

**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, 2021

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)

12780 El Camino Real

San Diego, CA

(Address of principal executive office)

33-0525145

(IRS Employer
Identification No.)

92130

(Zip Code)

(858) 617-7600

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.001 par value	NBIX	Nasdaq Global Select Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant 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 94,545,991 as of April 29, 2021.

NEUROCRINE BIOSCIENCES, INC.

TABLE OF CONTENTS

	<u>PAGE</u>
<u>Part I. Financial Information</u>	3
<u>Item 1. Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Income</u>	4
<u>Condensed Consolidated Statements of Stockholders' Equity</u>	5
<u>Condensed Consolidated Statements of Cash Flows</u>	6
<u>Notes to the Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	20
<u>Item 4. Controls and Procedures</u>	20
<u>Part II. Other Information</u>	21
<u>Item 1A. Risk Factors</u>	21
<u>Item 6. Exhibits</u>	45
<u>Signatures</u>	46

Part I. Financial Information

Item 1. Financial Statements

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

<i>(in millions, except per share data)</i>	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 352.6	\$ 187.1
Debt securities available-for-sale, at fair value (amortized cost \$520.2 million at March 31, 2021 and \$612.4 million at December 31, 2020)	521.1	613.9
Accounts receivable	147.8	157.1
Inventories	30.1	28.0
Other current assets	33.8	30.1
Total current assets	1,085.4	1,016.2
Deferred tax assets	325.6	319.4
Debt securities available-for-sale, at fair value (amortized cost \$249.6 million at March 31, 2021 and \$226.7 million at December 31, 2020)	249.6	227.1
Right-of-use assets	97.0	82.8
Equity securities	38.9	38.2
Property and equipment, net	45.3	44.6
Restricted cash	3.2	3.2
Other long-term assets	1.4	3.2
Total assets	<u>\$ 1,846.4</u>	<u>\$ 1,734.7</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 171.9	\$ 168.7
Other current liabilities	18.1	17.8
Total current liabilities	190.0	186.5
Convertible senior notes	322.0	317.9
Operating lease liabilities	107.5	94.4
Other long-term liabilities	21.3	9.7
Total liabilities	640.8	608.5
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5.0 shares authorized; no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 220.0 shares authorized; issued and outstanding shares were 94.5 at March 31, 2021 and 93.5 at December 31, 2020	0.1	0.1
Additional paid-in capital	1,897.8	1,849.7
Accumulated other comprehensive income	1.0	1.8
Accumulated deficit	(693.3)	(725.4)
Total stockholders' equity	1,205.6	1,126.2
Total liabilities and stockholders' equity	<u>\$ 1,846.4</u>	<u>\$ 1,734.7</u>

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
AND COMPREHENSIVE INCOME
(unaudited)

<i>(in millions, except per share data)</i>	Three Months Ended	
	March 31,	
	2021	2020
Revenues:		
Product sales, net	\$ 231.0	\$ 231.1
Collaboration revenue	5.6	6.0
Total revenues	236.6	237.1
Operating expenses:		
Cost of sales	2.9	2.1
Research and development	73.2	58.3
Selling, general and administrative	129.0	117.8
Total operating expenses	205.1	178.2
Operating income	31.5	58.9
Other (expense) income:		
Interest expense	(6.4)	(8.2)
Unrealized gain (loss) on restricted equity securities	0.7	(16.5)
Investment income and other, net	1.4	4.7
Total other expense, net	(4.3)	(20.0)
Income before (benefit from) provision for income taxes	27.2	38.9
(Benefit from) provision for income taxes	(4.9)	1.5
Net income	32.1	37.4
Unrealized loss on debt securities available-for-sale, net of tax	(0.8)	(2.8)
Comprehensive income	\$ 31.3	\$ 34.6
Net income per share, basic	\$ 0.34	\$ 0.40
Net income per share, diluted	\$ 0.33	\$ 0.39
Weighted average common shares outstanding, basic	94.2	92.6
Weighted average common shares outstanding, diluted	98.2	97.0

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)

(in millions)	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	\$				
Balances at December 31, 2020	93.5	\$ 0.1	\$ 1,849.7	\$ 1.8	\$ (725.4)	\$ 1,126.2
Net income	—	—	—	—	32.1	32.1
Unrealized loss on debt securities available-for-sale, net of tax	—	—	—	(0.8)	—	(0.8)
Share-based compensation expense	—	—	32.9	—	—	32.9
Issuances of common stock under stock plans	1.0	—	15.2	—	—	15.2
Balances at March 31, 2021	94.5	\$ 0.1	\$ 1,897.8	\$ 1.0	\$ (693.3)	\$ 1,205.6
Balances at December 31, 2019	92.3	\$ 0.1	\$ 1,768.1	\$ 1.4	\$ (1,132.7)	\$ 636.9
Net income	—	—	—	—	37.4	37.4
Unrealized loss on debt securities available-for-sale, net of tax	—	—	—	(2.8)	—	(2.8)
Share-based compensation expense	—	—	22.8	—	—	22.8
Issuances of common stock under stock plans	0.5	—	6.0	—	—	6.0
Balances at March 31, 2020	92.8	\$ 0.1	\$ 1,796.9	\$ (1.4)	\$ (1,095.3)	\$ 700.3

See accompanying notes to the condensed consolidated financial statements.

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

<i>(in millions)</i>	Three Months Ended March 31,	
	2021	2020
Cash Flows from Operating Activities:		
Net income	\$ 32.1	\$ 37.4
Reconciliation of net income to net cash provided by operating activities:		
Share-based compensation expense	32.9	22.8
Depreciation	2.5	2.1
Amortization of debt discount	3.9	5.0
Amortization of debt issuance costs	0.3	0.3
Change in fair value of equity security investments	(0.7)	16.5
Deferred income taxes	(6.2)	—
Other	2.6	0.4
Change in operating assets and liabilities:		
Accounts receivable	9.3	(22.1)
Inventories	(2.1)	(3.9)
Accounts payable and accrued liabilities	11.0	(16.2)
Other assets and liabilities, net	1.7	(6.8)
Net cash provided by operating activities	87.3	35.5
Cash Flows from Investing Activities:		
Purchases of debt securities available-for-sale	(93.7)	(172.0)
Sales and maturities of debt securities available-for-sale	161.3	206.5
Purchases of property and equipment	(4.5)	(1.3)
Net cash provided by investing activities	63.1	33.2
Cash Flows from Financing Activities:		
Issuances of common stock under benefit plans	15.2	6.0
Partial repurchase of convertible senior notes	(0.1)	—
Net cash provided by financing activities	15.1	6.0
Change in cash, cash equivalents and restricted cash	165.5	74.7
Cash, cash equivalents and restricted cash at beginning of period	190.3	115.5
Cash, cash equivalents and restricted cash at end of period	\$ 355.8	\$ 190.2
Supplemental Disclosure:		
Non-cash capital expenditures	\$ 0.1	\$ 0.8
Right-of-use assets acquired through operating leases	\$ 16.0	\$ —

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., or Neurocrine Biosciences, the Company, we, our or us, was incorporated in California in 1992 and reincorporated in Delaware in 1996. Neurocrine Continental, Inc., is a Delaware corporation and a wholly owned subsidiary of Neurocrine Biosciences. We also have two wholly owned Irish subsidiaries, Neurocrine Therapeutics, Ltd. and Neurocrine Europe, Ltd., both of which were formed in December 2014 and are inactive.

We are a neuroscience-focused, biopharmaceutical company dedicated to discovering, developing and delivering life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. Our diverse portfolio includes United States Food and Drug Administration, or FDA, approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis*, uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, we have specialized in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. (*in collaboration with AbbVie Inc.)

Basis of Presentation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP, for interim financial information and with the instructions of the Securities and Exchange Commission, or 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 our 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 Neurocrine Biosciences and our wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2020, included in our Annual Report on Form 10-K, or the 2020 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 the full year. The condensed consolidated balance sheet at December 31, 2020, has been derived from the audited financial statements as of that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

There were no significant changes to our significant accounting policies as disclosed in the 2020 Form 10-K.

Recently Adopted Accounting Pronouncements.

ASU 2019-12. On January 1, 2021, we adopted Accounting Standards Update, or ASU, 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, using the modified retrospective transition method. ASU 2019-12 simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application of Topic 740. The adoption of ASU 2019-12 did not result in a cumulative-effect adjustment to retained earnings. The comparative prior period information continues to be reported under the accounting standards in effect during those periods. The impact of the adoption is expected to be immaterial to our financial position, results of operations, and cash flows on an ongoing basis.

Recently Issued Accounting Pronouncements.

ASU 2020-06. In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments, and amends existing earnings-per-share, or EPS, guidance by requiring that an entity use the if-converted method when calculating diluted EPS for convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. We plan to adopt ASU 2020-06 effective January 1, 2022 using the modified retrospective transition method. We are currently evaluating the effect ASU 2020-06 will have on our consolidated financial statements and related disclosures.

2. Significant Collaboration and Licensing Agreements

Takeda Pharmaceutical Company Limited. We entered into an exclusive license agreement with Takeda Pharmaceutical Company Limited, or Takeda, which became effective in July 2020, to develop and commercialize certain compounds in Takeda's early to mid-stage psychiatry pipeline. Specifically, Takeda granted us an exclusive license to (i) luvadaxistat (NBI-1065844/TAK-831) for adults with negative symptoms of schizophrenia, (ii) NBI-1065845 (TAK-653) for treatment-resistant depression, (iii) NBI-1065846 (TAK-041) for anhedonia and (iv) four non-clinical stage assets.

With respect to luvadaxistat, Takeda will retain the right to opt-in to a profit-sharing arrangement pursuant to which we and Takeda will equally share in the operating profits and losses associated with luvadaxistat (in lieu of receiving payments for milestones and royalties), subject to certain exceptions. Subject to specified conditions, Takeda may elect to exercise such opt-in right for luvadaxistat before we initiate a Phase III clinical study.

With respect to NBI-1065845 and NBI-1065846, Takeda will retain the rights to opt-out of the profit-sharing arrangements pursuant to which Takeda would be entitled to receive royalties on the future net sales of such asset (in lieu of equally sharing in the operating profits and losses). Takeda may elect to exercise such opt-out rights immediately following the completion of the associated second Phase II clinical study or, under certain circumstances related to the development and commercialization activities to be performed by us, before the initiation of a Phase III clinical study for such asset.

Under the terms of the agreement, Takeda may be entitled to receive payments of up to \$1.9 billion upon the achievement of certain milestones associated with luvadaxistat and the four non-clinical stage assets, as well as receive royalties on the future net sales of such assets. We and Takeda will equally share in the operating profits and losses associated with NBI-1065845 and NBI-1065846.

Idorsia Pharmaceuticals Ltd. In May 2020, we entered a collaboration and licensing agreement with Idorsia Pharmaceuticals Ltd, or Idorsia, to license the global rights to NBI-827104 (ACT-709478), a potent, selective, orally active and brain penetrating T-type calcium channel blocker, in clinical development for the treatment of a rare pediatric epilepsy.

Under the terms of the agreement, Idorsia may be entitled to receive payments of up to \$1.7 billion upon the achievement of certain milestones as well as receive royalties on the future net sales of any collaboration product.

Xenon Pharmaceuticals, Inc. In December 2019, we entered into a license and collaboration agreement with Xenon Pharmaceuticals Inc., or Xenon, to identify, research, and develop sodium channel inhibitors, including clinical candidate NBI-921352 (XEN901) and three preclinical candidates.

Under the terms of the agreement, Xenon may be entitled to receive payments of up to \$1.7 billion upon the achievement of certain milestones as well as receive royalties on the future net sales of any collaboration product.

Voyager Therapeutics, Inc. We entered into a collaboration and license agreement with Voyager Therapeutics, Inc., or Voyager, which became effective in March 2019, to develop and commercialize four programs using Voyager's proprietary gene therapy platform. The four programs consist of the NBIb-1817 (VY-AADC) for Parkinson's disease program, the Friedreich's ataxia program and the rights to two undisclosed programs.

In February 2021, we notified Voyager of our termination of the NBIb-1817 for Parkinson's disease program. The effective date of this termination will be August 2, 2021. The termination does not apply to any other development program other than NBIb-1817 for Parkinson's disease, and our collaboration and license agreement with Voyager will otherwise continue in effect.

Under the terms of the agreement, Voyager may be entitled to receive payments of up to \$1.3 billion upon the achievement of certain milestones, as well as receive royalties on the future net sales of any collaboration product.

BIAL – Portela & Ca, S.A. We acquired the United States, or US, and Canada rights to ONGENTYS® (opicapone) from BIAL in the first quarter of 2017. We launched ONGENTYS in the US in September 2020, after receiving FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients in April 2020. Under the terms of the agreement, BIAL may be entitled to receive payments of up to \$75.0 million upon the achievement of certain milestones.

Mitsubishi Tanabe Pharma Corporation. In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation, or MTPC, for the development and commercialization of INGREZZA® (valbenazine) for movement disorders in Japan and other select Asian markets.

In February 2021, MTPC reported positive top-line results from the J-KINECT Phase III study, designed to evaluate the efficacy and safety of valbenazine in tardive dyskinesia. In April 2021, MTPC submitted a Marketing Authorization Application, or MAA, with the Ministry of Health and Welfare in Japan for valbenazine for the treatment of tardive dyskinesia. MTPC submission of valbenazine triggered a milestone payment of \$15.0 million, to be paid by MTPC to Neurocrine Biosciences and recognized as collaboration revenue in the second quarter of 2021.

In accordance with our continuing performance obligations, \$5.7 million of the \$30.0 million upfront payment received from MTPC is being deferred and will be recognized as collaboration revenue over the ongoing KINECT-HD study period using an input method according to costs incurred to-date relative to estimated total costs associated with the study. We recognized collaboration revenue of \$1.1 million and \$1.3 million for the three months ended March 31, 2021 and 2020, respectively, in connection with the ongoing KINECT-HD study, a placebo-controlled Phase III study of valbenazine in adult Huntington's disease patients with chorea.

Under the terms of the agreement, we are entitled to receive royalties on the future worldwide net sales of any collaboration product in select territories in Asia and may also be entitled to receive payments of up to \$70.0 million upon the achievement of certain milestones, including the \$15.0 million milestone payment triggered upon MTPC submission of valbenazine in April 2021.

AbbVie Inc. In June 2010, we entered into an exclusive worldwide collaboration with AbbVie Inc., or AbbVie, to develop and commercialize elagolix and all next-generation gonadotropin-releasing factor antagonists for women's and men's health.

AbbVie received approval for ORILISSA® (elagolix tablets) in the US and Canada in August and November 2018, respectively, after receiving FDA and Health Canada approval for ORILISSA for endometriosis in July and October 2018, respectively. In June 2020, AbbVie launched ORIAHNN® (elagolix, estradiol and norethindrone acetate capsules and elagolix capsules) in the US after receiving FDA approval for ORIAHNN for uterine fibroids in May 2020. We recognized sales-based royalties on AbbVie net sales of ORILISSA and ORIAHNN of \$4.5 million and \$4.7 million for the three months ended March 31, 2021 and 2020, respectively.

Under the terms of the agreement, we are entitled to receive royalties on the future worldwide net sales of any collaboration product and may also be entitled to receive payments of up to \$366.0 million upon the achievement of certain milestones.

3. Debt Securities

The following table summarizes the amortized cost, unrealized gain and loss recognized in accumulated other comprehensive income (loss), allowance for credit losses, and fair value of debt securities available-for-sale at March 31, 2021, aggregated by major security type and contractual maturity:

<i>(in millions)</i>	Contractual Maturity	Amortized Cost	Unrealized Gain	Unrealized Loss	Allowance for Credit Losses	Fair Value
Commercial paper	Within 1 year	\$ 93.2	\$ —	\$ —	\$ —	\$ 93.2
Corporate debt securities	Within 1 year	239.6	0.9	—	—	240.5
Securities of government-sponsored entities	Within 1 year	187.4	—	—	—	187.4
		<u>\$ 520.2</u>	<u>\$ 0.9</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 521.1</u>
Corporate debt securities	1 to 2 years	\$ 169.0	\$ 0.1	\$ (0.2)	\$ —	\$ 168.9
Securities of government-sponsored entities	1 to 2 years	80.6	0.1	—	—	80.7
		<u>\$ 249.6</u>	<u>\$ 0.2</u>	<u>\$ (0.2)</u>	<u>\$ —</u>	<u>\$ 249.6</u>

The following table summarizes the amortized cost, unrealized gain and loss recognized in accumulated other comprehensive income (loss), allowance for credit losses, and fair value of debt securities available-for-sale at December 31, 2020, aggregated by major security type and contractual maturity:

<i>(in millions)</i>	Contractual Maturity	Amortized Cost	Unrealized Gain	Unrealized Loss	Allowance for Credit Losses	Fair Value
Commercial paper	Within 1 year	\$ 82.2	\$ —	\$ —	—	\$ 82.2
Corporate debt securities	Within 1 year	299.3	1.4	—	—	300.7
Securities of government-sponsored entities	Within 1 year	230.9	0.1	—	—	231.0
		<u>\$ 612.4</u>	<u>\$ 1.5</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 613.9</u>
Corporate debt securities	1 to 2 years	\$ 144.8	\$ 0.4	\$ —	—	\$ 145.2
Securities of government-sponsored entities	1 to 2 years	81.9	0.1	(0.1)	—	81.9
		<u>\$ 226.7</u>	<u>\$ 0.5</u>	<u>\$ (0.1)</u>	<u>\$ —</u>	<u>\$ 227.1</u>

The following table summarizes debt securities available-for-sale in an unrealized loss position for which an allowance for credit losses has not been recorded at March 31, 2021 and December 31, 2020, aggregated by major security type and length of time in a continuous unrealized loss position:

<i>(in millions)</i>	Less Than 12 Months		12 Months or Longer		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
March 31, 2021:						
Corporate Debt Securities	\$ 164.6	\$ (0.2)	\$ —	\$ —	\$ 164.6	\$ (0.2)
December 31, 2020:						
Securities of government-sponsored entities	\$ 95.0	\$ (0.1)	\$ —	\$ —	\$ 95.0	\$ (0.1)

At March 31, 2021, our security portfolio consisted of 126 securities related to investments in debt securities available-for-sale, of which 39 securities were in an unrealized loss position.

