Pursuant to the Supply Agreement, Neurocrine will supply either API or Drug Product at a transfer price of (i) [...***...] and (ii) [...***...] and (iii) a price corresponding to the above (i) and (ii) in case of Drug Product in strength other than [...***...] per capsule. The transfer price may be changed due to unexpected cost increase, such as substantial increase of the raw material or other costs. In such case, Neurocrine shall notify MTPC of the proposed changed transfer price and reason for such change and the Parties shall agree with the revision of the transfer price in good faith. [...***...], then the Parties shall negotiate in good faith and agree with the revision of the transfer price. MTPC shall be solely responsible for formulating API supplied by or on behalf of Neurocrine (if so supplied) into Drug Product and for packaging and labeling such Drug Product manufactured by MTPC, or Drug Product supplied by or on behalf of Neurocrine, as the case may be, for commercial use in the Field in the MTPC Territory.

(b) MTPC's Manufacture and Transition. Notwithstanding Section 7.2(a), at any time, MTPC may assume responsibility for manufacturing and supplying API or Drug Product for commercial use in the MTPC Territory; provided that MTPC shall notify Neurocrine at least [...***...] prior to its anticipated establishment of such supply and keep Neurocrine reasonably informed of its progress in establishing such supply. Upon such notice, Neurocrine and MTPC will in good faith prepare and agree on a schedule and plan pursuant to which MTPC (directly or through its Affiliate or CMOs) will assume such manufacturing responsibility.

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For clarity, in case MTPC assumes the manufacturing and supplying API or Drug Product, Neurocrine shall not unreasonably refuse MTPC to right to use the CMO (including the CMO for the manufacturing of the starting material) that is the same as the one Neurocrine used to manufacture API or Drug Product. The Parties agree to discuss in good faith a joint purchasing arrangement, to the extent permitted by Applicable Law.

7.3 Formulation Activities. If MTPC desires to use a different formulation of Drug Product, in connection with Development or Commercialization of Compounds and Products in the Field in the MTPC Territory, from the one that Neurocrine is developing and using as of the Effective Date, MTPC shall be solely responsible for all related formulation and process development activities. In no event will Neurocrine be obligated to supply API or Drug Product under this Agreement or the Supply Agreement in a different formulation from the one that Neurocrine is developing and using as of the Effective Date, provided that Neurocrine shall provide MTPC with reasonable support and assistance at MTPC's reasonable request provided [...***...] advance notice is provided to Neurocrine. MTPC shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by Neurocrine to conduct such activities, provided that items and costs of such activities shall be discussed and agreed upon in advance between the Parties.

7.4 Technical Transfer. Upon reasonable request from MTPC, Neurocrine shall forthwith and cooperate with MTPC or its designated manufacturer and provide MTPC or its designated manufacturer with technical assistance, with respect to Neurocrine Technology in order to enable MTPC to use such Neurocrine Technology to manufacture and produce the API and Drug Product. Neurocrine shall use commercially reasonable efforts to complete such technical transfer within [...***...] after such request. Upon reasonable request from MTPC, Neurocrine shall forthwith and cooperate with MTPC or its designated analytical testing facility and provide MTPC or its designated analytical testing facility with technical assistance, with respect to Neurocrine Technology in order to enable MTPC to use such Neurocrine Technology to analyze the API and Drug Product. Neurocrine shall use commercially reasonable efforts to complete such technical transfer within [...***...] after such request. MTPC shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by Neurocrine to conduct such activities under this Section 7.4, provided that items and costs of such activities shall be discussed and agreed upon in advance between the Parties.

7.5 Information on Manufacture. To the extent Neurocrine, itself or through any Affiliate or CMO, supplies API and Drug Product for Development and Commercialization under this Agreement, Neurocrine shall make available to MTPC all information, in its possession and Neurocrine has the legal right to transfer, related to the Manufacture of API and Drug Product to enable MTPC to maintain or obtain the Regulatory Approval in the MTPC Territory. Neurocrine shall use commercially reasonable efforts to require that CMO allow Neurocrine to provide MTPC access to and the right to use all Manufacturing information, in CMO's possession, to the extent that such information is reasonably useful for Development or Commercialization of Compounds and Products in the Field for the MTPC Territory, including preparation and filing of MAAs for a Product with the applicable Regulatory Authorities in the MTPC Territory, in accordance with this Agreement. MTPC shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by Neurocrine to conduct such

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activities under this Section 7.5, provided that items and costs of such activities shall be discussed and agreed upon in advance between the Parties.

8. FEES AND PAYMENTS

8.1 Upfront Payment. MTPC shall make a one-time payment to Neurocrine of thirty million U.S. dollars (\$30,000,000) within thirty (30) days after the Effective Date. Such amount shall be subject to twenty percent (20.42%) withholding by MTPC (i.e., MTPC may withhold \$6,126,000 and make a net payment to Neurocrine of \$23,874,000), unless prior to such thirty (30) day period MTPC has received from Neurocrine the documents necessary or useful for avoiding withholding taxes (“Tax Withholding Avoidance Documents”). If MTPC so withholds, then MTPC will reasonably assist Neurocrine in obtaining a refund of the withheld amounts from the applicable Japanese tax authorities upon the receipt from Neurocrine of the Tax Withholding Avoidance Documents at a subsequent date. The examples of the Tax Withholding Avoidance Documents between Japan and United States in 2009 are: Form #3 (Application form for income tax convention), Form #17 (Application for enjoying income tax benefit), and Form #6166 (to be issued by Department of the Treasury, IRS, USA). Notwithstanding the foregoing, in the event that Neurocrine will fail to provide the Tax Withholding Avoidance Documents prior to such thirty (30) days period, the Parties may agree to extend the due date of upfront payment until Neurocrine will provide such Tax Withholding Avoidance Documents to MTPC.

8.2 Milestone Payments.

(a) Regulatory and Commercialization Milestone Payments.

(i) Neurocrine shall notify MTPC of the first achievement of each Milestone Event below (whether by Neurocrine or its Affiliate or a Neurocrine Collaborator). Within thirty (30) days after each such notice, MTPC shall pay to Neurocrine the non-refundable, non-creditable Milestone Payment corresponding to such Milestone Event as shown below.

Regulatory and Commercialization Milestone Events	Milestone Payments (in U.S. Dollars)
[...***...]	\$[...***...]
[...***...]	\$[...***...]
Or	Or
[...***...]	

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[...***...]	i) \$[...***...] and ii) \$[...***...]
-------------	----------------------------------------------

(ii) Within thirty (30) days after the first achievement of each Milestone Event below (whether by MTPC or any of its Affiliates or Sublicensees), MTPC shall pay to Neurocrine the non-refundable, non-creditable Milestone Payment corresponding to such Milestone Event as shown below.

Regulatory and Commercialization Milestone Events	Milestone Payments (in U.S. Dollars)
[...***...]	\$[...***...]
[...***...]	\$[...***...]
[...***...]	\$[...***...]
[...***...]	\$[...***...]

Notwithstanding the foregoing, in case the daily drug price of the Product determined by Regulatory Authority is lower than [...***...], then the Milestone Payment of \$[...***...] on [...***...] is to be a credit against the royalties payable to Neurocrine pursuant to the Section 8.3.

(iii) For clarity, the Milestone Payments set forth in this Section 8.2(a) shall be payable only once, upon the first achievement of the applicable Milestone Event for any Compound or Product. The maximum total amount payable under this Section 8.2(a) is [...***...].

(b) Annual Net Sales Milestones.

(i) Within thirty (30) days after the end of each Calendar Quarter in which aggregate annual Net Sales of all Products in the Field in the MTPC Territory first reach any threshold indicated in the Milestone Events listed below, MTPC shall pay to Neurocrine the corresponding non-refundable, non-creditable Milestone Payment set forth below:

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Annual Net Sales Milestone Events	Milestone Payments
[...***...]	\$[...***...]
[...***...]	\$[...***...]
[...***...]	\$[...***...]

(ii) For clarity, the annual Net Sales Milestone Payments set forth in this Section 8.2(b) shall be payable only once, upon the first achievement of the applicable Milestone Event and shall be additive so that if all three (3) Milestone Events set forth in Section 8.2(b)(i) are achieved in the same Calendar Year, MTPC shall pay to Neurocrine all three (3) Milestone Payments. The maximum total amount payable under this Section 8.2(b) is [...***...].

8.3 Royalty Payments.

(a) **Royalty Rate.** Subject to the terms and conditions of this Agreement, MTPC shall pay Neurocrine the royalties as set forth below on aggregate annual Net Sales of Products in each country in the MTPC Territory during the Royalty Term, as calculated by multiplying the applicable royalty rate set forth below by the corresponding amount of aggregate Net Sales of Products in such country in such Calendar Year.

Aggregate Annual Net Sales of Products of MTPC Territory (Tier)	Royalty Rate
Annual Net Sales up to [...***...]	[...***...]%
For a portion of Annual Net Sales in excess of [...***...]	[...***...]%
For the portion of Annual Net Sales in excess of [...***...]	[...***...]%

(b) **Royalty Term.** Royalties shall be paid on a Product-by-Product and country-by-country basis in the MTPC Territory from the First Commercial Sale of such Product in such country until the latest of (i) expiration of the last-to-expire Valid Claim of the Neurocrine Patents and Joint Patents covering the composition, method of manufacture or method of use in the Field of such Product in such country; or (ii) [...***...] after the First Commercial Sale of such Product in such country (the "**Royalty Term**"). Notwithstanding any other provision in this Agreement, (1) the royalty rates provided in Section 8.3(a) for such Product shall be reduced in such country by [...***...] during the Royalty Term after expiration of the last-to-expire Valid Claim of the Neurocrine Patents and the only Valid Claim still existing is a Valid Claim in a

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Joint Patent and/or a Valid Claim containing only Joint Compound Improvement Inventions until the expiration of the last-to-expire Valid Claim of the Joint Patents and/or the expiration of the last-to-expire Valid Claim containing only Joint Compound Improvement Inventions and (2) no royalty shall be paid on any Valid Claim in a Neurocrine Patent if such Valid Claim contains only MTPC Compound Improvement Inventions.

(c) **Generic Competition.** If one or more Generic Products to a Product is launched in any country in the MTPC Territory during the Royalty Term for such Product in such country, [...***...], the royalty rates provided in Section 8.3(a) for such Product shall be reduced in such country by [...***...] for the Calendar Quarter in which the applicable decline occurs and for all future Calendar Quarters, unless and until such Generic Products are no longer sold or the [...***...] increase above the threshold value described above.

(d) **Deduction for Third Party Settlements.** MTPC shall be responsible for all payments owed to any Third Party in connection with any settlement it enters under Section 10.5. On a Product-by-Product and country-by-country basis, MTPC may deduct [...***...] of royalty payments actually paid to such Third Party under such settlement agreement from any royalty payments owed to Neurocrine under this Section 8.3, provided that in no event shall the deductions under this Section 8.3(d) and Section 8.3(c) reduce royalties in any Calendar Quarter with respect to such Product in such country to less than [...***...] of the amount that would otherwise be due to Neurocrine.

9. PAYMENT; RECORDS; AUDITS

9.1 **Payment; Reports.** Royalty payments due by MTPC to Neurocrine under Section 8.3 shall be calculated and reported for each Calendar Quarter. The final report for each Calendar Quarter setting forth, on a country-by-country basis, Net Sales of Products by MTPC and its Affiliates and Sublicensees in the MTPC Territory in sufficient detail to permit confirmation of the accuracy of the royalty payment made, including, for each country, the number of Products sold, the gross sales and Net Sales of Products, including the deductions from gross sales to arrive at Net Sales, the royalties payable, the method used to calculate the royalties, the exchange rates used and any adjustments to royalties in accordance with Section 8.3, shall be provided to Neurocrine within [...***...] after the end of each Calendar Quarter. All royalty payments due under Section 8.3 shall be paid from MTPC's Japan offices within [...***...] after the end of each Calendar Quarter

9.2 **Exchange Rate; Manner and Place of Payment.** All references to dollars and "\$" herein shall refer to U.S. dollars. All references to yen and "¥" herein shall refer to the Japanese yen. All payments hereunder shall be payable in U.S. dollars. When conversion of payments from any currency other than U.S. dollars is required, such conversion shall be at an exchange rate equal to the average of the daily rates of exchange for the currency of the country from which such payments are payable to the U.S. dollar as published by *The Wall Street Journal*, Western U.S. Edition, during the Calendar Quarter in which the applicable sales were

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made. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Neurocrine, unless otherwise specified in writing by Neurocrine.

9.3 Taxes.

(a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible and in compliance with Applicable Laws, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use reasonable efforts to cooperate and coordinate with each other to achieve such objective. As such, MTPC shall not change the country from which its payments to Neurocrine originate without the prior written consent of Neurocrine.

(b) Payment of Tax. Neurocrine will pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are required to be withheld by MTPC from any payment made to Neurocrine under this Agreement, Neurocrine will provide the Tax Withholding Avoidance Documents to MTPC prior to such payment to Neurocrine for avoiding withholding taxes. In case the Tax Withholding Avoidance Documents are not available to MTPC at the due date of such payments to Neurocrine, MTPC will (i) deduct such taxes from the payment made to Neurocrine, (ii) timely pay the taxes to the proper taxing authority, and (iii) send proof of payment to Neurocrine and certify its receipt by the taxing authority within [...***...] following such payment. For purposes of this Section 9.3, each Party agrees to provide the other with reasonably requested assistance to enable the due deduction by MTPC and appropriate recovery by Neurocrine, which assistance includes provision of any tax forms and other information that may be reasonably necessary in order for MTPC not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral tax treaty, as the same may be amended from time to time. Notwithstanding the foregoing, in case the Tax Withholding Avoidance Documents are not available to MTPC at the due date of such payments to Neurocrine, the Parties may agree to extend the due date of upfront payment until Neurocrine will provide such Tax Withholding Avoidance Documents to MTPC.

9.4 Records; Audit. MTPC shall keep, and shall cause its Affiliates and Sublicensees to keep, complete and accurate records pertaining to the sale or other disposition of Products in sufficient detail to permit Neurocrine to confirm the accuracy of royalty payments due hereunder. Such records shall be kept for such period of time required by Applicable Laws, but no less than [...***...] following the end of the Calendar Quarter to which they pertain. Neurocrine shall have the right to cause an independent, international, certified public accounting firm reasonably acceptable to MTPC to audit such records to confirm Net Sales, royalties and other payments for a period covering not more than [...***...] following the Calendar Quarter to which they pertain. Such audits may be exercised during normal business hours upon reasonable prior written notice to MTPC. Prompt adjustments shall be made by the Parties to reflect the results of such audit. Neurocrine shall bear the full cost of such audit unless such audit discloses an underpayment by MTPC of more than [...***...] of the amount of royalties or other payments due under this Agreement for any applicable Calendar Quarter, in which case, MTPC shall bear the cost of such audit and shall promptly remit to Neurocrine the amount of any underpayment. Any overpayment by MTPC revealed by an audit shall be credited

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against future payment owed by MTPC to Neurocrine (and if no further payments are due, shall be refunded by Neurocrine at the request of MTPC).