Our investments in corporate debt securities in an unrealized loss position at March 31, 2021 are of high credit quality (rated A or higher). Unrealized losses on these investments were primarily due to changes in interest rates. We do not intend to sell these investments and it is not more likely than not that we will be required to sell these investments before recovery of their amortized cost basis.

Accrued interest receivables on debt securities available-for-sale totaled \$3.2 million and \$3.7 million at March 31, 2021 and December 31, 2020, respectively. We do not measure an allowance for credit losses for accrued interest receivables. For the purposes of identifying and measuring an impairment, accrued interest is excluded from both the fair value and amortized cost basis of the debt security. Uncollectible accrued interest receivables associated with an impaired debt security are reversed against interest income upon identification of the impairment. No accrued interest receivables were written off during the three months ended March 31, 2021 or 2020.

4. Fair Value Measurements

We record cash equivalents and investments in debt securities available-for-sale and equity securities at fair value based on a fair value hierarchy that distinguishes between assumptions based on market data (observable inputs) and our own assumptions (unobservable inputs). The fair value hierarchy consists of the following three levels:

Level 1 – Quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 – Quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3 – Unobservable inputs that reflect our own assumptions about the assumptions that market participants would use in pricing the asset or liability when there is little, if any, market activity for the asset or liability at the measurement date.

Investments in debt securities available-for-sale are classified as Level 2 and carried at fair value. We estimate the fair value of debt securities available-for-sale by utilizing third-party pricing services. These pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either

directly or indirectly, to estimate fair value. Such inputs include market pricing based on real-time trade data for similar instruments, issuer credit spreads, benchmark yields, broker/dealer quotes and other observable inputs. We validate valuations obtained from third-party pricing services by understanding the models used, obtaining market values from other pricing sources, and analyzing data in certain instances.

Investments in equity securities of certain companies that are subject to holding period restrictions longer than one year are classified as Level 3 and carried at fair value using an option pricing valuation model. The most significant assumptions within the option pricing valuation model are the stock price volatility, which is based on the historical volatility of similar companies, and the discount for lack of marketability related to the term of the restrictions.

The carrying amounts of accounts receivable and accounts payable and accrued liabilities approximate their fair values due to their short-term maturities.

Investments at March 31, 2021, which were measured at fair value on a recurring basis, consisted of the following:

<i>(in millions)</i>	Fair Value	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
Cash and cash equivalents:				
Cash and money market funds	\$ 352.6	\$ 352.6	\$ —	\$ —
Total cash and cash equivalents	352.6	352.6	—	—
Restricted cash:				
Certificates of deposit	3.2	3.2	—	—
Total restricted cash	3.2	3.2	—	—
Debt securities available-for-sale:				
Commercial paper	93.2	—	93.2	—
Corporate debt securities	409.4	—	409.4	—
Securities of government-sponsored entities	268.1	—	268.1	—
Total debt securities available-for-sale	770.7	—	770.7	—
Equity securities:				
Equity securities—biotechnology industry	38.9	—	—	38.9
Total equity securities	38.9	—	—	38.9
Total recurring fair value measurements	\$ 1,165.4	\$ 355.8	\$ 770.7	\$ 38.9

Investments at December 31, 2020, which were measured at fair value on a recurring basis, consisted of the following:

<i>(in millions)</i>	Fair Value	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
Cash and cash equivalents:				
Cash and money market funds	\$ 187.1	\$ 187.1	\$ —	\$ —
Total cash and cash equivalents	187.1	187.1	—	—
Restricted cash:				
Certificates of deposit	3.2	3.2	—	—
Total restricted cash	3.2	3.2	—	—
Debt securities available-for-sale:				
Commercial paper	82.2	—	82.2	—
Corporate debt securities	445.9	—	445.9	—
Securities of government-sponsored entities	312.9	—	312.9	—
Total debt securities available-for-sale	841.0	—	841.0	—
Equity securities:				
Equity securities—biotechnology industry	38.2	—	—	38.2
Total equity securities	38.2	—	—	38.2
Total recurring fair value measurements	\$ 1,069.5	\$ 190.3	\$ 841.0	\$ 38.2

The following table presents a reconciliation of equity security investments, which were measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

<i>(in millions)</i>	Three Months Ended March 31,	
	2021	2020
Balance at beginning of period	\$ 38.2	\$ 55.9
Unrealized gain (loss) included in earnings	0.7	(16.5)
Balance at end of period	<u>\$ 38.9</u>	<u>\$ 39.4</u>

At March 31, 2021, the discount for lack of marketability used in the valuation analysis of equity security investments ranged from 12.0% to 15.0% (weighted average of 13.3%). The discount for lack of marketability was weighted by the relative fair value of the instruments. A significant increase (decrease) in the discount for lack of marketability in isolation would result in a significantly lower (higher) fair value measurement. Unrealized gains and losses on equity security investments are included in other income (expense), net.

5. Inventories

Inventories consisted of the following:

<i>(in millions)</i>	March 31, 2021	December 31, 2020
Raw materials	\$ 14.8	\$ 16.6
Work in process	2.5	2.4
Finished goods	12.8	9.0
Total inventories	<u>\$ 30.1</u>	<u>\$ 28.0</u>

6. Cash, Cash Equivalents and Restricted Cash

The following table presents a reconciliation of cash, cash equivalents and restricted cash to amounts shown in the condensed consolidated statements of cash flows.

<i>(in millions)</i>	March 31, 2021	March 31, 2020
Cash and cash equivalents	\$ 352.6	\$ 187.0
Restricted cash	3.2	3.2
Total cash, cash equivalents and restricted cash	<u>\$ 355.8</u>	<u>\$ 190.2</u>

7. Leases

We have operating leases for our office and laboratory facilities, including our corporate headquarters, with terms that expire from 2025 through 2031. We have two options to extend the term of the operating lease for our corporate headquarters for a period of ten years each. However, as we were not reasonably certain to exercise either of those options at lease commencement, neither option was recognized as part of the associated operating lease right-of-use, or ROU, asset or liability. In connection with our operating leases, in lieu of cash security deposits, Wells Fargo Bank, N.A., issued letters of credit on our behalf, which are secured by deposits totaling \$3.2 million.

Our operating lease cost was \$3.4 million and \$2.5 million for the three months ended March 31, 2021 and 2020, respectively. Cash paid for amounts included in the measurement of lease liabilities was \$2.6 million and \$2.1 million for the three months ended March 31, 2021 and 2020, respectively.

Our operating leases had a weighted average remaining lease term of 9.8 years at March 31, 2021 and 10.3 years at December 31, 2020, and a weighted average discount rate of 5.3% at March 31, 2021 and 5.6% at December 31, 2020.

Approximate future minimum lease payments under operating leases were as follows:

<i>(in millions)</i>	March 31, 2021
Year ending December 31, 2021 (9 months remaining)	\$ 9.1
Year ending December 31, 2022	14.9
Year ending December 31, 2023	15.5
Year ending December 31, 2024	16.0
Year ending December 31, 2025	15.5
Thereafter	85.4
Total operating lease payments	156.4
Less accreted interest	36.7
Total operating lease liabilities	119.7
Less current operating lease liabilities	12.2
Noncurrent operating lease liabilities	\$ 107.5

⁽¹⁾ Amounts presented in the table above exclude \$5.8 million of non-cancelable future minimum lease payments for operating leases that have not yet commenced.

⁽²⁾ Current operating lease liabilities are included in other current liabilities on the condensed consolidated balance sheets.

8. Convertible Senior Notes

On May 2, 2017, we completed a private placement of \$517.5 million in aggregate principal amount of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes, and entered into an indenture agreement, or the 2024 Indenture, with respect to the 2024 Notes. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase \$136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of \$186.9 million in cash. At March 31, 2021, \$381.2 million aggregate principal amount of the 2024 Notes remained outstanding. Interest on the 2024 Notes is due semi-annually on May 15 and November 15 of each year.

Holders of the 2024 Notes may convert the 2024 Notes at any time prior to the close of business on the business day immediately preceding May 15, 2024, only under the following circumstances:

- (i) during any calendar quarter (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than 130% of the conversion price on each applicable trading day;
- (ii) during the five business-day period immediately after any five consecutive trading-day period (the measurement period) in which the trading price (as defined in the 2024 Indenture) per \$1,000 principal amount of the 2024 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day;
- (iii) upon the occurrence of specified corporate events, including a merger or a sale of all or substantially all of our assets; or
- (iv) if we call the 2024 Notes for redemption, until the close of business on the business day immediately preceding the redemption date.

On or after January 15, 2024, until the close of business on the scheduled trading day immediately preceding May 15, 2024, holders may convert their 2024 Notes at any time.

Upon conversion, holders will receive the principal amount of their 2024 Notes and any excess conversion value, calculated based on the per share volume-weighted average price for each of the 30 consecutive trading days during the observation period (as more fully described in the 2024 Indenture). For both the principal and excess conversion value, holders may receive cash, shares of our common stock or a combination of cash and shares of our common stock, at our option.

It is our intent and policy to settle conversions through combination settlement, which essentially involves repayment of an amount of cash equal to the “principal portion” and delivery of the “share amount” in excess of the principal portion in shares of common stock or cash. In general, for each \$1,000 in principal, the “principal portion” of cash upon settlement is defined as the lesser of \$1,000, and the conversion value during the 25-day observation period as described in the 2024 Indenture. The conversion value is the sum of the daily conversion value which is the product of the effective conversion rate divided by 25 days and the daily volume weighted average price, or VWAP, of our common stock. The “share amount” is the

cumulative “daily share amount” during the observation period, which is calculated by dividing the daily VWAP into the difference between the daily conversion value (i.e., conversion rate x daily VWAP) and \$1,000.

The initial conversion rate for the 2024 Notes is 13.1711 shares of common stock per \$1,000 principal amount, which is equivalent to an initial conversion price of approximately \$75.92 per share of our common stock. At the initial conversion rate, settlement of the 2024 Notes for shares of our common stock would approximate 5.0 million shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. The initial conversion price of the 2024 Notes represented a premium of approximately 42.5% to the closing sale price of \$53.28 per share of our common stock on the Nasdaq Global Select Market on April 26, 2017, the date that we priced the private offering of the 2024 Notes.

In the event of conversion, holders would forgo all future interest payments, any unpaid accrued interest and the possibility of further stock price appreciation. Upon the receipt of conversion requests, the settlement of the 2024 Notes will be paid pursuant to the terms of the 2024 Indenture. In the event that all of the 2024 Notes are converted, we would be required to repay the \$381.2 million in principal value and any conversion premium in any combination of cash and shares of our common stock, at our option.

We may not redeem the 2024 Notes prior to May 15, 2021. On or after May 15, 2021, we may redeem for cash all or part of the 2024 Notes if the last reported sale price (as defined in the 2024 Indenture) of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending on, and including, the trading day immediately before the date which we provide notice of redemption. The redemption price will equal the sum of (i) 100% of the principal amount of the 2024 Notes being redeemed, plus (ii) accrued and unpaid interest, including additional interest, if any, to, but excluding, the redemption date. No sinking fund is provided for the 2024 Notes.

If we undergo a fundamental change, as defined in the 2024 Indenture, subject to certain conditions, holders of the 2024 Notes may require us to repurchase for cash all or part of their 2024 Notes at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, if a “make-whole fundamental change” (as defined in the 2024 Indenture) occurs prior to January 15, 2024, we will, in certain circumstances, increase the conversion rate for a holder who elects to convert its notes in connection with the make-whole fundamental change.

The 2024 Notes are our general unsecured obligations that rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2024 Notes, and equal in right of payment to our unsecured indebtedness.

While the 2024 Notes are currently classified as a long-term liability, the future convertibility and associated balance sheet classification will be monitored at each quarterly reporting date and analyzed dependent upon market prices of our common stock during the prescribed measurement periods. In the event that the holders of the 2024 Notes have the election to convert the 2024 Notes at any time during the prescribed measurement period, the 2024 Notes would then be considered a current obligation and classified as such. We are not aware of any current events or market conditions that would allow holders of the 2024 Notes to convert the 2024 Notes.

We are required to separately account for the liability and equity components of the 2024 Notes as they may be settled entirely or partially in cash upon conversion in a manner that reflects our economic interest cost. The liability component of the instrument was valued in a manner that reflects the market interest rate for a similar nonconvertible instrument at the date of issuance. The initial carrying value of the liability component of \$368.3 million was calculated using a 7.5% assumed borrowing rate. The equity component of \$149.2 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the 2024 Notes and was recorded in additional paid-in capital on the consolidated balance sheet at the issuance date. That equity component is treated as a discount on the liability component of the 2024 Notes, which is amortized over the seven-year term of the 2024 Notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. At March 31, 2021, the remaining period over which the discount on the liability component will be amortized was approximately 3.1 years.

We allocated the total transaction costs of approximately \$14.7 million related to the issuance of the 2024 Notes to the liability and equity components of the 2024 Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the seven-year term of the 2024 Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity.

The 2024 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by us. The 2024 Indenture contains customary events of default with respect to the 2024 Notes, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the 2024 Notes will automatically become due and payable.

The 2024 Notes, net of discounts and deferred financing costs, consisted of the following:

<i>(in millions)</i>	March 31, 2021	December 31, 2020
Principal	\$ 381.2	\$ 381.3
Deferred financing costs	(3.7)	(4.0)
Debt discount, net	(55.5)	(59.4)
Net carrying amount	<u>\$ 322.0</u>	<u>\$ 317.9</u>

The 2024 Notes were recorded at the estimated value of a similar non-convertible instrument on the date of issuance and accretes to the face value of the 2024 Notes over their seven-year term. The fair value of the 2024 Notes, which was estimated utilizing market quotations from an over-the-counter trading market (Level 2), was \$511.3 million at March 31, 2021 and \$514.3 million at December 31, 2020.

9. Net Income Per Share

Net income per share was calculated as follows:

<i>(in millions, except per share data)</i>	Three Months Ended March 31,	
	2021	2020
Net income - basic and diluted	\$ 32.1	\$ 37.4
Weighted-average common shares outstanding:		
Basic	94.2	92.6
Effect of dilutive securities:		
Stock options	2.1	2.4
Restricted stock	0.5	0.5
2024 Notes	1.4	1.5
Diluted	<u>98.2</u>	<u>97.0</u>
Net income per share:		
Basic	\$ 0.34	\$ 0.40
Diluted	\$ 0.33	\$ 0.39

Convertible debt instruments that may be settled entirely or partly in cash (such as the 2024 Notes) may, in certain circumstances where the borrower has the ability and intent to settle in cash, be accounted for under the treasury stock method. We issued the 2024 Notes with a combination settlement feature, which we have the ability and intent to use upon conversion of the 2024 Notes, to settle the principal amount of debt for cash and the excess of the principal portion in shares of our common stock. As a result, of the approximately 5.0 million shares underlying the 2024 Notes, only the shares required to settle the excess of the principal portion are considered under the treasury stock method.

Shares which have been excluded from diluted per share amounts because their effect would have been anti-dilutive were 2.7 million and 3.3 million for the three months ended March 31, 2021 and 2020, respectively.

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 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, 2020 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, 2020.

Overview

We are a neuroscience-focused, biopharmaceutical company dedicated to discovering, developing and delivering life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. Our diverse portfolio includes United States Food and Drug Administration, or FDA, approved treatments for tardive dyskinesia, Parkinson’s disease, endometriosis*, uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, we have specialized in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. (*in collaboration with AbbVie Inc.)