9.5 Late Payments. In the event that any payment due under this Agreement is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due at the rate of [...***...] per month; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

10. INTELLECTUAL PROPERTY

10.1 Ownership.

(a) Data. All Data generated in connection with any Development, regulatory, manufacturing or commercial activities with respect to any Compound or Product conducted by or on behalf of MTPC or its Affiliates or Sublicensees (the "**MTPC Data**") shall be the sole and exclusive property of MTPC or its Affiliates or Sublicensees, as applicable; provided, however, MTPC assigns and shall assign, all Data related to MTPC Compound Improvement Inventions and Joint Compound Improvement Inventions to Neurocrine upon Neurocrine's request. All Data generated in connection with any Development, regulatory, manufacturing or commercial activities with respect to any Compound or Product conducted by or on behalf of Neurocrine and its Affiliates and Neurocrine Collaborators (the "**Neurocrine Data**") shall be the sole and exclusive property of Neurocrine or its Affiliates or Neurocrine Collaborators, as applicable.

(b) Inventions. Inventorship of any Inventions will be determined in accordance with the standards of inventorship and conception under U.S. patent laws. The Parties will work together to resolve any issues regarding inventorship or ownership of Inventions. Ownership of Inventions will be allocated as follows:

(i) Neurocrine will solely own all Inventions, and Patents claiming such Inventions, that relate to the composition, manufacture or use of any Compound, or any improvement of any such composition, manufacture or use (each, a "**Compound Invention**"), including all Joint Compound Improvement Inventions and all MTPC Compound Improvement Inventions. All Compound Inventions will be included in the Neurocrine Know-How, and Patents claiming such Compound Inventions, Joint Compound Improvement Inventions or MTPC Compound Improvement Inventions will be included in the Neurocrine Patents. MTPC assigns, and shall assign, all of its rights in all Joint Compound Improvement Inventions and all MTPC Compound Improvement Inventions to Neurocrine and all of its rights in Patents claiming all Joint Compound Improvement Inventions and all MTPC Compound Improvement Inventions.

(ii) Inventions discovered, made, conceived, or conceived and reduced to practice solely by one (1) or more employees or contractors of Neurocrine or its Affiliates, and Patents claiming such Inventions, after the Effective Date and during the Term of this Agreement, shall be solely owned by Neurocrine, and Inventions, other than Compound Inventions, Joint Compound Improvement Inventions or MTPC Compound Improvement Inventions, discovered, made, conceived, or conceived and reduced to practice solely by one

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(1) or more employees or contractors of MTPC or its Affiliates, and Patents claiming such Inventions, after the Effective Date and during the Term of this Agreement, shall be solely owned by MTPC.

(iii) Joint Inventions and Joint Patents (which for clarity exclude Compound Inventions, Joint Compound Improvement Inventions or MTPC Compound Improvement Inventions and Patents claiming Compound Inventions, Joint Compound Improvement Inventions or MTPC Compound Improvement Inventions) shall be jointly owned by Neurocrine and MTPC. Subject to the rights and licenses granted under this Agreement, each Party shall have the right to use, and to grant licenses to use, any Joint Invention and Joint Patents in its own Territory (MTPC in the MTPC Territory and Neurocrine outside of the MTPC Territory) without the other Party's consent, without a duty to account to the other Party for such use or license, provided however, that each Party shall notify the other Party in writing on such license granted to the Third Party, and each Party hereby waives any right it may have under the laws of any country to require any such consent or accounting.

10.2 Patent Prosecution and Maintenance.

(a) Neurocrine Patents.

(i) Subject to this Section 10.2(a), Neurocrine shall have the sole right, but not the obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of all Neurocrine Patents, by counsel of its own choice. [...***...]. Neurocrine shall keep MTPC reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of Neurocrine Patents, including content, timing and jurisdiction of the filing of such Neurocrine Patents, and shall consult with, and consider in good faith the requests and suggestions of, MTPC with respect to strategies for filing and prosecuting Neurocrine Patents.

(ii) In the event that Neurocrine desires to abandon or cease prosecution or maintenance of any Neurocrine Patent, Neurocrine shall provide reasonable prior written notice to MTPC of such intention to abandon (which notice shall, to the extent possible, be given no later than [...***...] prior to the next deadline for any action that must be taken with respect to any such Neurocrine Patent in the relevant patent office). In such case, upon MTPC's written election provided no later than [...***...] after such notice from Neurocrine, MTPC shall have the right to assume prosecution and maintenance of such Neurocrine Patent at MTPC's expense. In such case, MTPC shall keep Neurocrine reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of Neurocrine Patents, including content, timing and jurisdiction of the filing of such Neurocrine Patents. If MTPC does not provide such election within [...***...] after such notice from Neurocrine, Neurocrine may, in its sole discretion, continue prosecution and maintenance of such Neurocrine Patent or discontinue prosecution and maintenance of such Neurocrine Patent.

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(b) MTPC Patents.

(i) Subject to this Section 10.2(b), MTPC shall have the sole right, but not the obligation, to control the preparation, filing, prosecution (including any interferences, reissue proceedings and re-examinations) and maintenance of all MTPC Patents worldwide, at its sole cost and expense and by counsel of its own choice. MTPC shall keep Neurocrine reasonably informed of the status of filing, prosecution and maintenance of the MTPC Patents, and shall consult with, and consider in good faith the requests and suggestions of, Neurocrine with respect to strategies for filing and prosecuting MTPC Patents.

(ii) In the event that MTPC desires to abandon or cease prosecution or maintenance of any MTPC Patent, MTPC shall provide reasonable prior written notice to Neurocrine of such intention to abandon (which notice shall, to the extent possible, be given no later than [...***...] prior to the next deadline for any action that must be taken with respect to any such MTPC Patent in the relevant patent office). In such case, upon Neurocrine's written election provided no later than [...***...] after such notice from MTPC, Neurocrine shall have the right to assume prosecution and maintenance of such MTPC Patent at Neurocrine's expense. If Neurocrine does not provide such election within [...***...] after such notice from MTPC, MTPC may, in its sole discretion, continue prosecution and maintenance of such MTPC Patent or discontinue prosecution and maintenance of such MTPC Patent.

(c) Joint Patents.

(i) Neurocrine shall have the first right, but not the obligation, to prepare, file, prosecute (including any interferences, reissue proceedings and re-examinations) and maintain Joint Patents using a patent counsel selected by Neurocrine and reasonably acceptable to MTPC. MTPC shall reimburse Neurocrine for all external patent fees and costs incurred with respect to the preparation, filing, prosecution and maintenance of Joint Patents in the MTPC Territory within [...***...] from the date of invoice for such costs and expenses provided by Neurocrine. In the event that MTPC does not reimburse Neurocrine for such external patent fees and costs for any Joint Patent in the MTPC or notifies Neurocrine in writing that it elects to cease reimbursing Neurocrine for such external patent fees and costs for any Joint Patent in the MTPC Territory, MTPC shall execute such documents and perform such acts, at MTPC's expense, as may be reasonably necessary to effect an assignment of MTPC's entire right, title, and interest in and to such Joint Patent to Neurocrine, and such Patent shall cease to be either a Joint Patent or a Neurocrine Patent and shall no longer be subject to the licenses and other rights granted by Neurocrine to MTPC under this Agreement. Neurocrine shall agree to furnish MTPC with copies of all documents relevant to such preparation, filing, prosecution and maintenance with respect to such Joint Patent in sufficient time to allow for review by MTPC, to incorporate in good faith the comments of MTPC prior to taking any action to implement such decisions and to otherwise keep MTPC reasonably informed of the status of the preparation, filing, prosecution and maintenance of such Joint Patent in the MTPC Territory.

(ii) In the event that Neurocrine desires to abandon or cease prosecution or maintenance of any Joint Patent in the MTPC Territory (except in the event the Parties

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mutually decide to abandon or cease prosecution, maintenance or enforcement of such Joint Patent), Neurocrine shall provide reasonable prior written notice to MTPC of such intention to abandon (which notice shall, to the extent possible, be given no later than [...***...] prior to the next deadline for any action that must be taken with respect to any such Joint Patent in the relevant patent office). In such case, MTPC may elect to continue prosecution or maintenance of any such Joint Patent in the MTPC Territory at its sole discretion and own expense, in which case, all rights in such Joint Patent in the MTPC Territory shall be assigned to MTPC. Neurocrine shall execute such documents and perform such acts, at its own expense, as may be reasonably necessary to effect an assignment of its entire right, title, and interest in and to such Joint Patent in the MTPC Territory to MTPC. Any such assignment shall be completed in a timely manner to allow MTPC to continue prosecution and maintenance of any such Joint Patent and any such Joint Patent so assigned and shall no longer be subject to the licenses and other rights granted by Neurocrine to MTPC under this Agreement.

10.3 Cooperation of the Parties. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of Patents under Section 10.2 and in the obtaining and maintenance of any patent term extensions, supplementary protection certificates and their equivalent with respect thereto respectively, at its own cost (except as expressly set forth otherwise in this Article 10). Such cooperation includes: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by Section 10.2; and (b) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

10.4 Infringement by Third Parties.

(a) Notice. In the event that either Neurocrine or MTPC becomes aware of any infringement or threatened infringement by a Third Party of any Neurocrine Patent, MTPC Patent or Joint Patent, or any declaratory judgment or equivalent action challenging any Neurocrine Patent, MTPC Patent or Joint Patent in connection with any such infringement, it will notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement, or declaratory judgment or equivalent action, filed by such Third Party.

(b) Neurocrine Patents.

(i) Subject to this Section 10.4(b), Neurocrine shall have the first right, as between Neurocrine and MTPC, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any Neurocrine Patent, at its own expense and by counsel of its own choice. MTPC shall have the right, at its own expense, to be represented in any such action in the MTPC Territory by counsel of its own choice, and Neurocrine and its counsel will reasonably cooperate with MTPC and its counsel in strategizing, preparing and prosecuting any such action or proceeding in the MTPC Territory. If Neurocrine fails to bring an action or proceeding with respect to infringement of any Neurocrine Patent in the MTPC Territory within (A) [...***...] following the

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notice of alleged infringement or declaratory judgment or (B) [...***...] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, MTPC shall have the right, but not the obligation, to bring and control any such action in the MTPC Territory at its own expense and by counsel of its own choice, and Neurocrine shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(ii) Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to Neurocrine Patents shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding on a pro rata basis, and any remaining compensatory damages relating to Products (including lost sales or lost profits with respect to Products) shall be retained by the Party that brought and controlled such action or proceeding, and in the case that MTPC brought and controlled such action or proceeding, such remaining compensatory damages shall be deemed to be Net Sales subject to royalty payments to Neurocrine in accordance with the royalty provisions of Section 8.3, and any punitive damages shall be equally shared by the Parties.

(c) MTPC Patents.

(i) MTPC shall have the sole right, as between Neurocrine and MTPC, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any MTPC Patent in the MTPC Territory, at its own expense and by counsel of its own choice, subject to this Section 10.4(c)(i). Any recovery or damages realized as a result of such action or proceeding by MTPC with respect to MTPC Patents in the MTPC Territory shall be used first to reimburse MTPC's documented out-of-pocket legal expenses relating to the action or proceeding, and any remaining compensatory, punitive, or other damages relating to Products (including lost sales or lost profits with respect to Products) shall be deemed to be Net Sales under Section 8.3(a) of this Agreement.

(ii) Subject to this Section 10.4(c)(ii), Neurocrine shall have the first right, as between Neurocrine and MTPC, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any MTPC Patent outside the MTPC Territory, at its own expense and by counsel of its own choice. MTPC shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and Neurocrine and its counsel will reasonably cooperate with MTPC and its counsel in strategizing, preparing and prosecuting any such action or proceeding. If Neurocrine fails to bring an action or proceeding with respect to infringement or challenge of any MTPC Patent outside the MTPC Territory within (A) [...***...] following the notice of alleged infringement or (B) [...***...] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, MTPC shall have the right to bring and control any such action at its own expense and by counsel of its own choice, and Neurocrine shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to MTPC Patents outside the MTPC Territory shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding on a pro rata basis, and any remaining compensatory

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damages relating to Products (including lost sales or lost profits with respect to Products) shall be retained by the Party that brought and controlled such action or proceeding, and any punitive damages shall be equally shared by the Parties.

(d) Joint Patents.

(i) Subject to this Section 10.4(d)(i), MTPC shall have the first right, as between MTPC and Neurocrine, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any Joint Patent in the MTPC Territory, at its own expense and by counsel of its own choice, and Neurocrine shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If MTPC fails to bring an action or proceeding with respect to infringement or challenge of any Joint Patent within (A) [...***...] following the notice of alleged infringement or (B) [...***...] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, Neurocrine shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and MTPC shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to Joint Patents in the MTPC Territory shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding on a pro rata basis, and any remaining compensatory damages relating to Products (including lost sales or lost profits with respect to Products) shall be retained by the Party that brought and controlled such action or proceeding, and in the case that MTPC brought and controlled such action or proceeding, such remaining compensatory damages shall be deemed to be Net Sales subject to royalty payments to Neurocrine in accordance with the royalty provisions of Section 8.3, and any punitive damages shall be equally shared by the Parties.

(ii) Subject to this Section 10.4(d)(ii), Neurocrine shall have the first right, as between Neurocrine and MTPC, but not the obligation, to bring and control any action or proceeding with respect to infringement or challenge of any Joint Patent outside the MTPC Territory, at its own expense and by counsel of its own choice, and MTPC shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If Neurocrine fails to bring an action or proceeding with respect to infringement or challenge of any Joint Patent within (A) [...***...] following the notice of alleged infringement or (B) [...***...] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, MTPC shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and Neurocrine shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to Joint Patents outside the MTPC Territory shall be used first to reimburse the Parties' documented out-of-pocket legal expenses relating to the action or proceeding on a pro rata basis, and any remaining compensatory damages relating to Products (including lost sales or lost profits with respect to Products) shall be retained by the Party that brought and controlled such action or proceeding, and any punitive damages shall be equally shared by the Parties.

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(e) **Cooperation.** In the event a Party brings an action in accordance with this Section 10.4, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party to such action.