We launched INGREZZA® (valbenazine) in the United States, or US, with our specialty sales force in May 2017, after receiving FDA approval for INGREZZA as the first FDA-approved drug for the treatment of tardive dyskinesia in April 2017. In September 2020, we launched ONGENTYS® (opicapone) in the US leveraging our existing INGREZZA commercial infrastructure after receiving FDA approval for ONGENTYS for Parkinson’s disease in April 2020. INGREZZA net product sales represent the significant majority of our total net product sales.

Our partner AbbVie Inc., or AbbVie, launched ORILISSA® (elagolix tablets) in the US and Canada in August and November 2018, respectively, after receiving FDA and Health Canada approval for ORILISSA for endometriosis in July and October 2018, respectively. In June 2020, AbbVie launched ORIAHNN® (elagolix, estradiol and norethindrone acetate capsules and elagolix capsules) in the US after receiving FDA approval for ORIAHNN for uterine fibroids in May 2020. We receive royalties at tiered percentage rates on AbbVie net sales of ORILISSA and ORIAHNN.

In addition, we have a rapidly expanding pipeline of potential treatments and gene therapies for diseases such as Huntington’s disease, or HD, congenital adrenal hyperplasia, or CAH, epilepsy, schizophrenia and depression.

Pipeline Highlights:

INGREZZA:

- In February 2021, the Mitsubishi Tanabe Pharma Corporation, or MTPC, reported positive top-line results from the J-KINECT Phase III Study, designed to evaluate the efficacy and safety of valbenazine in tardive dyskinesia. Detailed results from this trial will be presented at a future medical conference. In April 2021, MTPC submitted a Marketing Authorization Application, or MAA, with the Ministry of Health and Welfare in Japan for valbenazine for the treatment of tardive dyskinesia. MTPC submission of valbenazine triggered a milestone payment of \$15.0 million, to be paid by MTPC to Neurocrine Biosciences and recognized as collaboration revenue in the second quarter of 2021.

Luvadaxistat (NBI-1065844/TAK-831):

- On March 2, 2021, we announced that investigational drug luvadaxistat did not meet its primary endpoint in the Phase II INTERACT study in adults with negative symptoms of schizophrenia. Luvadaxistat met both secondary endpoints of cognitive assessment. We plan to initiate a Phase II study for the treatment of cognitive impairment associated with schizophrenia, or CIAS, by the end of 2021.

NBib-1817 (VY-AADC):

- In February 2021, we notified Voyager Therapeutics, Inc., or Voyager, of our termination of the NBib-1817 for Parkinson’s disease program. The effective date of this termination will be August 2, 2021. The termination does not apply to any other development program other than NBib-1817 for Parkinson’s disease, and our collaboration and license agreement with Voyager will otherwise continue in effect.

COVID-19

The global COVID-19 pandemic has dramatically changed the ways in which we live and interact with one another. While we adapt to this new shared reality, our mission remains unchanged: to discover and develop life-changing treatments for people with serious, challenging and under-addressed disorders.

While we are unable to reliably estimate the duration or extent of any potential business disruption or financial impact during this time, including any impacts on INGREZZA product sales or R&D expense, we remain committed to (1) prioritizing the safety, health and well-being of patients and their caregivers, healthcare providers and our employees; (2) ensuring patients with tardive dyskinesia are well supported and have continued uninterrupted access to INGREZZA, for which we currently do not expect any supply disruption; and (3) advancing ongoing clinical studies.

As part of this commitment, we implemented a “Work from Home Policy” in early March 2020 for employees not involved in business-critical activities. For employees involved in business-critical activities, we implemented safety measures designed to comply with federal, state and local guidelines. We have since developed and are implementing plans regarding the opening of our sites to enable our employees to return to work in our corporate offices and the field, which plans take into account applicable public health authority and local government guidelines and which are designed to ensure community and employee safety. However, the effects of the COVID-19 pandemic continue to rapidly evolve and even if our employees more broadly return to work in our corporate offices and the field, we may nevertheless have to resume a remote work model. We continue to evaluate our remote work model and the impact of global spikes or surges in COVID-19 infection and hospitalization rates.

Due to the impact of COVID-19, we initially paused enrollment of new patients in several of our clinical studies. Beginning in the third quarter of 2020, we began enrolling patients in our HD and CAH studies. To date, we have not experienced any interruption of our supply of drug products needed to support our ongoing clinical studies. We recognize, however, that we may have to make further operational adjustments to our ongoing and planned clinical studies and that patient enrollment and new clinical trial site initiations may be further slowed due to the COVID-19 pandemic, especially if it is further prolonged or grows in severity.

Most hospitals, community mental health facilities, physicians’ offices, pharmacies, and other healthcare facilities have implemented policies that limited access of patients and our employees to such facilities and limited the ability of patients, pharmacies, and prescribers to interact with each other. Due to these policies, our field force has been utilizing digital, video, and telephonic engagement tools and tactics, which may be less effective than our ordinary processes. The ultimate impact of the COVID-19 pandemic, including any lasting effects on our revenue and the way we conduct our business, is highly uncertain and subject to continued change.

We continue to believe that existing funds, cash generated from operations, and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditures, debt service requirements and other business development initiatives that we plan to strategically pursue. However, the circumstances surrounding the COVID-19 pandemic are volatile and subject to rapid change. Despite our mitigation efforts, we may experience delays or an inability to execute on our clinical and preclinical development plans, reduced revenues or other adverse impacts to our business, which are described in more detail in “Risk Factors” in Part I, Item 1A of this Quarterly Report on Form 10-Q. We recognize that this pandemic will continue to present unique challenges for us throughout 2021, and potentially into 2022.

Results of Operations for the Three Months Ended March 31, 2021 and 2020

Revenues

The following table presents revenues by category.

(in millions)	Three Months Ended March 31,	
	2021	2020
Product sales, net	\$ 231.0	\$ 231.1
Collaboration revenue	5.6	6.0
Total revenues	<u>\$ 236.6</u>	<u>\$ 237.1</u>

Product Sales, Net. Net product sales were \$231.0 million for the three months ended March 31, 2021, compared with \$231.1 million in the comparable period last year, reflecting a slowdown in INGREZZA sales volume growth, largely attributable to

the impact of COVID-19 on our customers. ONGENTYS net product sales were \$1.4 million for the three months ended March 31, 2021.

Collaboration Revenue. Collaboration revenue reflects royalties earned on AbbVie net sales of ORLISSA and ORIAHNN and license fees earned under our collaboration agreement with Mitsubishi Tanabe Pharma Corporation, or MTPC. Collaboration revenue was \$5.6 million for the three months ended March 31, 2021, compared with \$6.0 million in the comparable period last year.

Operating Expenses

Cost of Sales. Cost of sales was \$2.9 million for the three months ended March 31, 2021, compared with \$2.1 million in the comparable period last year.

Research and Development. We support our drug discovery and development efforts through the commitment of significant resources to discovery, R&D programs and business development opportunities.

Costs are reflected in the applicable development stage based upon the program status when incurred. Therefore, the same program could be reflected in different development stages in the same reporting period. For several of our programs, the R&D activities are part of our collaborative and other relationships.

Late stage consists of costs incurred related to product candidates in Phase II registrational studies and onwards. Early stage consists of costs incurred related to product candidates in post-investigational new drug application, or IND, through Phase II non-registrational studies. Research and discovery consists of pre-IND costs. Payroll and benefits consists of costs incurred for salaries and wages, payroll taxes, benefits and share-based compensation associated with employees involved in ongoing R&D activities. Share-based compensation may fluctuate from period to period based on factors that are not within our control, such as our stock price on the dates share-based grants are issued. Facilities and other consists of indirect costs incurred in support of overall R&D activities and non-specific programs, including activities that benefit multiple programs, such as management costs, as well as depreciation, information technology and facility-based expenses. These costs are not allocated to a specific program or stage.

The following table presents R&D expense by category:

<i>(in millions)</i>	Three Months Ended March 31,	
	2021	2020
Late stage	\$ 13.0	\$ 13.0
Early stage	5.5	4.6
Research and discovery	9.4	9.2
Payroll and benefits	35.5	23.9
Facilities and other	9.8	7.6
Total R&D expense	<u>\$ 73.2</u>	<u>\$ 58.3</u>

R&D expense was \$73.2 million for the three months ended March 31, 2021, compared with \$58.3 million in the comparable period last year, primarily reflecting increased investment to support advancing our expanded clinical portfolio and higher personnel expenses driven by a non-cash share-based compensation charge of \$6.4 million related to the modification of certain share-based awards.

Selling, General and Administrative. Selling, general and administrative, or SG&A, expense was \$129.0 million for the three months ended March 31, 2021, compared with \$117.8 million in the comparable period last year, primarily reflecting increased investment to support our commercialization activities and continued investment in INGREZZA.

Other Expense, Net

Other expense, net, was \$4.3 million for the three months ended March 31, 2021, compared with \$20.0 million in the comparable period last year. Periodic fluctuations in other expense, net, primarily reflect unrealized gains or losses recognized to adjust our equity investments in Voyager and Xenon Pharmaceuticals Inc. to fair value.

(Benefit from) Provision for Income Taxes

The benefit from income taxes was \$4.9 million for the three months ended March 31, 2021, compared with a provision for income taxes of \$1.5 million in the comparable period last year. Our effective tax rate for the three months ended March 31, 2021 was lower than federal and state statutory rates primarily due to excess tax benefits related to stock compensation. On

December 31, 2020, we released substantially all of our valuation allowance against our net operating losses and other deferred tax assets. Beginning in the first quarter of 2021, we began recording a provision for income taxes using an effective tax rate approximating federal and state statutory rates. Due to our ability to offset our pre-tax income against previously benefited federal net operating losses, no federal cash tax is expected in 2021.

Net Income

Net income was \$32.1 million, or \$0.33 diluted earnings per share, for the three months ended March 31, 2021, compared with \$37.4 million, or \$0.39 diluted earnings per share, in the comparable period last year, primarily reflecting increased investment in commercial initiatives and to support advancing our expanded clinical portfolio.

Liquidity and Capital Resources

At March 31, 2021, our cash, cash equivalents and debt security investments totaled \$1.1 billion compared with \$1.0 billion at December 31, 2020.

Net cash provided by operating activities was \$87.3 million for the three months ended March 31, 2021, compared with \$35.5 million in the comparable period last year, primarily reflecting increased working capital on timing of accounts receivable collections and accounts payable payments.

Net cash provided by investing activities was \$63.1 million for the three months ended March 31, 2021, compared with \$33.2 million in the comparable period last year, reflecting timing differences related to purchases, sales, and maturities of debt securities available-for-sale and changes in our portfolio-mix.

Net cash provided by financing activities was \$15.1 million for the three months ended March 31, 2021, compared with \$6.0 million in the comparable period last year, reflecting proceeds from issuances of our common stock.

Convertible Senior Notes. In May 2017, we completed a private placement of \$517.5 million in aggregate principal amount of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase \$136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of \$186.9 million in cash. At March 31, 2021, \$381.2 million aggregate principal amount of the 2024 Notes remained outstanding. We may not redeem the 2024 Notes prior to May 15, 2021. On or after this date, at our election, we may redeem all, or any portion, of the 2024 Notes under certain circumstances. The 2024 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by us. There are customary events of default with respect to the 2024 Notes, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the 2024 Notes will automatically become due and payable.

Critical Accounting Policies and Estimates

There were no changes to our critical accounting policies as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

Interest Rate Risk

We are exposed to interest rate risk on our short-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 twelve months. If a 1% change in interest rates were to have occurred on March 31, 2021, it 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, we have concluded that we do not have a material financial market risk exposure.

Recently Issued Accounting Pronouncements

For a summary of new accounting pronouncements which may be applicable to us, see Note 1 to the condensed consolidated financial statements included in this report.

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 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 Officer, of any changes to our internal control over financial reporting that occurred during our last fiscal quarter and that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Our evaluation did not identify significant changes in our internal controls 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, 2021, 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 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. The risk factors set forth below with an asterisk (*) contain changes to the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Summary Risk Factors

We face risks and uncertainties related to our business, many of which are beyond our control. In particular, risks associated with our business include:

- We may not be able to continue to successfully commercialize INGREZZA, ONGENTYS, or any of our product candidates if they are approved in the future.
- If physicians and patients do not continue to accept INGREZZA or do not accept ONGENTYS, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.
- Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products that could limit our product revenues and delay sustained profitability.
- Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have significant sales and marketing efforts or manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.
- 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.
- Our clinical studies may be delayed for safety or other reasons, or fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.
- We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.
- Use of our approved products or those of our collaborators could be associated with side effects or adverse events.
- We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced.
- We currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA, ONGENTYS or any 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 currently depend on a limited number of third-party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA or ONGENTYS, could materially and adversely affect our ability to successfully commercialize INGREZZA or ONGENTYS.
- 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 or impact our commercialization of INGREZZA, ONGENTYS or any product candidate approved by the FDA.
- We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, or violate the terms of these licenses, we could lose our rights to those technologies and drug candidates or be forced to pay damages.
- Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations.

- We have a history of losses and expect to increase our expenses for the foreseeable future, and we may not be able to sustain profitability.
- We have recently increased the size of our organization and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.
- Our customers are concentrated and therefore the loss of a significant customer may harm our business.
- If we cannot raise additional funding, we may be unable to complete development of our product candidates or establish commercial and manufacturing capabilities in the future.
- Health care reform measures and other recent legislative initiatives could adversely affect our business.
- 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.

Risks Related to Our Company

We may not be able to continue to successfully commercialize INGREZZA, ONGENTYS, or any of our product candidates if they are approved in the future.

Our ability to produce INGREZZA revenues consistent with expectations ultimately depends on our ability to successfully commercialize INGREZZA and secure adequate third-party reimbursement. Our experience in marketing and selling pharmaceutical products began with INGREZZA's approval in 2017, when we hired our sales force and established our distribution and reimbursement capabilities, all of which are necessary to successfully commercialize our current and future products. We have continued to invest in our commercial infrastructure and distribution capabilities in the past four years, including our sales force expansion in late 2018. While our team members and consultants have experience marketing and selling pharmaceutical products, we may face difficulties related to managing the rapid growth of our personnel and infrastructure, and there can be no guarantee that we will be able to maintain the personnel, systems, arrangements and capabilities necessary to continue to successfully commercialize INGREZZA, or to successfully commercialize ONGENTYS or any product candidate approved by the FDA in the future.

In addition, our business has been and may continue to be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic. Most hospitals, community mental health facilities, and other healthcare facilities have implemented policies that limit access of our sales representatives, medical affairs personnel, and patients to such facilities. Due to these closures and our work from home decisions, our field force is currently functioning utilizing digital and telephonic engagement tools and tactics, which may be less effective than our ordinary sales and marketing and medical education programs. The ultimate impact of the COVID-19 pandemic, including any lasting effects on the way we conduct our business, is highly uncertain and subject to change. If we fail to maintain successful marketing, sales and reimbursement capabilities, our product revenues may suffer.

If physicians and patients do not continue to accept INGREZZA or do not accept ONGENTYS or our sales and marketing efforts are not effective, we may not generate sufficient revenue.

The commercial success of INGREZZA or ONGENTYS will depend upon the acceptance of those products as safe and effective by the medical community and patients.

The market acceptance of INGREZZA or ONGENTYS could be affected by a number of factors, including:

- the timing of receipt of marketing approvals for indications;
- the safety and efficacy of the products;
- the pricing of our products;
- the availability of healthcare payor coverage and adequate reimbursement for the products;
- public perception regarding any products we may develop;
- the success of existing competitor products addressing our target markets or the emergence of equivalent or superior products; and
- the cost-effectiveness of the products.

If the medical community and patients do not continue to accept our products as being safe, effective, superior and/or cost-effective, we may not generate sufficient revenue.

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

Our ability to continue to commercialize INGREZZA successfully or to commercialize ONGENTYS, will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available. The continuing efforts of government and third-party payors to contain or reduce the costs of health care and the price of prescription drugs 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.

Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available regardless of whether they are approved by the FDA for that particular use.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the US. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. In addition, communications from government officials regarding health care costs and pharmaceutical pricing could have a negative impact on our stock price, even if such communications do not ultimately impact coverage or reimbursement decisions for our products.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, gene therapy treatments, which we are developing pursuant to our collaboration and license agreement with Voyager, face additional uncertainty related to pricing and reimbursement. As an example, there are a limited number of gene therapy products currently approved for coverage and reimbursement by the Centers for Medicare & Medicaid Services, or CMS.