10.5 Infringement of Third Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the manufacture, Development, importation, use, marketing or sale of any Compound or Product in the MTPC Territory infringes or may infringe the intellectual property rights of a Third Party (each an “**Infringement Claim**”). The notice shall set forth the facts of the Infringement Claim in reasonable detail. MTPC shall have the first right to control any defense of any such claim at its own expense and by counsel of its own choice, and Neurocrine shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If MTPC fails to defend against such action, or notifies Neurocrine that it does not intend to defend against such action, within (A) [...***...] following the notice of alleged infringement or (B) [...***...] before the time limit, if any, set forth in the appropriate laws and regulations for the response to such action, whichever comes first, Neurocrine shall have the right, but not the obligation, to defend any such action at its own expense and by counsel of its own choice, and MTPC shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If MTPC enters into a settlement of any such action with the applicable Third Party, and such action relates to a claim that Neurocrine Technology infringes the intellectual property rights of such Third Party, that provides for royalty payments to such Third Party by MTPC, then MTPC shall have the right to credit [...***...] of such payments against royalties payable to Neurocrine, as and to the extent set forth in Section 8.3. Notwithstanding the foregoing, any actions subject to Section 14.1 will be governed by Section 14.1 and not by this Section 10.5.

10.6 Consent for Settlement. Neither Party shall unilaterally enter into any settlement or compromise of any action or proceeding under this Article 10 that would in any manner alter, diminish, or be in derogation of the other Party’s rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably withheld.

10.7 Trademarks. MTPC shall own and be responsible for all trademarks, trade names, branding or logos related to Products in the Field in the MTPC Territory. Subject to consultation with Neurocrine through the JDC, MTPC shall be responsible for selecting, registering, prosecuting, defending, and maintaining all such marks at MTPC’s sole discretion, cost and expense.

10.8 Neurocrine Controlled Patents Outside the MTPC Territory. For clarity, Neurocrine reserves all rights to prepare, file, prosecute (including any interferences, reissue proceedings and re-examinations), maintain, defend and enforce all Patents owned or controlled by Neurocrine related to Compounds and Products outside the MTPC Territory (other than Joint Patents). In the event that Neurocrine becomes aware of any infringement or threatened infringement by a Third Party of any Neurocrine Patent outside the MTPC Territory, or any declaratory judgment or equivalent action challenging any Neurocrine Patent in connection with any such infringement outside the MTPC Territory, Neurocrine shall notify MTPC in writing to that effect.

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11. REPRESENTATIONS AND WARRANTIES

11.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof, (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action, (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it, and (d) it has the right to grant the licenses granted by it under this Agreement.

11.2 Mutual Covenants.

(a) Employees, Consultants and Contractors. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants and contractors who perform Development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign Inventions in a manner consistent with the provisions of this Agreement.

(b) Debarment. Each Party represents, warrants and covenants to the other Party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to any Compound or Product. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates or Neurocrine Collaborators or Sublicensees, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

(c) Compliance. Each Party covenants as follows:

(i) In the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with all Applicable Laws, rules and regulations.

(ii) Such Party and its and its Affiliates' employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize

the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including, without limitation, either Party (and each Party represents and warrants that as of the Effective Date, such Party, and to its knowledge, its and its Affiliates' employees and contractors, have not directly or indirectly promised, offered or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Public Official or Entity or any other person in connection with the performance of such Party's obligations under this Agreement, and each Party covenants that it and its Affiliates' employees and contractors shall not, directly or indirectly, engage in any of the foregoing).

(iii) Such Party and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not cause such other Party's Indemnitees to be in violation of the FCPA, Export Control Laws, or any other Applicable Laws, rules or regulations or otherwise cause any reputational harm to such other Party.

(iv) Such Party shall immediately notify the other Party if such Party has any information or suspicion that there may be a violation of the FCPA, Export Control Laws, or any other Applicable Laws, rules or regulations in connection with the performance of this Agreement or the Development, manufacture or Commercialization of any Product.

(v) In connection with the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates' employees and contractors to comply with such Party's own anti-corruption and anti-bribery policy, a copy of which has been provided to the other Party prior to the Effective Date.

(vi) The other Party will have the right, upon reasonable prior written notice and during such Party's regular business hours, to audit such Party's books and records in the event that a suspected violation of any of the representations, warranties or covenants in this Section 11.2(c) needs to be investigated.

(vii) In the event that such Party has violated or been suspected of violating any of the representations, warranties or covenants in this Section 11.2(c), such Party will cause its or its Affiliates' personnel or others working under its direction or control to submit to periodic training that such Party will provide on anti-corruption law compliance.

(viii) Such Party will, at the other Party's request, annually certify to such other Party in writing such Party's compliance, in connection with the performance of such Party's obligations under this Agreement, with the representations, warranties or covenants in Section 11.2(c).

(ix) Each Party shall have the right to suspend or terminate this Agreement in its entirety where there is a credible finding, after a reasonable investigation, that

the other Party, in connection with performance of such other Party's obligations under this Agreement, has violated the FCPA.

11.3 Additional Neurocrine Representations, Warranties and Covenants. Neurocrine represents, warrants and covenants, as applicable, to MTPC that, as of the Effective Date:

(a) The Letter Agreement lists all Patents in the MTPC Territory as of the Effective Date that claim the composition of matter or use of NBI-98854;

(b) Neurocrine has made available to MTPC for its review all information and documents related to Neurocrine Technology requested by MTPC and all Safety Data;

(c) Neurocrine has not received any written notice from a Third Party that the Development of any Compound or Product conducted by Neurocrine prior to the Effective Date has infringed any Patents of any Third Party;

(d) Neurocrine has not as of the Effective Date, and will not during the Term, grant any right to any Third Party under the Neurocrine Technology or Joint Patents that would conflict with the rights granted to MTPC hereunder;

(e) no claim or action has been brought or, to Neurocrine's knowledge, threatened in writing by any Third Party alleging that the Neurocrine Patents are invalid or unenforceable, and no Neurocrine Patent is the subject of any interference, opposition, cancellation or other protest proceeding;

(f) to Neurocrine's knowledge as of the Effective Date, the Development, manufacture, use, importation, offer for sale and sale of NBI-98854 in the Field in the MTPC Territory does not infringe the issued Patents of any Third Party or any patent applications, if issued in the same form when they were published, in the MTPC Territory; and

(g) to Neurocrine's knowledge, no Third Party is infringing or misappropriating or has infringed or misappropriated the Neurocrine Technology in the MTPC Territory.

11.4 Additional MTPC Representations, Warranties and Covenants. MTPC represents, warrants and covenants to Neurocrine that, as of the Effective Date, MTPC has not granted, and will not grant during the Term, any right to any Third Party under the MTPC Technology that would conflict with the rights granted to Neurocrine hereunder. MTPC also represents and warrants to Neurocrine that it has reviewed all documents, data and other information provided from Neurocrine related to the Neurocrine Technology, and that it has had the opportunity to request any such information it requires.

11.5 Disclaimer. Except as expressly set forth in this Agreement, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH

PARTY HEREUNDER ARE PROVIDED "AS IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. Without limiting the foregoing, (a) neither Party represents or warrants that any data obtained from conducting clinical trials in one country or jurisdiction will comply with the laws and regulations of any other country or jurisdiction, and (b) neither Party represents or warrants the success of any study or test conducted by pursuant to this Agreement or the safety or usefulness for any purpose of the technology it provides hereunder.

12. INDEMNIFICATION

12.1 Indemnification by Neurocrine. Neurocrine hereby agrees to defend, indemnify and hold harmless MTPC, its Affiliates and Sublicensees and their respective directors, officers, employees and agents (each, an "**MTPC Indemnitee**") from and against any and all liabilities, expenses and losses, including reasonable legal expenses and attorneys' fees (collectively, "**Losses**"), to which any MTPC Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) the Development, use, handling, storage, sale or other disposition of any Compound or Product by Neurocrine or its Affiliates or Neurocrine Collaborators (excluding any activities by or on behalf of MTPC or its Affiliates or Sublicensees), (b) the negligence or willful misconduct of any Neurocrine Indemnitee, or (c) the breach by Neurocrine of any warranty, representation, covenant or agreement made by Neurocrine in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of the negligence or willful misconduct of any MTPC Indemnitee or the breach by MTPC of any warranty, representation, covenant or agreement made by MTPC in this Agreement or the Supply Agreement.

12.2 Indemnification by MTPC. MTPC hereby agrees to defend, indemnify and hold harmless Neurocrine, its Affiliates and the Neurocrine Collaborators and their respective directors, officers, employees and agents (each, a "**Neurocrine Indemnitee**") from and against any and all Losses to which any Neurocrine Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise out of: (a) the Development, use, handling, storage, sale or other disposition of any Compound or Product by MTPC or its Affiliates or Sublicensees (excluding any activities by or on behalf of Neurocrine or its Affiliates or Neurocrine Collaborators), (b) the negligence or willful misconduct of any MTPC Indemnitee, or (c) the breach by MTPC of any warranty, representation, covenant or agreement made by MTPC in this Agreement; except, in each case (a)-(c), to the extent such Losses arise out of the negligence or willful misconduct of any Neurocrine Indemnitee or the breach by Neurocrine of any warranty, representation, covenant or agreement made by Neurocrine in this Agreement or the Supply Agreement.

12.3 Procedure. A Party that intends to claim indemnification under this Article 12 (the “*Indemnitee*”) shall promptly notify the indemnifying Party (the “*Indemnitor*”) in writing of any Third Party claim, demand, action or other proceeding (each, a “*Claim*”) in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have sole control of the defense or settlement thereof. The Indemnitee may participate at its expense in the Indemnitor’s defense of and settlement negotiations for any Claim with counsel of the Indemnitee’s own selection. The indemnity arrangement in this Article 12 shall not apply to amounts paid in settlement of any action with respect to a Claim, if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld or delayed unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Third Party Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 12 if and to the extent the Indemnitor is actually prejudiced thereby. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

12.4 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

12.5 Limitation of Liability. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 13 AND UNLESS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *PROVIDED, HOWEVER, THAT THIS SECTION 12.5 SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY’S INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 12.*

13. CONFIDENTIALITY

13.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, [...***...], the receiving Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the other Party under to this Agreement, and both Parties shall keep confidential and, subject to Sections 13.2 and 13.3 and 13.5, shall not publish or otherwise disclose the terms of this Agreement. Each Party may use the other Party’s Confidential Information only to the extent required to accomplish the purposes of this Agreement, including exercising its rights or performing its obligations. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but no less than reasonable care) to ensure that its employees, agents, consultants, contractors and other representatives do not disclose or make any unauthorized use of the Confidential Information of the other Party. Each Party will promptly notify the other upon

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discovery of any unauthorized use or disclosure of the Confidential Information of the other Party.

13.2 Exceptions. The obligations of confidentiality and restriction on use under Section 13.1 will not apply to any information that the receiving Party can prove by competent written evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available to the public; (b) is known by the receiving Party at the time of receiving such information, other than by previous disclosure of the disclosing Party, or its Affiliates, employees, agents, consultants, or contractors; (c) is hereafter furnished to the receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by the receiving Party without the use of Confidential Information belonging to the disclosing Party.

13.3 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing, prosecuting, or maintaining Patents as permitted by this Agreement;
- (b) regulatory filings for Products that such Party has a license or right to Develop hereunder in a given country or jurisdiction;
- (c) prosecuting or defending litigation as permitted by this Agreement;
- (d) complying with applicable court orders or governmental regulations; and
- (e) disclosure to its and its Affiliates' employees, consultants, contractors and agents, to Neurocrine Collaborators (in the case of Neurocrine) and to Sublicensees (in the case of MTPC), in each case on a need-to-know basis in connection with the Development, manufacture and Commercialization of Compounds and Products in accordance with the terms of this Agreement and the Supply Agreement, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; and
- (f) disclosure to potential and actual investors, acquirers, licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 13.3(c) or (d), it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such Confidential Information at least as diligent as such Party would use to protect its own confidential information, but in no event less than

reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. Any information disclosed pursuant to Section 13.3(c) or (d) shall remain Confidential Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 13.

13.4 Publications. Each Party shall have the right to review and comment on any material proposed for disclosure or publication by the other Party regarding results of and other information regarding the other Party's Development activities with respect to Products, whether by oral presentation, manuscript or abstract if, in the reasonable opinion of the submitting Party, may negatively affect Development and/or Commercialization of Products in the MTPC Territory (for Neurocrine publications) or outside the MTPC Territory (for MTPC publications), as the case may be. For the sake of clarity, any press release or other disclosures to the investment community by a Party shall follow the process set forth in Section 13.5 below, and not the process contained in this Section 13.4. Before any such material is submitted for publication or presentation of any such material is made, each Party shall deliver a complete copy to the other Party at least [...***...] prior to submitting the material to a publisher or initiating any other disclosure. Each Party shall review any such material and give its comments to the other Party within [...***...] of the receipt of such material. With respect to oral presentation materials and abstracts, each Party shall make reasonable efforts to expedite review of such materials and abstracts, and shall return such items as soon as practicable to the other Party with appropriate comments, if any, but in no event later than [...***...] from receipt. Each Party shall comply with the other Party's request to delete references to its Confidential Information in any such material and agrees to delay any submission for publication or other public disclosure for a period of up to an additional [...***...] for the purpose of preparing and filing appropriate patent applications.

13.5 Publicity; Public Disclosures. The Parties agree to issue an initial press release substantially in the form agreed to prior to the Effective Date, to issue it on or as promptly as practicable following, the Effective Date. It is understood that each Party may desire or be required to issue subsequent press releases relating to this Agreement or activities hereunder. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press releases prior to the issuance thereof, to the extent practicable, provided that a Party may not unreasonably withhold, condition or delay consent to such releases, and that either Party may issue such press releases or make such disclosures to the SEC or other applicable agency as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations or for appropriate market disclosure. Each Party shall provide the other Party with advance notice of legally required disclosures to the extent practicable. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by a Party with the SEC or as otherwise required by Applicable Laws; provided that each Party shall have the right to make any such filing as it reasonably determines necessary under Applicable Laws. In addition, following the initial press release announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

13.6 Prior Confidentiality Agreement. As of the Effective Date, the terms of this Article 13 shall supersede any prior non-disclosure, secrecy or confidentiality agreement

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between the Parties (or their Affiliates) relating to the subject of this Agreement, including the Confidentiality Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

13.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that a Party would suffer upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 13. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 13.