If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize INGREZZA, ONGENTYS or any other product candidate for which we obtain marketing approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

****Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have significant sales and marketing efforts or manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.***

Our business could be adversely affected by the effects of health pandemics or epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. As a result of the ongoing COVID-19 pandemic, we may experience disruptions that could severely impact our supply chain, ongoing and future clinical trials and commercialization of INGREZZA and ONGENTYS. For example, the COVID-19 pandemic has resulted in increased travel restrictions and the shutdown or delay of business activities in various regions, including San Diego, California, where our headquarters are located. In response to state and local restrictions, we implemented work-from-home policies for all employees except certain key essential members involved in business-critical activities. We have since developed and are implementing plans regarding the opening of our sites to enable our employees to return to work in our corporate offices and the field, which

plans take into account applicable public health authority and local government guidelines and which are designed to ensure community and employee safety. The effects of the stay at home order and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, we may face several challenges or disruptions upon a return back to the workplace if and when the COVID-19 pandemic subsides, including re-integration challenges by our employees and distractions to management related to such transition. These and similar, and perhaps more severe, disruptions in our operations due to the COVID-19 pandemic could negatively impact our business, operating results and financial condition.

Quarantines, stay at home orders and other state and local restrictions, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

In addition, clinical site initiation and patient enrollment may be delayed due to concerns for patient safety and prioritization of healthcare resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients, principal investigators and site staff (who as healthcare providers may have heightened exposure to COVID-19) may be hindered, which would adversely impact our clinical trial operations. For example, due to the impact of the COVID-19 pandemic, we initially paused enrollment of new patients in several of our clinical trials. Since then, we have begun enrolling patients again in the Phase III study of valbenazine for chorea in HD and the Phase IIa pediatric study of crinacerfont in CAH. However, increases in COVID-19 cases or hospitalizations in the future could cause us to again limit or suspend our patient enrollment and screening activities.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic is currently resulting in disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global COVID-19 pandemic continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations.

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

We are commercializing and performing research on or developing products for the treatment of several disorders including endometriosis, tardive dyskinesia, uterine fibroids, essential tremor, classic congenital adrenal hyperplasia, pain, Parkinson's disease, Friedreich's ataxia, and other neurological and endocrine-related diseases and disorders, and there are a number of competitors to our products and product candidates. If one or more of our competitors' products or programs are successful, the market for our products may be reduced or eliminated.

- With respect to INGREZZA for tardive dyskinesia, we compete with Teva Pharmaceutical Industries, which received FDA approval for AUSTEDO to treat tardive dyskinesia in August 2017, and several clinical development-stage programs targeting tardive dyskinesia and related movement disorders. Additionally, there are a number of commercially available medicines used to treat tardive dyskinesia off-label, such as Xenazine (tetrabenazine) and

generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin.

- In endometriosis, ORLISSA and ORIAHNN each compete with several FDA-approved products for the treatment of endometriosis, uterine fibroids, infertility, and central precocious puberty. Additionally, there is also competition from surgical intervention, including hysterectomies and ablations. Separate from these options, there are many programs in clinical development which serve as potential future competition. Lastly, there are numerous medicines used to treat the symptoms of disease (vs. endometriosis or uterine fibroids directly) which may also serve as competition: oral contraceptives, NSAIDs and other pain medications including opioids.
- With respect to ONGENTYS for Parkinson's disease, there are currently two other FDA-approved COMT inhibitors. ONGENTYS competes directly with these two drugs and their generic equivalents. Additionally, there are a number of alternative adjunctive treatment options (FDA-approved and in clinical development) for Parkinson's patients which compete with ONGENTYS, including various L-dopa preparations, dopamine agonists, MAO-B inhibitors and others. In terms of potential future competition, there are several programs in late-stage clinical development.
- As for CAH, high doses of corticosteroids are the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive ACTH levels. In the US alone, there are more than two dozen companies manufacturing steroid-based products. Additionally, there are several clinical development-stage programs targeting CAH and several companies developing medicinal treatments for CAH.
- Our investigational treatments for potential use in epilepsy may in the future compete with numerous approved anti-seizure medications, or ASMs, and development-stage programs being pursued by several other companies. Commonly used ASMs, among others, include phenytoin, levetiracetam, brivaracetam, cenobamate, carbamazepine, clobazam, lamotrigine, valproate, oxcarbazepine, topiramate, lacosamide, perampamil and cannabidiol. There are currently no FDA-approved treatments specifically indicated for the early infantile epileptic encephalopathies SCN8A-DEE and EE-CSWS; however, a number of different ASMs are currently used in these patient populations.
- The investigational treatment luvadaxistat for the negative symptoms of schizophrenia may in the future compete with off-label antipsychotic and antidepressant medicines, including citalopram, sertraline, and amisulpride. In addition, there are several development-stage programs being pursued by other companies, including pimavanserin, roluperidone, RO6889450 and sodium benzoate. Currently, there are no FDA approved treatments specifically indicated for the negative symptoms of schizophrenia.
- Our investigational treatments for potential use in endocrinology, neurology, and psychiatry, as well as our investigational gene therapies, may in the future compete with numerous approved products and development-stage programs being pursued by several other companies.

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, marketing and distribution experience; and
- production facilities.

Moreover, increased competition in certain disorders or therapies may make it more difficult for us to recruit or enroll patients in our clinical trials for similar disorders or therapies.

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 with the exceptions of INGREZZA, which has been approved by the FDA for tardive dyskinesia, ONGENTYS, which has been approved by the FDA for Parkinson's disease, ORLISSA (partnered with AbbVie), which has been approved by the FDA for the management of moderate to severe endometriosis pain in women, and ORIAHNN (partnered with AbbVie), which has been approved by the FDA for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. Only a small number of research and development programs ultimately result in commercially successful drugs. In addition, to date the FDA has

granted regulatory approval for only a very limited number of gene therapy products and the clinical development of a gene therapy product may result in unforeseen adverse events.

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;
- 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 product candidates encounters any of these potential problems, we may never successfully market that product candidate.

Our clinical trials may be delayed for safety or other reasons or 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 and the outcomes are uncertain.

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

- the FDA or similar foreign regulatory authority may not allow an IND application or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA may require additional preclinical studies as a condition of the initiation of Phase I clinical studies, or additional clinical studies for progression from Phase I to Phase II, or Phase II to Phase III, or for 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 or other 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;
- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- the results may not be statistically significant;
- patient recruitment and enrollment may be slower or more difficult than expected;
- the FDA may not accept the data from any trial or trial site outside of the US;
- patients may drop out of the trials;
- unforeseen disruptions or delays may occur, caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic; and
- regulatory requirements may change.

These risks and uncertainties impact all of our clinical programs and any of the clinical, regulatory or operational events described above could change our planned clinical and regulatory activities. In addition, due to the impact of the COVID-19 pandemic, we paused enrollment of new patients in several of our clinical trials, and increases in COVID-19 cases or hospitalizations in the future could cause us to further limit or suspend our patient enrollment and screening activities. Additionally, any of these events described above could result in suspension of a program and/or obviate any filings for necessary regulatory approvals.

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.

Even if the clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.

We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates. For example, we collaborate with AbbVie for the manufacture and commercialization of two of our commercial products, ORLISSA and ORIAHNN, and for the continued development of elagolix. We collaborate with MTPC for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. We also rely on BIAL for the commercial supply of ONGENTYS. In addition, we collaborate with Xenon for the development of NBI-921352, Idorsia for the development of NBI-827104 and Takeda for the development of luvadaxistat, NBI-1065845, and NBI-1065846.

Our current and future collaborations and licenses could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our products or product candidates;
- we may not be able to influence our strategic collaborator's decisions regarding the development and collaboration of our partnered product and product candidates, and as a result, our collaboration partners may not pursue or prioritize the development and commercialization of those partnered products and product candidates in a manner that is in our best interest;
- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may not conduct collaborative activities in a timely manner, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may sell, transfer or divest assets or programs related to our partnered product or product candidates;
- disagreements or disputes may arise between us and our strategic collaborators that result in delays or in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and commercialization and may increase the cost of developing and commercializing our products or product candidates; and
- strategic collaborators could develop, either alone or with others, products or product candidates that may compete with ours.

If any of these issues arise, it may delay and/or negatively impact the development and commercialization of drug candidates and, ultimately, our generation of product revenues.

We may not be able to successfully commercialize ONGENTYS.

In April 2020, we received FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients, and in September 2020, we launched the commercial sale of ONGENTYS with our existing INGREZZA infrastructure. The successful commercialization of ONGENTYS is subject to many risks, and there are numerous examples of unsuccessful product launches and failures, including by pharmaceutical companies with more experience and resources than us. If we are unable to effectively train our employees and equip them with effective materials, including medical and sales literature to help them inform and educate health care practitioners about the benefits of ONGENTYS and its proper administration, our commercialization of ONGENTYS may not be successful. Even if we are successful in effectively training and equipping our sales force, there are many factors that could cause the commercialization of ONGENTYS to be unsuccessful, including a number of factors that are outside our control. Health care practitioners may not prescribe ONGENTYS and patients may be unwilling to use ONGENTYS if insurance coverage is not provided or reimbursement is inadequate. In addition, our ability to train our employees and effectively communicate with potential prescribers could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic.

Use of our approved products or those of our collaborators could be associated with side effects or adverse events.

As with most pharmaceutical products, use of our approved products or those of our collaborators could be associated with side effects or adverse events which can vary in severity (from minor adverse reactions to death) and frequency (infrequent or prevalent). Side effects or adverse events associated with the use of our products or those of our collaborators may be observed at any time, including after a product is commercialized, and reports of any such side effects or adverse events may negatively impact demand for our or our collaborators' products or affect our or our collaborators' ability to maintain regulatory approval for such products. Side effects or other safety issues associated with the use of our approved products or those of our collaborators could require us or our collaborators to modify or halt commercialization of these products or expose us to product liability lawsuits which will harm our business. We or our collaborators may be required by regulatory agencies to conduct additional studies regarding the safety and efficacy of our products which we have not planned or anticipated. Furthermore, there can be no assurance that we or our collaborators will resolve any issues related to any product related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition.

The limited precedent for gene therapy approvals makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for the product candidates we are developing through our collaboration with Voyager.

The FDA has limited experience in the review and approval of gene therapy products. The limited precedent for gene therapy approvals makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for the product candidates we are developing through our collaboration with Voyager.

Regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. As a result, the regulatory review process may take longer or cost more than we anticipate, including requirements for additional preclinical studies or clinical trials, and delay or prevent approval and commercialization of our gene therapy product candidates we are developing through our collaboration with Voyager. While the FDA has issued draft guidance for the development of gene therapies and proposed rules that would streamline certain requirements to which gene therapies are currently subject, it remains to be seen as to whether such initiatives will ultimately increase the speed of drug development in gene therapies such as the product candidates we are developing through our collaboration with Voyager.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be harmed. If our gene therapy products are approved but fail to achieve market acceptance among physicians, patients, hospitals, third-party payors or others in the medical community, we will not be able to generate significant revenue.

We currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA, ONGENTYS or any 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 commercialization of our products. We have limited experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Establishing internal commercial manufacturing capabilities would require significant time and resources, and we may not be able to timely or successfully

establish such capabilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes, including INGREZZA and ONGENTYS. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products, including INGREZZA and ONGENTYS. 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, including BIAL and its suppliers, 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. In addition, the manufacture of gene therapy products, which will be necessary under our collaboration and license agreement with Voyager, is technically complex and necessitates substantial expertise and capital investment. Our reliance on contract manufacturers also exposes us to the following risks:

- contract manufacturers may encounter difficulties in achieving volume production, quality control or 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 US Drug Enforcement Administration, and other agencies to ensure strict compliance with cGMP 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 reduce our profit margin, if any, on the sale of INGREZZA, ONGENTYS, or our future products and our ability to develop and deliver products on a timely and competitive basis.

We currently depend on a limited number of third-party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA or ONGENTYS, could materially and adversely affect our ability to successfully commercialize INGREZZA or ONGENTYS.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredients, or API, and the finished product in sufficient quantities while meeting detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products may encounter difficulties in production, such as difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, compliance with strictly enforced US, state, and non-US regulations, and disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic. We depend on a limited number of suppliers for the production of INGREZZA and its API. If our third-party suppliers for INGREZZA encounter these or any other manufacturing, quality or compliance difficulties, we may be unable to meet commercial demand for INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA. In addition, under the terms of our agreement with BIAL, although we are responsible for the management of all ONGENTYS commercialization activities, we rely on BIAL and its suppliers to supply all drug product for the commercialization of ONGENTYS. BIAL relies on third-party contract manufacturers to produce ONGENTYS. These contract manufacturers may encounter difficulties in achieving volume production, quality control, or quality assurance. As a result, these contract manufacturers may not be able to adequately produce ONGENTYS in commercial quantities when required, which may impact our ability to deliver ONGENTYS on a timely basis.

In addition, if our suppliers fail or refuse to supply us with INGREZZA or its API for any reason, it would take a significant amount of time and expense to qualify a new supplier. The FDA and similar international regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in pharmaceutical products. The loss of a supplier could require us to obtain regulatory clearance and to incur validation and other costs associated with the transfer of the API or product manufacturing processes. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to meet FDA or a similar international regulatory body's requirements for approval, there could be a shortage of INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA. If BIAL is unable or refuses to supply us with ONGENTYS drug product for any reason, or does

not meet FDA or international regulators' requirements for approval, we have limited opportunity to qualify a new supplier. This could materially and adversely affect our ability to successfully commercialize ONGENTYS.

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, or 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 our 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 do not and will not have access to all information regarding the products and product candidates we licensed to AbbVie.

We do not and will not have access to all information regarding elagolix, including potentially material information about commercialization plans, medical information strategies, clinical trial design and execution, safety reports from clinical trials, safety reports, regulatory affairs, process development, manufacturing 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 elagolix 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 commercialization efforts related to elagolix, or the status of the clinical development or regulatory approval pathway of other product candidates licensed to it, we may make operational and/or investment decisions that we would not have made had we been fully informed, which may materially and adversely affect our business and operations.

We are subject to ongoing obligations and continued regulatory review for INGREZZA. Additionally, our other product candidates, if approved, could be subject to labeling and other post-marketing requirements and restrictions.

Regulatory approvals for any of our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. For example, with respect to the FDA's approval of INGREZZA for tardive dyskinesia in April 2017, we are subject to certain post-marketing requirements and commitments. In addition, with respect to INGREZZA, and any product candidate that the FDA or a comparable foreign regulatory authority approves, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices for any clinical trials that we conduct post-approval. Failure to comply with these ongoing regulatory requirements, or later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, changes in the product's label, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- product injunctions or the imposition of civil or criminal penalties.

The occurrence of any of these events may adversely affect our business, prospects and ability to achieve or sustain profitability on a sustained basis.

Gene therapy treatments, which we are developing pursuant to our collaboration and license agreement with Voyager, may be perceived as unsafe or may result in unforeseen adverse events. Negative public opinion and increased regulatory scrutiny of gene therapy may adversely affect our ability to initiate or continue clinical development or obtain regulatory approvals for gene therapy product candidates or the commercialization of gene therapy products.

Gene therapy remains a novel technology, with few gene therapy products approved to date in the US. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. Even if we are able to successfully complete clinical development of a gene therapy product and obtain commercial approval, the success of our collaboration with Voyager will depend upon physicians who specialize in the treatment of genetic diseases targeted by gene therapy product candidates, prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations, negative public opinion related to gene therapy products, or safety issues identified in our clinical trials may delay or impair the development and commercialization of our gene therapy product candidates or demand for any gene therapy products we develop.

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 or impact our commercialization of INGREZZA, ONGENTYS or any product candidate approved by the FDA.

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, including the successful commercialization of INGREZZA, ONGENTYS or any product candidate approved by the FDA. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future, along with personnel with experience marketing and selling pharmaceutical products, 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 and individuals with experience marketing and selling pharmaceutical products. We may face particular retention challenges in light of the recent rapid growth in our personnel and infrastructure and the perceived impact of those changes upon our corporate culture. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy and our commercialization strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

If the market opportunities for our products and product candidates are smaller than we believe they are, our revenues may be adversely affected, and our business may suffer.

Certain of the diseases that INGREZZA, ONGENTYS and our other product candidates are being developed to address are in underserved and underdiagnosed populations. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who will seek treatment utilizing our products or product candidates, may not be accurate. If our estimates of the prevalence or number of patients potentially on therapy prove to be inaccurate, the market opportunities for INGREZZA, ONGENTYS and our other product candidates may be smaller than we believe they are, our prospects for generating expected revenue may be adversely affected and our business may suffer.

We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, or violate the terms of these licenses, we could lose our rights to those technologies and drug candidates or be forced to pay damages.

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. 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. For example, BIAL may terminate our license agreement, pursuant to which we have rights to commercialize ONGENTYS, if we fail to use commercially reasonable efforts to comply with specified obligations under the license agreement, or if we otherwise breach the license agreement. In addition, several of our collaboration and license agreements allow our licensors to terminate such agreements if we challenge the validity or enforceability of certain intellectual property rights or if we commit a material breach in whole or in part of the agreement and do not cure such breach within the agreed upon cure period. In addition, if we were to violate any of the terms of our licenses, we could become subject to damages. 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.

****Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations.***

In May 2017, we sold \$517.5 million aggregate principal amount of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase \$136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of \$186.9 million in cash. At March 31, 2021, \$381.2 million aggregate principal amount of the 2024 Notes remained outstanding. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the 2024 Notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under the 2024 Notes and any additional indebtedness that we may incur. In addition, our cash needs may increase in the future. In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

****The conditional conversion feature of the 2024 Notes, if triggered, may adversely affect our financial condition, operating results, or liquidity.***

In the event the conditional conversion feature of the 2024 Notes is triggered, holders of 2024 Notes will be entitled to convert their 2024 Notes at any time during specified periods at their option. If one or more of the holders of the 2024 Notes elects to convert their notes, unless we satisfy our conversion obligation by delivering only shares of our common stock, we would be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. The conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of our common stock during the prescribed measurement periods.

We have a history of losses and expect to increase our expenses for the foreseeable future, and we may not be able to sustain profitability.

Since our inception, we have incurred significant net losses and negative cash flow from operations. At December 31, 2020, we had an accumulated deficit of \$0.7 billion as a result of historical operating losses.

We received FDA approval for INGREZZA for tardive dyskinesia in April 2017 and for ONGENTYS for Parkinson's disease in April 2020. Our partner AbbVie received FDA approval for ORILISSA for endometriosis in July 2018 and for ORIAHNN for uterine fibroids in May 2020. However, we have not yet obtained regulatory approvals for any other product candidates. Even if we continue to succeed in commercializing INGREZZA, or if we successfully commercialize ONGENTYS or are successful in developing and commercializing any of our other product candidates, we may not be able to sustain profitability. We also expect to continue to incur significant operating and capital expenditures as we:

- commercialize INGREZZA for tardive dyskinesia;
- commercialize ONGENTYS for Parkinson's disease;
- 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, sales and marketing personnel.

We expect to increase our expenses and other investments in the coming years as we fund our operations, in-licensing or acquisition opportunities, and capital expenditures. While we were profitable for the year ended December 31, 2020, our future operating results and profitability may fluctuate from period to period due to the factors described above, and we will need to generate significant revenues to achieve and maintain profitability and positive cash flow on a sustained basis. We may not be able to generate these revenues, and we may never achieve profitability on a sustained basis in the future. Our failure to maintain or increase profitability on a sustained basis could negatively impact the market price of our common stock.

****We have recently increased the size of our organization and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.***

At March 31, 2021, we had approximately 865 full-time employees. Although we have substantially increased the size of our organization, we may need to add additional qualified personnel and resources, especially now that we have a commercial sales force. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates.

Our future financial performance and our ability to commercialize INGREZZA, ONGENTYS and any other product candidates that receive regulatory approval will depend, in part, on our ability to manage any future growth effectively. In particular, as we commercialize INGREZZA and ONGENTYS, we will need to support the training and ongoing activities of our sales force and will likely need to continue to expand the size of our employee base for managerial, operational, financial and other resources. To that end, we must be able to successfully:

- manage our development efforts effectively;
- integrate additional management, administrative and manufacturing personnel;
- further develop our marketing and sales organization; and
- maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals. Our failure to accomplish any of these goals could harm our financial results and prospects.

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.

****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 financial results are unpredictable and may fluctuate, for among other reasons, due to seasonality and timing of customer purchases and commercial sales of INGREZZA, impact of the commercial launch of ONGENTYS and ORIAHNN, royalties from out-licensed products, the impact of Medicare Part D coverage, 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, contract research payments, fluctuations in our effective tax rate, and disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic. 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 financial results in a quarter. While we were profitable for the quarter ended March 31, 2021, our future operating results and profitability may fluctuate from period to period, and even if we become profitable on a quarterly or annual basis, we may not be able to sustain or increase our profitability. Moreover, as our company and our market capitalization have grown, our

financial performance has become increasingly subject to quarterly and annual comparisons with the expectations of securities analysts or investors. The failure of our financial results to meet these expectations, either in a single quarterly or annual period over a sustained period time, could cause our stock price to decline.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flows, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act, enacted many significant changes to the US tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future US tax expense.

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

Our net operating loss, or NOL, carryforwards generated in tax years beginning on or prior to December 31, 2017, are only permitted to be carried forward for 20 years under applicable US tax law. Under the Tax Act, as modified by the CARES Act, our federal NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We do not believe we have experienced any previous ownership changes, but the determination is complex and there can be no assurance we are correct. Furthermore, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control.

As a result, our pre-2018 NOL carryforwards may expire prior to being used and our NOL carryforwards generated in tax years beginning after December 31, 2017, will be subject to a percentage limitation to the extent utilized in tax years beginning after December 31, 2020 and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California passed legislation imposing limits on the usability of California state NOLs and certain tax credits in tax years beginning after 2019 and before 2023. As a result, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

****Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.***

Our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

In addition, on December 31, 2020, we determined, based on our facts and circumstances, that it was more likely than not that a substantial portion of our deferred tax assets would be realized and, as a result, substantially all of our valuation allowance against our deferred tax assets was released. Therefore, beginning in 2021, we commenced recording income tax expense at

an estimated tax rate that will likely approximate statutory tax rates, which could result in a significant reduction in our net income and net income per share.

****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 for these securities has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The COVID-19 pandemic, for example, has negatively affected the stock market and investor sentiment and has resulted in significant volatility. Furthermore, especially as we and our market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts' forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, which is based on assumptions that may be incorrect or that may change from quarter to quarter, the market price of our common stock could decline. Over the course of the last twelve months, the price of our common stock has ranged from approximately \$83 per share to approximately \$136 per share. The market price of our common stock may fluctuate in response to many factors, including:

- sales of INGREZZA and ORILISSA;
- impact of the commercial launch of ONGENTYS and ORIAHNN;
- the status and cost of our post-marketing commitments for INGREZZA and ONGENTYS;
- the results of our clinical trials;
- reports of safety issues related to INGREZZA, ONGENTYS, ORILISSA, or ORIAHNN;
- developments concerning new and existing collaboration agreements;
- announcements of technological innovations or new therapeutic products by us or others;
- general economic and market conditions, including economic and market conditions affecting the biotechnology industry;
- 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;
- additions or departures of key personnel;
- fluctuations in our operating results;
- potential litigation matters;
- government regulation;
- government and third-party payor coverage and reimbursement;
- failure of any of our product candidates, if approved, to achieve commercial success;
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic; and
- public concern as to the safety of our drugs.

In addition, we recently became a member of the S&P MidCap 400 index. If we cease to be represented in the S&P MidCap 400 index, or other indexes or indexed products, as a result of our market capitalization falling below the threshold for inclusion in the index, certain institutional shareholders may, due to their internal policies and investment guidelines, be required to sell their shareholdings. Such sales may result in further negative pressure on our stock price and, when combined with reduced trading volume and liquidity, could adversely affect the value of your investment and your ability to sell your shares.

Our customers are concentrated and therefore the loss of a significant customer may harm our business.

We have entered into agreements for the distribution of INGREZZA with a limited number of specialty pharmacy providers and a specialty distributor, and all of our product sales are to these customers. Two of these customers represented approximately 86% of our product revenue for the year ended December 31, 2020 and a significant majority of our accounts receivable balance at December 31, 2020. If any of these significant customers becomes subject to bankruptcy, is unable to

pay us for our products or is acquired by a company that wants to terminate the relationship with us, or if we otherwise lose any of these significant customers, our revenue, results of operations and cash flows would be adversely affected. Even if we replace the loss of a significant customer, we cannot predict with certainty that such transition would not result in a decline in our revenue, results of operations and cash flows.

****If we cannot raise additional funding, we may be unable to complete development of our product candidates or establish commercial and manufacturing capabilities in the future.***

We may require additional funding to continue our research and 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, and the cost of product in-licensing and any possible acquisitions. In addition, 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 twelve months. However, these resources might be insufficient to conduct research and development programs, the cost of product in-taking and possible acquisitions, fully commercialize products and operate the company to the full extent currently planned. If we cannot obtain adequate funds, we may be required to curtail significantly our commercial plans or 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:

- the commercial success of INGREZZA, ONGENTYS, ORILISSA, and/or ORIAHNN;
- debt service obligations on the 2024 Notes;
- continued scientific progress in our R&D and clinical 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;
- developments related to any future litigation;
- 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. In addition, during the second quarter of 2017, we issued the 2024 Notes and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase \$136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of \$186.9 million in cash. At March 31, 2021, \$381.2 million aggregate principal amount of the 2024 Notes remained outstanding. Additional equity or debt financing might not be available on reasonable terms, if at all. In addition, disruptions due to the COVID-19 pandemic could make it more difficult for us to access capital. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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 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 selling, 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.

Increasing use of social media could give rise to liability and result in harm to our business.

Our employees are increasingly utilizing social media tools and our website as a means of communication. Despite our efforts to monitor social media communications, there is risk that the unauthorized use of social media by our employees to communicate about our products or business, or any inadvertent disclosure of material, nonpublic information through these means, may result in violations of applicable laws and regulations, which may give rise to liability and result in harm to our business. In addition, there is also risk of inappropriate disclosure of sensitive information, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse impact on our business, financial condition and results of operations. Furthermore, negative posts or comments about us or our products on social media could seriously damage our reputation, brand image and goodwill.

Risks Related to Our Industry

****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 payors to contain or reduce the costs of health care and to lower drug prices. In the US, 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 US 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 federal and state legislation impose 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 provided 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.

Additionally, in March 2010, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was signed into law, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our drug products and potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports, specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive legal and political challenges to certain aspects of the ACA. Since January 2017, several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA have been put into place. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. The Tax Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a US District Court Judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the US Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The US Supreme Court is currently reviewing the constitutionality of the ACA. Although it is unknown when a decision will be made, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began February 15, 2021 and will remain open through August 15, 2021. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, on February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2030, except for a temporary suspension from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it remains unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the US Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under

Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. The Most Favored Nation regulations mandate participation by identified Medicare Part B providers and will apply in all US states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. On December 28, 2020, the US District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. In particular, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain sustained profitability or commercialize our drugs.

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.

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 current and future sales, marketing, patient co-payment assistance and education programs.

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates and their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives; and
- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state laws that require disclosure of price increases above certain identified thresholds as well as of new commercial launches in the state; state and local laws that require the registration of pharmaceutical sales representatives; state and local “drug take back” laws and regulations; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. While our interactions with healthcare professionals, including our speaker programs and other arrangements, such as our contributions to patient assistance programs, have been structured to comply with these laws and related guidance, 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, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 once commercialized outside the US will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We could face liability if a regulatory authority determines that we are promoting INGREZZA, ONGENTYS or any of our product candidates that receives regulatory approval, for “off-label” uses.

A company may not promote “off-label” uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product’s FDA-approved label in the US or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician’s choice of drug treatment made in the physician’s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product’s FDA approved labeling. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of our products, including INGREZZA and ONGENTYS, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management’s attention could be diverted to handle any such alleged violations. If the FDA or any

other governmental agency initiates an enforcement action against us, or if we are the subject of a *qui tam* suit brought by a private plaintiff on behalf of the government, and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

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 US 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 US 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 US.

If we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed.

A product candidate that receives orphan drug designation can benefit from a streamlined regulatory process as well as potential commercial benefits following approval. Currently, this designation provides market exclusivity in the US and the EU for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs.

In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug. We may

not be successful obtaining orphan drug designations for any indications and, even if we succeed, such orphan drug designations may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position.

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.

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, or by employees of our commercial partners 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, to maintain the confidentiality of our trade secrets or the trade secrets of our commercial partners, 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 action against our employees, independent contractors, principal investigators, consultants, commercial partners or vendors for violations of these laws could result in significant civil, criminal, and administrative penalties, fines, and imprisonment.

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

The use of any of our potential products in clinical trials, and the sale of any approved products, including INGREZZA and ONGENTYS, 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 product liability insurance coverage for our clinical trials in the amount of \$45.0 million per occurrence and \$45.0 million in the aggregate. In addition, we have product liability insurance related to the sale of INGREZZA and ONGENTYS in the amount of \$45.0 million per occurrence and \$45.0 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 from any current or future clinical trials or approved products. 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. Furthermore, regardless of the eventual outcome of a product liability claim, any product liability claim against us may decrease demand for our approved products, including INGREZZA and ONGENTYS, damage our reputation, result in regulatory investigations that could require costly recalls or product modifications, cause clinical trial participants to withdrawal, result in costs to defend the related litigation, decrease our revenue, and divert management's attention from managing our business.

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.

Cyber security breaches and other disruptions could compromise our information, including the theft of our intellectual property, and could expose us to liability, which would cause our business and reputation to suffer.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect and store confidential and sensitive electronic 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 electronic information remains secure and is perceived to be secure. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the volume of data we retain, make such systems potentially vulnerable to breakdown, malicious intrusion, security breaches and other cyber-attacks. Additionally, natural disasters, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), terrorism, war and telecommunication and electrical failures may result in damage to or the interruption or impairment of key business processes, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal information. Information security risks have significantly increased in recent years in part due to the proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign private parties and state actors. A security breach or privacy violation that leads to disclosure or modification of or prevents access to personally identifiable information or other protected information could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. Similarly, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Significant disruptions of our information technology systems or breaches of data security could have a material adverse effect on our business, financial condition and results of operations.

Compliance with evolving US and global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. For example, the EU's General Data Protection Regulation, or GDPR, imposes strict obligations on the processing of personal data, including personal health data, and the free movement of such data. The GDPR applies to any company established in the EU as well as any company outside the EU that processes personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, obligations relating to: processing health and other sensitive data; obtaining consent of individuals; providing notice to individuals regarding data processing activities; responding to data subject requests; taking certain measures when engaging third-party processors; notifying data subjects and regulators of data breaches; implementing safeguards to protect the security and confidentiality of personal data; and transferring personal data to countries outside the EU, including the US. The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue or 20 million euros, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as EU regulations governing clinical trial data and other healthcare data, could require us to change our business practices or lead to government enforcement actions, private litigation or significant penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Additionally, the California Consumer Privacy Act, or CCPA, which went into effect in 2020, created new individual privacy rights for California consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. For example, the CCPA requires covered companies to provide additional disclosures to California consumers, and provides such consumers with new rights, such as the ability to opt out of certain disclosures of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the US, which could increase our potential liability and adversely affect our business.

Item 6. Exhibits

The following exhibits are filed as part of, or incorporated by reference into, this report:

Exhibit

3.1	Description:	Certificate of Incorporation, as amended
	Reference:	Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on November 5, 2018
3.2	Description:	Bylaws, as amended
4.1	Description:	Form of Common Stock Certificate
	Reference:	Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-03172)
4.2	Description:	Indenture, dated as of May 2, 2017, by and between the Company and U.S. Bank National Association, as Trustee
	Reference:	Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on May 2, 2017
4.3	Description:	Form of Note representing the Company's 2.25% Convertible Notes due 2024
	Reference:	Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on May 2, 2017
10.1*	Description:	Collaboration Agreement dated June 15, 2010, by and between Abbott International Luxembourg S.a.r.l. and the Company as amended on August 31, 2011
10.2*	Description:	First Amendment to Collaboration and License Agreement Dated August 31, 2011 between the Company and Abbott International Luxembourg S.a.r.l.
10.3*	Description:	Collaboration and License Agreement dated March 31, 2015 between Mitsubishi Tanabe Pharma Corporation and the Company
10.4*	Description:	License Agreement dated February 9, 2017 between BIAL- Portela & CA, S.A. and the Company
31.1	Description:	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Description:	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32**	Description:	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	Description:	Inline XBRL Instance Document. – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Description:	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Description:	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Description:	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Description:	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Description:	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Description:	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101)

* Certain information in this exhibit is omitted because it is both not material and is the type that the registrant treats as private or confidential.

** 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.

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.