14. TERM AND TERMINATION

14.1 Term. This Agreement shall commence on the Effective Date and, unless terminated earlier as provided in this Article 14 or by mutual written agreement of the Parties, shall continue until the expiration of the last Royalty Term in the MTPC Territory (the “**Term**”). Upon expiration (but not termination) of this Agreement, MTPC’s licenses under Section 2.1 will become perpetual, irrevocable, non-exclusive, fully paid-up and royalty free.

14.2 Termination for Cause.

(a) Material Breach. Each Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and has not cured such breach within [...***...] ([...***...] with respect to any payment breach) after notice of such breach from the non-breaching Party.

(b) Bankruptcy. Each Party shall have the right to terminate this Agreement in its entirety upon written notice to the other Party if such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors or becomes a party to any proceeding or action of the type described above and such proceeding is not dismissed within [...***...] after the commencement thereof.

14.3 Termination for Patent Challenge. Neurocrine shall have the right to terminate this Agreement in its entirety upon written notice to MTPC if MTPC or any of its Affiliates or Sublicensees directly, or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Neurocrine Patent.

14.4 Termination by MTPC. MTPC shall have the right to terminate this Agreement at any time for any reason or for no reason upon [...***...] written notice to Neurocrine.

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14.5 Effects of Termination for in Certain Situations. Upon any termination of this Agreement by Neurocrine pursuant to Section 14.2, 14.3 or the termination of this Agreement by MTPC pursuant to 14.4, the following will apply:

(a) Termination of Licenses and Other Rights. All licenses granted to MTPC will automatically terminate, all other rights and obligations of the Parties under this Agreement will terminate, and all sublicenses under the Neurocrine Technology granted from MTPC to any Sublicensee will automatically terminate, in each case on the effective date of termination; provided however, MTPC shall have a fully-paid, perpetual license to the MTPC Compound Improvement Inventions.

(b) Assignments. Neurocrine shall notify MTPC within [...***...] after the effective date of termination whether it wishes to obtain the assignments set forth in Sections 14.5(b)(i)-(iii). All such assignments under Sections 14.5(b)(i)-(iii) will be without cost to Neurocrine.

(i) Regulatory Filings. As promptly as practicable (and in any event within [...***...]) after such notice, MTPC shall: (A) to the extent not previously provided to Neurocrine, deliver to Neurocrine true, correct and complete copies of all Regulatory Filings (including Regulatory Approvals) for Products in the Field in the MTPC Territory, and provide to Neurocrine all MTPC Know-How not previously disclosed to Neurocrine; (B) and hereby does, effective upon such termination, transfer and assign, or cause to be transferred or assigned, to Neurocrine or its designee (or to the extent not so assignable, take all reasonable actions to make available to Neurocrine or its designee the benefits of) all Regulatory Filings (including Regulatory Approvals) for Products in the Field in the MTPC Territory, whether held in the name of MTPC or its Affiliate or Sublicensee; and (C) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect, evidence, register and record the transfer, assignment or other conveyance of rights under this Section 14.5(b)(i) to Neurocrine;

(ii) MTPC Technology. MTPC shall, and hereby does, effective upon such termination, assign to Neurocrine all of MTPC's and its Affiliates' right, title and interest in and to the MTPC Technology, and MTPC shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment, at Neurocrine's cost; and

(iii) Marks. MTPC shall, and hereby does, effective on such termination, assign to Neurocrine all of MTPC's and its Affiliates' right, title and interest in and to any and all Product-specific trademarks used by MTPC and its Affiliates in the MTPC Territory, including all goodwill therein, and MTPC shall promptly take such actions and execute such instruments, assignments and documents as may be necessary to effect, evidence, register and record such assignment, at Neurocrine's cost;

(c) Wind-Down. MTPC shall, as directed by Neurocrine, either wind-down any ongoing Development activities of MTPC and its Affiliates and Sublicensees with respect to any Products in the Field in the MTPC Territory in an orderly fashion or promptly transfer such Development activities to Neurocrine or its designee, in compliance with all Applicable Laws;

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(d) Transition Assistance. MTPC shall, at no cost to Neurocrine, provide reasonable consultation and assistance for a period of no more than [...***...] for the purpose of transferring or transitioning to Neurocrine all MTPC Know-How not already in Neurocrine's possession and, at Neurocrine's request, all then-existing commercial arrangements relating specifically to Compounds and Products that MTPC is able, using commercially reasonable efforts, to transfer or transition to Neurocrine, in each case, to the extent reasonably necessary or useful for Neurocrine to commence Developing, manufacturing, or Commercializing Products in the MTPC Territory. The foregoing shall include transferring, upon request of Neurocrine, any agreements with Third Party suppliers or vendors that specifically cover the supply or sale of Compounds or Products in the MTPC Territory. If any such contract between MTPC and a Third Party is not assignable to Neurocrine (whether by such contract's terms or because such contract does not relate specifically to Compounds or Products) but is otherwise reasonably necessary or useful for Neurocrine to commence Developing, manufacturing, or Commercializing Products in the MTPC Territory, or if MTPC manufactures the Product itself (and thus there is no contract to assign), then MTPC shall reasonably cooperate with Neurocrine to negotiate for the continuation of services or supply from such entity, or MTPC shall supply such Compound or Product, as applicable, to Neurocrine for a reasonable period (not to exceed [...***...]) until Neurocrine establishes an alternate, validated source of such services or supply of finished, packaged, labeled Product for the MTPC Territory. The cost to Neurocrine for such supply from MTPC shall be at MTPC's cost.

(e) Remaining Inventories. MTPC shall promptly deliver, at no charge, to Neurocrine all of the inventory of Compounds and Products held by MTPC as of the date of termination (that are not committed to be supplied to any Third Party or Sublicensee, in the ordinary course of business, as of the date of termination) at a price equal to MTPC's actual cost to acquire or manufacture such inventory.

14.6 Effects of Material Breach by Neurocrine. If Neurocrine materially breaches this Agreement and has not cured such breach within [...***...] after notice of such breach from MTPC (or, in the event the breach is not one that can be cured within [...***...], has not implemented a plan to cure such breach within [...***...]), MTPC shall have the right to seek the following remedies;

(a) In the case that MTPC will exercise its right to terminate this Agreement pursuant to Section 14.2(a), Section 14.5 (a)-(d) will apply, provided that, Neurocrine shall reimburse all reasonable internal (at a fully-burdened rate) and external costs incurred by MTPC to conduct such activities under Section 14.5(b)-(e), notwithstanding anything to the contrary in Section 14.5(b)-(e).

(b) In the case that MTPC will not exercise its right to terminate this Agreement pursuant to Section 14.2(a), this Agreement shall survive and remain in full force and effect except that MTPC may withhold any royalty payment obligations under Section 8.3 until such time as Neurocrine has cured such breach or implemented a plan to cure such breach, as the case may be.

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14.7 Confidential Information. Upon termination of this Agreement in its entirety, except to the extent that a Party obtains or retains the right to use the other Party's Confidential Information, each Party shall promptly return to the other Party, or delete or destroy, all relevant records and materials in such Party's possession or control containing Confidential Information of the other Party; provided that such Party may keep one copy of such materials for archival purposes only subject to continuing confidentiality obligations. All MTPC Know-How assigned to Neurocrine after the termination of this Agreement as set forth in Section 14.5 and 14.6(a) will be deemed Neurocrine's Confidential Information and no longer MTPC's Confidential Information.

14.8 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth below or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: Article 1, Section 4.5, Article 5, Sections 9.3, 9.4, 10.1, 10.2, 10.3, 10.6, 11.5, Articles 12 and 13, Sections 14.1, 14.5, 14.6, 14.7, 14.8, 14.9, 14.10, 14.11, Article 15, and Sections 16.1, 16.2, 16.3, 16.4, 16.6, 16.7, 16.8, 16.9, and 16.10.

14.9 Exercise of Right to Terminate. The use by either Party hereto of a termination right provided for under this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other Party with respect thereto; *provided, however*, that termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.

14.10 Damages; Relief. Subject to Section 14.8, termination of this Agreement shall not preclude either Party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.

14.11 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties agree that a Party that is a licensee of such rights under this Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party to this Agreement under the U.S. Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy or insolvency proceeding upon its written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, following the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party.

15. DISPUTE RESOLUTION

15.1 Objective. The Parties recognize that disputes as to matters (i) arising under, or relating to, this Agreement or (ii) either Party's rights and obligations hereunder may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 15 to resolve any such dispute if and when it arises.

15.2 Resolution by Executive Officers. Except as otherwise provided in Article 3, if an unresolved dispute as to matters arising under or relating to this Agreement or either Party's rights and obligations hereunder arises, either Party may refer such dispute to the Executive Officers, who shall meet in person or by telephone within [...***...] after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of such officers within such [...***...] period (as may be extended by mutual written agreement), such dispute shall be resolved in accordance with Section 15.3.

15.3 Arbitration.

(a) If the Parties do not resolve a dispute as provided in Section 15.2, and a Party wishes to pursue the matter, each such dispute that is not an Excluded Claim (defined below) shall be resolved by binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("**ICC**") as then in effect (the "**ICC Rules**"), which ICC Rules are deemed to be incorporated by reference into this clause. The arbitration award rendered in any such arbitration will be final and not appealable and may be executed by any court of competent jurisdiction. If either Party intends to commence binding arbitration of such dispute, such Party will provide written notice to the other Party informing the other Party of such intention and the issues to be resolved. Within [...***...] after the receipt of such notice, the other Party may, by written notice to the Party initiating binding arbitration, add additional issues to be resolved.

(b) The arbitration shall be conducted by a panel of three (3) arbitrators appointed in accordance with the ICC Rules, none of whom shall be a current or former employee or director, or a then-current stockholder, of either Party, their respective Affiliates or any Sublicensee. The place of arbitration shall be Honolulu, Hawaii, and all proceedings and communications shall be in English.

(c) It is the intention of the Parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than [...***...] after selection of the arbitrators, the Parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within [...***...] from such meeting. Failing any such mutual agreement, the arbitrators will design and the Parties shall follow procedures to such effect.

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(d) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non-compensatory damages, except as may be permitted by Section 12.5. The arbitrators shall have the power to order that all or part of the legal or other costs incurred by a Party in connection with the arbitration be paid by the other Party. Each Party shall bear an equal share of the arbitrators' and any administrative fees of arbitration.

(e) Except to the extent necessary to confirm or enforce an award or as may be required by Applicable Law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

(f) As used in this Section, the term "*Excluded Claim*" means a dispute, controversy or claim that concerns (i) the validity, enforceability or infringement of a patent, trademark or copyright or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

16 GENERAL PROVISIONS

16.1 Governing Law. This Agreement, and all questions regarding the existence, validity, interpretation, breach or performance of this Agreement, shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, United States, without reference to its conflicts of law principles, with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law.

16.2 Entire Agreement; Modification. This Agreement, together with the Letter Agreement and Supply Agreement, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

16.3 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

16.4 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

16.5 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided, however*, that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party's consent:

(a) in connection with the transfer or sale of all or substantially all of the business or assets of such Party relating to Products to a Third Party, whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise, provided that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring Party by operation of law (*e.g.*, in the context of a reverse triangular merger)), intellectual property rights of the acquiring Party to such transaction (if other than one of the Parties to this Agreement) shall not be included in the technology licensed hereunder; or

(b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties specified above, and the name of a Party appearing herein will be deemed to include the name of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Section 16.5 shall be null and void.

16.6 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

16.7 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by (a) air mail (postage prepaid) requiring return receipt, (b) overnight courier, or (c) facsimile confirmed thereafter by any of the foregoing, to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other in accordance with this Section 16.7. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt; (ii) if air mailed, five (5) days

after the date of postmark; (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries or (iv) if sent by facsimile, the date of confirmation of receipt if during the recipient's normal business hours, otherwise the next business day.

If to MTPC, notices must be addressed to:

Mitsubishi Tanabe Pharma Corporation
3-2-10 Dosho-machi Chuo-ku
Osaka 541-8505
Japan
Attention: General Manager,
Global Product Strategy Department
Facsimile: [...***...]

with a copy to:

Mitsubishi Tanabe Pharma Corporation
3-2-10 Dosho-machi Chuo-ku
Osaka 541-8505
Japan
Attention: General Manager
Legal Affairs & Intellectual Property Department
Facsimile: [...***...]

If to Neurocrine, notices must be addressed to:

Neurocrine Biosciences, Inc.
12780 El Camino Real
San Diego, CA 92130
USA
Attention: Chief Executive Officer
Facsimile: [...***...]

with a copy to:

Neurocrine Biosciences, Inc.
12780 El Camino Real
San Diego, CA 92130
USA
Attention: Chief Legal Officer
Facsimile: [...***...]

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16.8 Force Majeure. Each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement (other than failure to make payment when due) by reason of any event beyond such Party's reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, pandemic flu, or other natural forces, war, civil unrest, acts of terrorism, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within [...***...] after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

16.9 Interpretation. The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. The word "including" and similar words means including without limitation. The word "or" means "and/or" unless the context dictates otherwise because the subject of the conjunction are mutually exclusive. The words "herein," "hereof" and "hereunder" and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. All references to days in this Agreement mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

16.10 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

[SIGNATURE PAGE FOLLOWS]

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IN WITNESS WHEREOF, the Parties hereto have caused this COLLABORATION AND LICENSE AGREEMENT to be executed and entered into by their duly authorized representatives as of the Effective Date.

NEUROCRINE BIOSCIENCES, INC.

mitsubishi tanabe pharma corporation

By: /s/ Kevin C. Gorman

By: /s/ Masayuki Mitsuka

Name: Kevin C. Gorman, Ph.D.

Name: Masayuki Mitsuka, Ph.D.

Title: President & Chief Executive Officer

Title: President & Representative Director,

Chief Executive Officer

SIGNATURE PAGE TO COLLABORATION AND LICENSE AGREEMENT

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Kevin C. Gorman, President and Chief Executive Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neurocrine Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: April 30, 2015

/s/ Kevin C. Gorman

Kevin C. Gorman

President and Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Timothy P. Coughlin, Chief Financial Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neurocrine Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: April 30, 2015

/s/ Timothy P. Coughlin

Timothy P. Coughlin
Chief Financial Officer

**CERTIFICATIONS OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Neurocrine Biosciences, Inc. (Company) on Form 10-Q for the period ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (Report), I, Kevin C. Gorman, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and
- (2) That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

April 30, 2015

By: /s/ Kevin C. Gorman
Name: Kevin C. Gorman
Title: President and Chief Executive Officer

In connection with the Quarterly Report of Neurocrine Biosciences, Inc. (Company) on Form 10-Q for the period ended March 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (Report), I, Timothy P. Coughlin, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and
- (2) That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

April 30, 2015

By: /s/ Timothy P. Coughlin
Name: Timothy P. Coughlin
Title: Chief Financial Officer