Dated: May 5, 2021

/s/ Matthew C. Abernethy

Matthew C. Abernethy

Chief Financial Officer

(Duly authorized officer and Principal Financial Officer)

BYLAWS
OF
NEUROCRINE BIOSCIENCES, INC.
(a Delaware corporation)

BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(a Delaware corporation)

TABLE OF CONTENTS

	<u>Page</u>
ARTICLE I-CORPORATE OFFICES	1
1.1 REGISTERED OFFICE	1
1.2 OTHER OFFICES	1
ARTICLE II-MEETINGS OF STOCKHOLDERS	1
2.1 PLACE OF MEETINGS	1
2.2 ANNUAL MEETING	1
2.3 SPECIAL MEETING	1
2.4 NOTICE OF STOCKHOLDERS' MEETINGS	2
2.5 ADVANCE NOTICE OF STOCKHOLDER NOMINEES AND STOCKHOLDER BUSINESS	2
2.6 MANNER OF GIVING NOTICE; AFFIDAVIT OF NOTICE	2
2.7 QUORUM	3
2.8 ADJOURNED MEETING; NOTICE	3
2.9 VOTING	3
2.10 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING	4
2.11 RECORD DATE FOR STOCKHOLDER NOTICE; VOTING	4
2.12 PROXIES	4
2.13 ORGANIZATION	4
2.14 LIST OF STOCKHOLDERS ENTITLED TO VOTE	5
2.15 WAIVER OF NOTICE	5
ARTICLE III-DIRECTORS	5
3.1 POWERS	5
3.2 NUMBER OF DIRECTORS	5
3.3 ELECTION AND TERM OF OFFICE OF DIRECTORS	5
3.4 RESIGNATION AND VACANCIES	6
3.5 REMOVAL OF DIRECTORS	6
3.6 PLACE OF MEETINGS; MEETINGS BY TELEPHONE	6
3.7 FIRST MEETINGS	7
3.8 REGULAR MEETINGS	7
3.9 SPECIAL MEETINGS; NOTICE	7
3.10 QUORUM	7
3.11 WAIVER OF NOTICE	7
3.12 ADJOURNMENT	8
3.13 NOTICE OF ADJOURNMENT	8
3.14 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING	8
3.15 FEES AND COMPENSATION OF DIRECTORS	8
3.16 APPROVAL OF LOANS TO OFFICERS	8
3.17 SOLE DIRECTOR PROVIDED BY CERTIFICATE OF INCORPORATION	8
ARTICLE IV-COMMITTEES	9
4.1 COMMITTEES OF DIRECTORS	9
4.2 MEETINGS AND ACTION OF COMMITTEES	9
4.3 COMMITTEE MINUTES	9

TABLE OF CONTENTS

(Continued)

ARTICLE V-OFFICERS	10
5.1 OFFICERS	10
5.2 ELECTION OF OFFICERS	10
5.3 SUBORDINATE OFFICERS	10
5.4 REMOVAL AND RESIGNATION OF OFFICERS	10
5.5 VACANCIES IN OFFICES	10
5.6 CHAIRMAN OF THE BOARD	11
5.7 PRESIDENT	11
5.8 VICE PRESIDENTS	11
5.9 SECRETARY	11
5.10 CHIEF FINANCIAL OFFICER	11
5.11 ASSISTANT SECRETARY	12
5.12 ADMINISTRATIVE OFFICERS	12
5.13 AUTHORITY AND DUTIES OF OFFICERS	12
ARTICLE VI-INDEMNIFICATION OF DIRECTORS, OFFICERS, EMPLOYEES AND OTHER AGENTS	12
6.1 INDEMNIFICATION OF DIRECTORS AND OFFICERS	12
6.2 INDEMNIFICATION OF OTHERS	13
6.3 INSURANCE	13
ARTICLE VII-RECORDS AND REPORTS	13
7.1 MAINTENANCE AND INSPECTION OF RECORDS	13
7.2 INSPECTION BY DIRECTORS	14
7.3 ANNUAL STATEMENT TO STOCKHOLDERS	14
7.4 REPRESENTATION OF SHARES OF OTHER CORPORATIONS	14
7.5 CERTIFICATION AND INSPECTION OF BYLAWS	14
ARTICLE VIII-GENERAL MATTERS	14
8.1 RECORD DATE FOR PURPOSES OTHER THAN NOTICE AND VOTING	14
8.2 CHECKS; DRAFTS; EVIDENCES OF INDEBTEDNESS	15
8.3 CORPORATE CONTRACTS AND INSTRUMENTS: HOW EXECUTED	15
8.4 STOCK CERTIFICATES; TRANSFER; PARTLY PAID SHARES	15
8.5 SPECIAL DESIGNATION ON CERTIFICATES	16
8.6 LOST CERTIFICATES	16
8.7 TRANSFER AGENTS AND REGISTRARS	16
8.8 CONSTRUCTION; DEFINITIONS	16
ARTICLE IX-AMENDMENTS	16

BYLAWS
OF
NEUROCRINE BIOSCIENCES, INC.
(a Delaware corporation)

ARTICLE I

CORPORATE OFFICES

1.1 REGISTERED OFFICE

The registered office of the corporation shall be fixed in the certificate of incorporation of the corporation.

1.2 OTHER OFFICES

The board of directors may at any time establish branch or subordinate offices at any place or places where the corporation is qualified to do business.

ARTICLE II

MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS

Meetings of stockholders shall be held at any place within or outside the State of Delaware designated by the board of directors. In the absence of any such designation, stockholders' meetings shall be held at the principal executive office of the corporation.

2.2 ANNUAL MEETING

The annual meeting of stockholders shall be held each year on a date and at a time designated by the board of directors. In the absence of such designation, the annual meeting of stockholders shall be held on the third Tuesday in May in each year at 10:00 a.m. However, if such day falls on a legal holiday, then the meeting shall be held at the same time and place on the next succeeding full business day. At the meeting, directors shall be elected, and any other proper business may be transacted.

2.3 SPECIAL MEETING

A special meeting of the stockholders may be called at any time by the board of directors, or by the chairman of the board, or by the president, or by one or more stockholders holding shares in the aggregate entitled to cast more than fifty percent (50%) of the votes at that meeting. No other person or persons are permitted to call a special meeting.

If a special meeting is called by any person or persons other than the board of directors, then the request shall be in writing, specifying the time of such meeting and the general nature of the business proposed to be transacted, and shall be delivered personally or sent by registered mail or by telegraphic or other facsimile transmission to the chairman of the board, the president, or the secretary of the corporation. The officer receiving the request shall cause notice to be promptly given to the stockholders entitled to vote, in accordance with the provisions of Sections 2.4 and 2.6 of these bylaws, that a meeting will be held at the time requested by the person or persons calling the meeting, so long as that time is not less than thirty-five (35) nor more than sixty (60) days after the receipt of the request. If the notice is not given within twenty (20) days after receipt of the request, then the person or persons requesting the meeting may give the notice. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the board of directors may be held.

2.4 NOTICE OF STOCKHOLDERS' MEETINGS

All notices of meetings of stockholders shall be sent or otherwise given in accordance with Section 2.6 of these bylaws not less than ten (10) nor more than sixty (60) days before the date of the meeting. The notice shall specify the place, date and hour of the meeting and (i) in the case of a special meeting, the purpose or purposes for which the meeting is called (no business other than that specified in the notice may be transacted) or (ii) in the case of the annual meeting, those matters which the board of directors, at the time of giving the notice, intends to present for action by the stockholders (but any proper matter may be presented at the meeting for such action). The notice of any meeting at which directors are to be elected shall include the name of any nominee or nominees who, at the time of the notice, the board intends to present for election.

2.5 ADVANCE NOTICE OF STOCKHOLDER NOMINEES AND STOCKHOLDER BUSINESS

Subject to the rights of holders of any class or series of stock having a preference over the Common Stock as to dividends or upon liquidation,

(a) nominations for the election of directors, and

(b) business proposed to be brought before any stockholder meeting may be made by the board of directors or proxy committee appointed by the board of directors or by any stockholder entitled to vote in the election of directors generally if such nomination or business proposed is otherwise proper business before such meeting. However, any such stockholder may nominate one or more persons for election as directors at a meeting or propose business to be brought before a meeting, or both, only if such stockholder has given timely notice in proper written form of their intent to make such nomination or nominations or to propose such business. To be timely, such stockholder's notice must be delivered to or mailed and received at the principal executive offices of the corporation not less than one hundred twenty (120) calendar days in advance of the date specified in the corporation's proxy statement released to stockholders in connection with the previous year's annual meeting of stockholders; provided, however, that in the event that no annual meeting was held in the previous year or the date of the annual meeting has been changed by more than thirty (30) days from the date contemplated at the time of the previous year's proxy statement, notice by the stockholder to be timely must be so received a reasonable time before the solicitation is made. To be in proper form, a stockholder's notice to the secretary shall set forth:

- (i) the name and address of the stockholder who intends to make the nominations or propose the business and, as the case may be, of the person or persons to be nominated or of the business to be proposed;
- (ii) a representation that the stockholder is a holder of record of stock of the corporation entitled to vote at such meeting and, if applicable, intends to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice;
- (iii) if applicable, a description of all arrangements or understandings between the stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nomination or nominations are to be made by the stockholder;
- (iv) such other information regarding each nominee or each matter of business to be proposed by such stockholder as would be required to be included in a proxy statement filed pursuant to the proxy rules of the Securities and Exchange Commission had the nominee been nominated, or intended to be nominated, or the matter been proposed, or intended to be proposed by the board of directors; and
- (v) if applicable, the consent of each nominee to serve as director of the corporation if so elected.

The chairman of the meeting shall refuse to acknowledge the nomination of any person or the proposal of any business not made in compliance with the foregoing procedure.

2.6 MANNER OF GIVING NOTICE: AFFIDAVIT OF NOTICE

Written notice of any meeting of stockholders shall be given either personally or by first-class mail or by telegraphic or other written communication. Notices not personally delivered shall be sent charges prepaid and shall be addressed to the stockholder at the address of that stockholder appearing on the books of the corporation or given by the stockholder to the corporation for the purpose of notice. Notice shall be deemed to have been given at the time when delivered personally or deposited in the mail or sent by telegram or other means of written communication.

An affidavit of the mailing or other means of giving any notice of any stockholders' meeting, executed by the secretary, assistant secretary or any transfer agent of the corporation giving the notice, shall be prima facie evidence of the giving of such notice.

2.7 QUORUM

The holders of a majority in voting power of the stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of business except as otherwise provided by statute or by the certificate of incorporation. If, however, such quorum is not present or represented at any meeting of the stockholders, then either (i) the chairman of the meeting or (ii) the stockholders entitled to vote thereat, present in person or represented by proxy, shall have power to adjourn the meeting in accordance with Section 2.7 of these bylaws.

When a quorum is present at any meeting, the vote of the holders of a majority of the stock having voting power present in person or represented by proxy shall decide any question brought before such meeting, unless the question is one upon which, by express provision of the laws of the State of Delaware or of the certificate of incorporation or these bylaws, a different vote is required, in which case such express provision shall govern and control the decision of the question.

If a quorum be initially present, the stockholders may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum, if any action taken is approved by a majority of the stockholders initially constituting the quorum.

2.8 ADJOURNED MEETING; NOTICE

When a meeting is adjourned to another time and place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time and place thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting the corporation may transact any business that might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

2.9 VOTING

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.11 of these bylaws, subject to the provisions of Sections 217 and 218 of the General Corporation Law of Delaware (relating to voting rights of fiduciaries, pledgors and joint owners, and to voting trusts and other voting agreements).

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder, and stockholders shall not be entitled to cumulate their votes in the election of directors or with respect to any matter submitted to a vote of the stockholders.

Notwithstanding the foregoing, if the stockholders of the corporation are entitled, pursuant to Sections 2115 and 301.5 of the California Corporations Code, to cumulate their votes in the election of directors, each such stockholder shall be entitled to cumulate votes (i.e., cast for any candidate a number of votes greater than the number of votes that such stockholder normally is entitled to cast) only if the candidates' names have been properly placed in nomination (in accordance with these bylaws) prior to commencement of the voting, and the stockholder requesting cumulative voting has given notice prior to commencement of the voting of the stockholder's intention to cumulate votes. If cumulative voting is properly requested, each holder of stock, or of any class or classes or of a series or series thereof, who elects to cumulate votes shall be entitled to as many votes as equals the number of votes that (absent this provision as to cumulative voting) he or she would be entitled to cast for the election of directors with respect to his or her shares of stock multiplied by the number of directors to be elected by him, and he or she may cast all of such votes for a single director or may distribute them among the number to be voted for, or for any two or more of them, as he or she may see fit.

2.10 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise provided in the certificate of incorporation, any action required or permitted to be taken at any annual or special meeting of stockholders may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. Such consents shall be delivered to the corporation by delivery to its registered office in the state of Delaware, its principal place of business, or an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to a corporation's registered office shall be by hand or by certified or registered mail, return receipt requested.

2.11 RECORD DATE FOR STOCKHOLDER NOTICE: VOTING

For purposes of determining the stockholders entitled to notice of any meeting or to vote thereat, the board of directors may fix, in advance, a record date, which shall not precede the date upon which the resolution fixing the record date is adopted by the board of directors and which shall not be more than sixty (60) days nor less than ten (10) days before the date of any such meeting, and in such event only stockholders of record on the date so fixed are entitled to notice and to vote, notwithstanding any transfer of any shares on the books of the corporation after the record date.

If the board of directors does not so fix a record date, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the business day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the business day next preceding the day on which the meeting is held.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting unless the board of directors fixes a new record date for the adjourned meeting, but the board of directors shall fix a new record date if the meeting is adjourned for more than thirty (30) days from the date set for the original meeting.

The record date for any other purpose shall be as provided in Section 8.1 of these bylaws.

2.12 PROXIES

Every person entitled to vote for directors, or on any other matter, shall have the right to do so either in person or by one or more agents authorized by a written proxy signed by the person and filed with the secretary of the corporation, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. A proxy shall be deemed signed if the stockholder's name is placed on the proxy (whether by manual signature, typewriting, telegraphic transmission, telefacsimile or otherwise) by the stockholder or the stockholder's attorney-in-fact. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212(e) of the General Corporation Law of Delaware.

2.13 ORGANIZATION

The president, or in the absence of the president, the chairman of the board, or, in the absence of the president and the chairman of the board, one of the corporation's vice presidents, shall call the meeting of the stockholders to order, and shall act as chairman of the meeting. In the absence of the president, the chairman of the board, and all of the vice presidents, the stockholders shall appoint a chairman for such meeting. The chairman of any meeting of stockholders shall determine the order of business and the procedures at the meeting, including such matters as the regulation of the manner of voting and the conduct of business. The secretary of the corporation shall act as secretary of all meetings of the stockholders, but in the absence of the secretary at any meeting of the stockholders, the chairman of the meeting may appoint any person to act as secretary of the meeting.

2.14 LIST OF STOCKHOLDERS ENTITLED TO VOTE

The officer who has charge of the stock ledger of the corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten (10) days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present.

2.15 WAIVER OF NOTICE

Whenever notice is required to be given under any provision of the General Corporation Law of Delaware or of the certificate of incorporation or these bylaws, a written waiver thereof, signed by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice unless so required by the certificate of incorporation or these bylaws.

ARTICLE III

DIRECTORS

3.1 POWERS

Subject to the provisions of the General Corporation Law of Delaware and to any limitations in the certificate of incorporation or these bylaws relating to action required to be approved by the stockholders or by the outstanding shares, the business and affairs of the corporation shall be managed and all corporate powers shall be exercised by or under the direction of the board of directors.

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of six (6) members. The number of directors may be changed by an amendment to this bylaw, duly adopted by the board of directors or by the stockholders, or by a duly adopted amendment to the certificate of incorporation. The directors shall be divided into three classes, with the term of office of the first class, which class shall initially consist of two directors, to expire at the first annual meeting of stockholders following the 1996 Annual Meeting of Shareholders; the term of office of the second class, which class shall initially consist of two directors, to expire at the second annual meeting of stockholders following the 1996 Annual Meeting of Shareholders; the term of office of the third class, which class shall initially consist of two directors, to expire at the third annual meeting of stockholders following the 1996 Annual Meeting of Shareholders; and thereafter for each such term to expire at each third succeeding annual meeting of stockholders held after such election.

3.3 ELECTION AND TERM OF OFFICE OF DIRECTORS

Except as provided in Section 3.4 of these bylaws, directors shall be elected at each annual meeting of stockholders to hold office as provided in Section 3.2 of these bylaws. Each director, including a director elected or appointed to fill a vacancy, shall hold office until the expiration of the term for which elected and until a successor has been elected and qualified.

3.4 RESIGNATION AND VACANCIES

Any director may resign effective on giving written notice to the chairman of the board, the president, the secretary or the board of directors, unless the notice specifies a later time for that resignation to become effective. If the resignation of a director is effective at a future time, the board of directors may elect a successor to take office when the resignation becomes effective.

Vacancies in the board of directors may be filled by a majority of the remaining directors, even if less than a quorum, or by a sole remaining director; however, a vacancy created by the removal of a director by the vote of the stockholders or by court order may be filled only by the affirmative vote of a majority of the shares represented and voting at a duly held meeting at which a quorum is present (which shares voting affirmatively also constitute a majority of the required quorum). Each director so elected shall hold office for a term expiring at the next annual meeting of the stockholders at which the term of office of the class to which such director has been elected expires.

Unless otherwise provided in the certificate of incorporation or these bylaws:

(i) Vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.

(ii) Whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the certificate of incorporation, vacancies and newly created directorships of such class or classes or series may be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected.

If at any time, by reason of death or resignation or other cause, the corporation should have no directors in office, then any officer or any stockholder or an executor, administrator, trustee or guardian of a stockholder, or other fiduciary entrusted with like responsibility for the person or estate of a stockholder, may call a special meeting of stockholders in accordance with the provisions of the certificate of incorporation or these bylaws, or may apply to the Court of Chancery for a decree summarily ordering an election as provided in Section 211 of the General Corporation Law of Delaware.

If, at the time of filling any vacancy or any newly created directorship, the directors then in office constitute less than a majority of the whole board (as constituted immediately prior to any such increase), then the Court of Chancery may, upon application of any stockholder or stockholders holding at least ten (10) percent of the total number of the shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by the provisions of Section 211 of the General Corporation Law of Delaware as far as applicable.

3.5 REMOVAL OF DIRECTORS

Unless otherwise restricted by statute, by the certificate of incorporation or by these bylaws, any director or the entire board of directors may be removed, with cause, by the holders of a majority of the shares then entitled to vote at an election of directors.

3.6 PLACE OF MEETINGS; MEETINGS BY TELEPHONE

Regular meetings of the board of directors may be held at any place within or outside the State of Delaware that has been designated from time to time by resolution of the board. In the absence of such a designation, regular meetings shall be held at the principal executive office of the corporation. Special meetings of the board may be held at any place within or outside the State of Delaware that has been designated in the notice of the meeting or, if not stated in the notice or if there is no notice, at the principal executive office of the corporation.

Any meeting of the board, regular or special, may be held by conference telephone or similar communication equipment, so long as all directors participating in the meeting can hear one another; and all such participating directors shall be deemed to be present in person at the meeting.

3.7 FIRST MEETINGS

The first meeting of each newly elected board of directors shall be held at such time and place as shall be fixed by the vote of the stockholders at the annual meeting. In the event of the failure of the stockholders to fix the time or place of such first meeting of the newly elected board of directors, or in the event such meeting is not held at the time and place so fixed by the stockholders, the meeting may be held at such time and place as shall be specified in a notice given as hereinafter provided for special meetings of the board of directors, or as shall be specified in a written waiver signed by all of the directors.

3.8 REGULAR MEETINGS

Regular meetings of the board of directors may be held without notice at such time as shall from time to time be determined by the board of directors. If any regular meeting day shall fall on a legal holiday, then the meeting shall be held at the same time and place on the next succeeding full business day.

3.9 SPECIAL MEETINGS: NOTICE

Special meetings of the board of directors for any purpose or purposes may be called at any time by the chairman of the board, the president, any vice president, the secretary or any two directors.

Notice of the time and place of special meetings shall be delivered personally or by telephone to each director or sent by first-class mail, telecopy or telegram, charges prepaid, addressed to each director at that director's address as it is shown on the records of the corporation. If the notice is mailed, it shall be deposited in the United States mail at least four (4) days before the time of the holding of the meeting. If the notice is delivered personally or by telephone, telecopy or telegram, it shall be delivered personally or by telephone or to the telegraph company at least forty-eight (48) hours before the time of the holding of the meeting. Any oral notice given personally or by telephone may be communicated either to the director or to a person at the office of the director who the person giving the notice has reason to believe will promptly communicate it to the director. The notice need not specify the purpose or the place of the meeting, if the meeting is to be held at the principal executive office of the corporation.

3.10 QUORUM

A majority of the authorized number of directors shall constitute a quorum for the transaction of business, except to adjourn as provided in Section 3.12 of these bylaws. Every act or decision done or made by a majority of the directors present at a duly held meeting at which a quorum is present shall be regarded as the act of the board of directors, subject to the provisions of the certificate of incorporation and applicable law.

A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any action taken is approved by at least a majority of the quorum for that meeting.

3.11 WAIVER OF NOTICE

Notice of a meeting need not be given to any director (i) who signs a waiver of notice, whether before or after the meeting, or (ii) who attends the meeting other than for the express purpose of objecting at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened. All such waivers shall be filed with the corporate records or made part of the minutes of the meeting. A waiver of notice need not specify the purpose of any regular or special meeting of the board of directors.

3.12 ADJOURNMENT

A majority of the directors present, whether or not constituting a quorum, may adjourn any meeting of the board to another time and place.

3.13 NOTICE OF ADJOURNMENT

Notice of the time and place of holding an adjourned meeting of the board need not be given unless the meeting is adjourned for more than twenty-four (24) hours. If the meeting is adjourned for more than twenty-four (24) hours, then notice of the time and place of the adjourned meeting shall be given before the adjourned meeting takes place, in the manner specified in Section 3.9 of these bylaws, to the directors who were not present at the time of the adjournment.

3.14 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Any action required or permitted to be taken by the board of directors may be taken without a meeting, provided that all members of the board individually or collectively consent in writing to that action. Such action by written consent shall have the same force and effect as a unanimous vote of the board of directors. Such written consent and any counterparts thereof shall be filed with the minutes of the proceedings of the board of directors.

3.15 FEES AND COMPENSATION OF DIRECTORS

Directors and members of committees may receive such compensation, if any, for their services and such reimbursement of expenses as may be fixed or determined by resolution of the board of directors. This Section 3.15 shall not be construed to preclude any director from serving the corporation in any other capacity as an officer, agent, employee or otherwise and receiving compensation for those services.

3.16 APPROVAL OF LOANS TO OFFICERS

The corporation may lend money to, or guarantee any obligation of, or otherwise assist any officer or other employee of the corporation or any of its subsidiaries, including any officer or employee who is a director of the corporation or any of its subsidiaries, whenever, in the judgment of the directors, such loan, guaranty or assistance may reasonably be expected to benefit the corporation. The loan, guaranty or other assistance may be with or without interest and may be unsecured, or secured in such manner as the board of directors shall approve, including, without limitation, a pledge of shares of stock of the corporation. Nothing contained in this section shall be deemed to deny, limit or restrict the powers of guaranty or warranty of the corporation at common law or under any statute.

3.17 SOLE DIRECTOR PROVIDED BY CERTIFICATE OF INCORPORATION

In the event only one director is required by these bylaws or the certificate of incorporation, then any reference herein to notices, waivers, consents, meetings or other actions by a majority or quorum of the directors shall be deemed to refer to such notice, waiver, etc., by such sole director, who shall have all the rights and duties and shall be entitled to exercise all of the powers and shall assume all the responsibilities otherwise herein described as given to the board of directors.

ARTICLE IV

COMMITTEES

4.1 COMMITTEES OF DIRECTORS

The board of directors may, by resolution adopted by a majority of the authorized number of directors, designate one (1) or more committees, each consisting of two or more directors, to serve at the pleasure of the board. The board may designate one (1) or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. The appointment of members or alternate members of a committee requires the vote of a majority of the authorized number of directors. Any committee, to the extent provided in the resolution of the board, shall have and may exercise all the powers and authority of the board, but no such committee shall have the power or authority to (i) amend the certificate of incorporation (except that a committee may, to the extent authorized in the resolution or resolutions providing for the issuance of shares of stock adopted by the board of directors as provided in Section 151(a) of the General Corporation Law of Delaware, fix the designations and any of the preferences or rights of such shares relating to dividends, redemption, dissolution, any distribution of assets of the corporation or the conversion into, or the exchange of such shares for, shares of any other class or classes or any other series of the same or any other class or classes of stock of the corporation), (ii) adopt an agreement of merger or consolidation under Sections 251 or 252 of the General Corporation Law of Delaware, (iii) recommend to the stockholders the sale, lease or exchange of all or substantially all of the corporation's property and assets, (iv) recommend to the stockholders a dissolution of the corporation or a revocation of a dissolution or (v) amend the bylaws of the corporation; and, unless the board resolution establishing the committee, the bylaws or the certificate of incorporation expressly so provide, no such committee shall have the power or authority to declare a dividend, to authorize the issuance of stock, or to adopt a certificate of ownership and merger pursuant to Section 253 of the General Corporation Law of Delaware.

4.2 MEETINGS AND ACTION OF COMMITTEES

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the following provisions of Article III of these bylaws: Section 3.6 (place of meetings; meetings by telephone), Section 3.8 (regular meetings), Section 3.9 (special meetings; notice), Section 3.10 (quorum), Section 3.11 (waiver of notice), Section 3.12 (adjournment), Section 3.13 (notice of adjournment) and Section 3.14 (board action by written consent without meeting), with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the board of directors and its members; provided, however, that the time of regular meetings of committees may be determined either by resolution of the board of directors or by resolution of the committee, that special meetings of committees may also be called by resolution of the board of directors, and that notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The board of directors may adopt rules for the government of any committee not inconsistent with the provisions of these bylaws.

4.3 COMMITTEE MINUTES

Each committee shall keep regular minutes of its meetings and report the same to the board of directors when required.

ARTICLE V

OFFICERS

5.1 OFFICERS

The Corporate Officers of the corporation shall be a president, a secretary and a chief financial officer. The corporation may also have, at the discretion of the board of directors, a chairman of the board, one or more vice presidents (however denominated), one or more assistant secretaries, a treasurer and one or more assistant treasurers, and such other officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws. Any number of offices may be held by the same person.

In addition to the Corporate Officers of the Company described above, there may also be such Administrative Officers of the corporation as may be designated and appointed from time to time by the president of the corporation in accordance with the provisions of Section 5.12 of these bylaws.

5.2 ELECTION OF OFFICERS

The Corporate Officers of the corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 or Section 5.5 of these bylaws, shall be chosen by the board of directors, subject to the rights, if any, of an officer under any contract of employment, and shall hold their respective offices for such terms as the board of directors may from time to time determine.

5.3 SUBORDINATE OFFICERS

The board of directors may appoint, or may empower the president to appoint, such other Corporate Officers as the business of the corporation may require, each of whom shall hold office for such period, have such power and authority, and perform such duties as are provided in these bylaws or as the board of directors may from time to time determine.

The president may from time to time designate and appoint Administrative Officers of the corporation in accordance with the provisions of Section 5.12 of these bylaws.

5.4 REMOVAL AND RESIGNATION OF OFFICERS

Subject to the rights, if any, of a Corporate Officer under any contract of employment, any Corporate Officer may be removed, either with or without cause, by the board of directors at any regular or special meeting of the board or, except in case of a Corporate Officer chosen by the board of directors, by any Corporate Officer upon whom such power of removal may be conferred by the board of directors.

Any Corporate Officer may resign at any time by giving written notice to the corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice; and, unless otherwise specified in that notice, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the corporation under any contract to which the Corporate Officer is a party.

Any Administrative Officer designated and appointed by the president may be removed, either with or without cause, at any time by the president. Any Administrative Officer may resign at any time by giving written notice to the president or to the secretary of the corporation.

5.5 VACANCIES IN OFFICES

A vacancy in any office because of death, resignation, removal, disqualification or any other cause shall be filled in the manner prescribed in these bylaws for regular appointments to that office.

5.6 CHAIRMAN OF THE BOARD

The chairman of the board, if such an officer be elected, shall, if present, preside at meetings of the board of directors and exercise such other powers and perform such other duties as may from time to time be assigned to him by the board of directors or as may be prescribed by these bylaws. If there is no president, then the chairman of the board shall also be the chief executive officer of the corporation and shall have the powers and duties prescribed in Section 5.7 of these bylaws.

5.7 PRESIDENT

Subject to such supervisory powers, if any, as may be given by the board of directors to the chairman of the board, if there be such an officer, the president shall be the chief executive officer of the corporation and shall, subject to the control of the board of directors, have general supervision, direction and control of the business and the officers of the corporation. He or she shall preside at all meetings of the stockholders and, in the absence or nonexistence of a chairman of the board, at all meetings of the board of directors. He or she shall have the general powers and duties of management usually vested in the office of president of a corporation, and shall have such other powers and perform such other duties as may be prescribed by the board of directors or these bylaws.

5.8 VICE PRESIDENTS

In the absence or disability of the president, and if there is no chairman of the board, the vice presidents, if any, in order of their rank as fixed by the board of directors or, if not ranked, a vice president designated by the board of directors, shall perform all the duties of the president and when so acting shall have all the powers of, and be subject to all the restrictions upon, the president. The vice presidents shall have such other powers and perform such other duties as from time to time may be prescribed for them respectively by the board of directors, these bylaws, the president or the chairman of the board.

5.9 SECRETARY

The secretary shall keep or cause to be kept, at the principal executive office of the corporation or such other place as the board of directors may direct, a book of minutes of all meetings and actions of the board of directors, committees of directors and stockholders. The minutes shall show the time and place of each meeting, whether regular or special (and, if special, how authorized and the notice given), the names of those present at directors' meetings or committee meetings, the number of shares present or represented at stockholders' meetings and the proceedings thereof.

The secretary shall keep, or cause to be kept, at the principal executive office of the corporation or at the office of the corporation's transfer agent or registrar, as determined by resolution of the board of directors, a share register or a duplicate share register, showing the names of all stockholders and their addresses, the number and classes of shares held by each, the number and date of certificates evidencing such shares and the number and date of cancellation of every certificate surrendered for cancellation.

The secretary shall give, or cause to be given, notice of all meetings of the stockholders and of the board of directors required to be given by law or by these bylaws. He or she shall keep the seal of the corporation, if one be adopted, in safe custody and shall have such other powers and perform such other duties as may be prescribed by the board of directors or by these bylaws.

5.10 CHIEF FINANCIAL OFFICER

The chief financial officer shall keep and maintain, or cause to be kept and maintained, adequate and correct books and records of accounts of the properties and business transactions of the corporation, including accounts of its assets, liabilities, receipts, disbursements, gains, losses, capital, retained earnings and shares. The books of account shall at all reasonable times be open to inspection by any director for a purpose reasonably related to his position as a director.

The chief financial officer shall deposit all money and other valuables in the name and to the credit of the corporation with such depositaries as may be designated by the board of directors. He or she shall disburse the funds of the corporation as may be ordered by the board of directors, shall render to the president and directors, whenever they request it, an account of all of his or her transactions as chief financial officer and of the financial condition of the corporation, and shall have such other powers and perform such other duties as may be prescribed by the board of directors or these bylaws.

5.11 ASSISTANT SECRETARY

The assistant secretary, if any, or, if there is more than one, the assistant secretaries in the order determined by the board of directors (or if there be no such determination, then in the order of their election) shall, in the absence of the secretary or in the event of his or her inability or refusal to act, perform the duties and exercise the powers of the secretary and shall perform such other duties and have such other powers as the board of directors may from time to time prescribe.

5.12 ADMINISTRATIVE OFFICERS

In addition to the Corporate Officers of the corporation as provided in Section 5.1 of these bylaws and such subordinate Corporate Officers as may be appointed in accordance with Section 5.3 of these bylaws, there may also be such Administrative Officers of the corporation as may be designated and appointed from time to time by the president of the corporation. Administrative Officers shall perform such duties and have such powers as from time to time may be determined by the president or the board of directors in order to assist the Corporate Officers in the furtherance of their duties. In the performance of such duties and the exercise of such powers, however, such Administrative Officers shall have limited authority to act on behalf of the corporation as the board of directors shall establish, including but not limited to, limitations on the dollar amount and on the scope of agreements or commitments that may be made by such Administrative Officers on behalf of the corporation, which limitations may not be exceeded by such individuals or altered by the president without further approval by the board of directors.

5.13 AUTHORITY AND DUTIES OF OFFICERS

In addition to the foregoing powers, authority and duties, all officers of the corporation shall respectively have such authority and powers and perform such duties in the management of the business of the corporation as may be designated from time to time by the board of directors.

ARTICLE VI

INDEMNIFICATION OF DIRECTORS, OFFICERS, EMPLOYEES AND OTHER AGENTS

6.1 INDEMNIFICATION OF DIRECTORS AND OFFICERS

The corporation shall, to the maximum extent and in the manner permitted by the General Corporation Law of Delaware as the same now exists or may hereafter be amended, indemnify any person against expenses (including attorneys' fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred in connection with any threatened, pending or completed action, suit, or proceeding in which such person was or is a party or is threatened to be made a party by reason of the fact that such person is or was a director or officer of the corporation. For purposes of this Section 6.1, a "director" or "officer" of the corporation shall mean any person (i) who is or was a director or officer of the corporation, (ii) who is or was serving at the request of the corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, or (iii) who was a director or officer of a corporation which was a predecessor corporation of the corporation or of another enterprise at the request of such predecessor corporation.

The corporation shall be required to indemnify a director or officer in connection with an action, suit, or proceeding (or part thereof) initiated by such director or officer only if the initiation of such action, suit, or proceeding (or part thereof) by the director or officer was authorized by the Board of Directors of the corporation.

The corporation shall pay the expenses (including attorney's fees) incurred by a director or officer of the corporation entitled to indemnification hereunder in defending any action, suit or proceeding referred to in this Section 6.1 in advance of its final disposition; provided, however, that payment of expenses incurred by a director or officer of the corporation in advance of the final disposition of such action, suit or proceeding shall be made only upon receipt of an undertaking by the director or officer to repay all amounts advanced if it should ultimately be determined that the director or officer is not entitled to be indemnified under this Section 6.1 or otherwise.

The rights conferred on any person by this Article shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of the corporation's certificate of incorporation, these bylaws, agreement, vote of the stockholders or disinterested directors or otherwise.

Any repeal or modification of the foregoing provisions of this Article shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification.

6.2 INDEMNIFICATION OF OTHERS

The corporation shall have the power, to the maximum extent and in the manner permitted by the General Corporation Law of Delaware as the same now exists or may hereafter be amended, to indemnify any person (other than directors and officers) against expenses (including attorneys' fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred in connection with any threatened, pending or completed action, suit, or proceeding, in which such person was or is a party or is threatened to be made a party by reason of the fact that such person is or was an employee or agent of the corporation. For purposes of this Section 6.2, an "employee" or "agent" of the corporation (other than a director or officer) shall mean any person (i) who is or was an employee or agent of the corporation, (ii) who is or was serving at the request of the corporation as an employee or agent of another corporation, partnership, joint venture, trust or other enterprise, or (iii) who was an employee or agent of a corporation which was a predecessor corporation of the corporation or of another enterprise at the request of such predecessor corporation.

6.3 INSURANCE

The corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify him or her against such liability under the provisions of the General Corporation Law of Delaware.

ARTICLE VII

RECORDS AND REPORTS

7.1 MAINTENANCE AND INSPECTION OF RECORDS

The corporation shall, either at its principal executive office or at such place or places as designated by the board of directors, keep a record of its stockholders listing their names and addresses and the number and class of shares held by each stockholder, a copy of these bylaws as amended to date, accounting books and other records of its business and properties.

Any stockholder of record, in person or by attorney or other agent, shall, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose the corporation's stock ledger, a list of its stockholders, and its other books and records and to make copies or extracts therefrom. A proper purpose shall mean a purpose reasonably related to such person's interest as a stockholder. In every instance where an attorney or other agent is the person who seeks the right to inspection, the demand under oath shall be accompanied by a power of attorney or such other writing that authorizes the attorney or other agent to so act on behalf of the stockholder. The demand under oath shall be directed to the corporation at its registered office in Delaware or at its principal place of business.

7.2 INSPECTION BY DIRECTORS

Any director shall have the right to examine (and to make copies of) the corporation's stock ledger, a list of its stockholders and its other books and records for a purpose reasonably related to his or her position as a director.

7.3 ANNUAL STATEMENT TO STOCKHOLDERS

The board of directors shall present at each annual meeting, and at any special meeting of the stockholders when called for by vote of the stockholders, a full and clear statement of the business and condition of the corporation.

7.4 REPRESENTATION OF SHARES OF OTHER CORPORATIONS

The chairman of the board, if any, the president, any vice president, the chief financial officer, the secretary or any assistant secretary of this corporation, or any other person authorized by the board of directors or the president or a vice president, is authorized to vote, represent and exercise on behalf of this corporation all rights incident to any and all shares of the stock of any other corporation or corporations standing in the name of this corporation. The authority herein granted may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

7.5 CERTIFICATION AND INSPECTION OF BYLAWS

The original or a copy of these bylaws, as amended or otherwise altered to date, certified by the secretary, shall be kept at the corporation's principal executive office and shall be open to inspection by the stockholders of the corporation, at all reasonable times during office hours.

ARTICLE VIII

GENERAL MATTERS

8.1 RECORD DATE FOR PURPOSES OTHER THAN NOTICE AND VOTING

For purposes of determining the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the board of directors may fix, in advance, a record date, which shall not precede the date upon which the resolution fixing the record date is adopted and which shall not be more than sixty (60) days before any such action. In that case, only stockholders of record at the close of business on the date so fixed are entitled to receive the dividend, distribution or allotment of rights, or to exercise such rights, as the case may be, notwithstanding any transfer of any shares on the books of the corporation after the record date so fixed, except as otherwise provided by law.

If the board of directors does not so fix a record date, then the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the board of directors adopts the applicable resolution.

8.2 CHECKS; DRAFTS; EVIDENCES OF INDEBTEDNESS

From time to time, the board of directors shall determine by resolution which person or persons may sign or endorse all checks, drafts, other orders for payment of money, notes or other evidences of indebtedness that are issued in the name of or payable to the corporation, and only the persons so authorized shall sign or endorse those instruments.

8.3 CORPORATE CONTRACTS AND INSTRUMENTS; HOW EXECUTED

The board of directors, except as otherwise provided in these bylaws, may authorize and empower any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the corporation; such power and authority may be general or confined to specific instances. Unless so authorized or ratified by the board of directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

8.4 STOCK CERTIFICATES; TRANSFER; PARTLY PAID SHARES

The shares of the corporation shall be represented by certificates, provided that the board of directors of the corporation may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Notwithstanding the adoption of such a resolution by the board of directors, every holder of stock represented by certificates and, upon request, every holder of uncertificated shares, shall be entitled to have a certificate signed by, or in the name of the corporation by, the chairman or vice-chairman of the board of directors, or the president or vice-president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of such corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if he or she were such officer, transfer agent or registrar at the date of issue.

Certificates for shares shall be of such form and device as the board of directors may designate and shall state the name of the record holder of the shares represented thereby; its number; date of issuance; the number of shares for which it is issued; a summary statement or reference to the powers, designations, preferences or other special rights of such stock and the qualifications, limitations or restrictions of such preferences and/or rights, if any; a statement or summary of liens, if any; a conspicuous notice of restrictions upon transfer or registration of transfer, if any; a statement as to any applicable voting trust agreement; if the shares be assessable, or, if assessments are collectible by personal action, a plain statement of such facts.

Upon surrender to the secretary or transfer agent of the corporation of a certificate for shares duly endorsed or accompanied by proper evidence of succession, assignment or authority to transfer, it shall be the duty of the corporation to issue a new certificate to the person entitled thereto, cancel the old certificate and record the transaction upon its books.

The corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, or upon the books and records of the corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

8.5 SPECIAL DESIGNATION ON CERTIFICATES

If the corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the corporation shall issue to represent such class or series of stock; provided, however, that, except as otherwise provided in Section 202 of the General Corporation Law of Delaware, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the corporation shall issue to represent such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

8.6 LOST CERTIFICATES

Except as provided in this Section 8.6, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the corporation and cancelled at the same time. The board of directors may, in case any share certificate or certificate for any other security is lost, stolen or destroyed, authorize the issuance of replacement certificates on such terms and conditions as the board may require; the board may require indemnification of the corporation secured by a bond or other adequate security sufficient to protect the corporation against any claim that may be made against it, including any expense or liability, on account of the alleged loss, theft or destruction of the certificate or the issuance of the replacement certificate.

8.7 TRANSFER AGENTS AND REGISTRARS

The board of directors may appoint one or more transfer agents or transfer clerks, and one or more registrars, each of which shall be an incorporated bank or trust company-either domestic or foreign, who shall be appointed at such times and places as the requirements of the corporation may necessitate and the board of directors may designate.

8.8 CONSTRUCTION; DEFINITIONS

Unless the context requires otherwise, the general provisions, rules of construction and definitions in the General Corporation Law of Delaware shall govern the construction of these bylaws. Without limiting the generality of this provision, as used in these bylaws, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both an entity and a natural person.

ARTICLE IX

AMENDMENTS

The original or other bylaws of the corporation may be adopted, amended or repealed by the stockholders entitled to vote or by the board of directors of the corporation. The fact that such power has been so conferred upon the directors shall not divest the stockholders of the power, nor limit their power to adopt, amend or repeal bylaws.

Whenever an amendment or new bylaw is adopted, it shall be copied in the book of bylaws with the original bylaws, in the appropriate place. If any bylaw is repealed, the fact of repeal with the date of the meeting at which the repeal was enacted or the filing of the operative written consent(s) shall be stated in said book.

CERTIFICATE OF ADOPTION OF BYLAWS
OF
NEUROCRINE BIOSCIENCES, INC.
ADOPTION BY INCORPORATOR

The undersigned person appointed in the certificate of incorporation to act as the Incorporator of Neurocrine Biosciences, Inc. hereby adopts the foregoing bylaws, comprising twenty-two (22) pages, as the bylaws of the corporation.

Effective as of March 21, 1996.

/s/ Richard S. Arnold, Jr .

Richard S. Arnold, Jr.
Incorporator

Certificate by Secretary of Adoption by Incorporator

The undersigned hereby certifies that he is the duly elected, qualified, and acting Secretary of Neurocrine Biosciences, Inc. and that the foregoing bylaws, comprising twenty-two (22) pages, were adopted as the bylaws of the corporation effective as of March 21, 1996, by the person appointed in the certificate of incorporation to act as the Incorporator of the corporation.

IN WITNESS WHEREOF, the undersigned has hereunto set his hand and affixed the corporate seal this 21 st day of March 1996.

/s/ Michael J . O'Donnell

Michael J. O'Donnell
Secretary

**CERTIFICATE OF AMENDMENT OF
BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A Delaware Corporation)**

On April 2, 1996, the Board of Directors and the sole stockholder of the corporation approved the amendment of Section 2.3 and Section 3.5 of the Bylaws of the corporation to read as follows:

2.3 SPECIAL MEETING

A special meeting of the stockholders may be called at any time by the board of directors, or by the chairman of the board, or by the president, or by one or more stockholders holding shares in the aggregate entitled to cast more than ten percent (10%) of the votes at that meeting. No other person or persons are permitted to call a special meeting.

If a special meeting is called by any person or persons other than the board of directors, then the request shall be in writing, specifying the time of such meeting and the general nature of the business proposed to be transacted, and shall be delivered personally or sent by registered mail or by telegraphic or other facsimile transmission to the chairman of the board, the president, or the secretary of the corporation. The officer receiving the request shall cause notice to be promptly given to the stockholders entitled to vote, in accordance with the provisions of Sections 2.4 and 2.6 of these bylaws, that a meeting will be held at the time requested by the person or persons calling the meeting, so long as that time is not less than thirty-five (35) nor more than sixty (60) days after the receipt of the request. If the notice is not given within twenty (20) days after receipt of the request, then the person or persons requesting the meeting may give the notice. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the board of directors may be held.

3.5 REMOVAL OF DIRECTORS

Unless otherwise restricted by statute, by the certificate of incorporation or by these bylaws, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors.

**CERTIFICATE OF AMENDMENT OF
BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A Delaware Corporation)**

On May 27, 1997, the stockholders of the corporation approved the amendment of Section 3.2 of the Bylaws of the corporation to read as follows:

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of seven (7) members. The number of directors may be changed by an amendment to this bylaw, duly adopted by the board of directors or by the stockholders, or by a duly adopted amendment to the certificate of incorporation. The directors shall be divided into three classes, with the term of office of the first class, which class shall initially consist of two directors, to expire at the first annual meeting of stockholders following the 1996 Annual Meeting of Shareholders; the term of office of the second class, which class shall initially consist of two directors, to expire at the second annual meeting of stockholders following the 1996 Annual Meeting of Shareholders; the term of office of the third class, which class shall initially consist of two directors, to expire at the third annual meeting of stockholders following the 1996 Annual Meeting of Shareholders; and thereafter for each such term to expire at each third succeeding annual meeting of stockholders held after such election.

**CERTIFICATE OF AMENDMENT OF
BY-LAWS OF
NEUROCRINE BIOSCIENCES, INC.
(a Delaware Corporation)**

On May 28, 2004 the Board of Directors of Neurocrine Biosciences, Inc. approved the amendment of Section 3.2 of the By-Laws of the corporation to read as follows:

3.2 Number of Directors . The Board of Directors shall consist of eight (8) members. The number of Directors may be changed by an amendment to this by-law adopted by the Board of Directors or by the stockholders or by a duly adopted amendment to the certificate of incorporation. The Directors shall be divided into three classes, with the term of office of the first class (Class I Directors), which will initially consist of three Directors, to expire at the 2006 Annual Meeting of Shareholders; the term of office of the second class (Class II Directors), which will initially consist of three (3) Directors, to expire at the 2008 Annual Meeting of Shareholders; the term of office of the third class (Class III Directors), which will initially consist of two (2) Directors, to expire at the 2005 Annual Meeting of Shareholders; and thereafter for each such term to expire at each third succeeding Annual Meeting of Shareholders held after such election.

**CERTIFICATE OF AMENDMENT OF
BY-LAWS OF
NEUROCRINE BIOSCIENCES, INC.
(a Delaware Corporation)**

On February 3, 2010 the Board of Directors of Neurocrine Biosciences, Inc. approved the amendment of Section 3.2 of the By-Laws of the corporation to read as follows:

3.2 Number of Directors . The Board of Directors shall consist of nine (9) members. The number of Directors may be changed by an amendment to this by-law adopted by the Board of Directors or by the stockholders or by a duly adopted amendment to the certificate of incorporation. The Directors shall be divided into three classes, with the term of office of the first class (Class I Directors), which will initially consist of three (3) Directors, to expire at the 2012 Annual Meeting of Shareholders; the term of office of the second class (Class II Directors), which will initially consist of three (3) Directors, to expire at the 2010 Annual Meeting of Shareholders; the term of office of the third class (Class III Directors), which will initially consist of three (3) Directors, to expire at the 2011 Annual Meeting of Shareholders; and thereafter for each such term to expire at each third succeeding Annual Meeting of Shareholders held after such election.

**CERTIFICATE OF AMENDMENT
OF BY-LAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A DELAWARE CORPORATION)**

On February 23, 2012, the Board of Directors of Neurocrine Biosciences, Inc. approved the amendment of Section 3.2 of the By-Laws of the corporation to read as follows:

3.2 Number of Directors . The Board of Directors shall consist of eight (8) members. The number of Directors may be changed by an amendment to this by-law adopted by the Board of Directors or by the stockholders or by a duly adopted amendment to the certificate of incorporation. The Directors shall be divided into three classes, with the term of office of the first class (Class I Directors), which will initially consist of two (2) Directors, to expire at the 2012 Annual Meeting of Shareholders; the term of office of the second class (Class II Directors), which will initially consist of three (3) Directors, to expire at the 2013 Annual Meeting of Shareholders; the term of office of the third class (Class III Directors), which will initially consist of three (3) Directors, to expire at the 2014 Annual Meeting of Shareholders; and thereafter for each such term to expire at each third succeeding Annual Meeting of Shareholders held after such election.

**CERTIFICATE OF AMENDMENT
OF BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A DELAWARE CORPORATION)**

On September 30, 2015, the Board of Directors of Neurocrine Biosciences, Inc. approved the amendment of Section 3.2 of the Bylaws of the corporation to read as follows:

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of ten (10) members. The number of directors may be changed by an amendment to this bylaw, duly adopted by the board of directors or by the stockholders, or by a duly adopted amendment to the certificate of incorporation. The directors shall be divided into three classes, with the term of office of the first class (Class I Directors), which class shall initially consist of four (4) directors, to expire at the 2018 annual meeting of stockholders; the term of office of the second class (Class II Directors), which class shall initially consist of three (3) directors, to expire at the 2016 annual meeting of stockholders; the term of office of the third class (Class III Directors), which class shall initially consist of three (3) directors, to expire at the 2017 annual meeting of stockholders; and thereafter for each such term to expire at each third succeeding annual meeting of stockholders held after such election.

**CERTIFICATE OF AMENDMENT
OF BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A DELAWARE CORPORATION)**

On May 19, 2016, the Board of Directors of Neurocrine Biosciences, Inc. approved the amendment of Section 3.2 of the Bylaws of the corporation to read as follows:

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of nine (9) members. The number of directors may be changed by an amendment to this bylaw, duly adopted by the board of directors or by the stockholders, or by a duly adopted amendment to the certificate of incorporation. The directors shall be divided into three classes, with the term of office of the first class (Class I Directors), which class shall initially consist of three (3) directors, to expire at the 2018 annual meeting of stockholders; the term of office of the second class (Class II Directors), which class shall initially consist of three (3) directors, to expire at the 2016 annual meeting of stockholders; the term of office of the third class (Class III Directors), which class shall initially consist of three (3) directors, to expire at the 2017 annual meeting of stockholders; and thereafter for each such term to expire at each third succeeding annual meeting of stockholders held after such election.

**CERTIFICATE OF AMENDMENT
OF BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A DELAWARE CORPORATION)**

On September 21, 2016, the Board of Directors of Neurocrine Biosciences, Inc. approved an amendment of the Bylaws of the corporation to add a new Article X, which shall read in its entirety as follows:

ARTICLE X

FORUM FOR ADJUDICATION OF DISPUTES

Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court located within the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the corporation, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the corporation to the corporation or the corporation's stockholders, (c) any action asserting a claim arising pursuant to any provision of the General Corporation Law of Delaware, the certificate of incorporation or the bylaws of the corporation, or (d) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the corporation shall be deemed to have notice of and consented to the provisions of this Article.

**CERTIFICATE OF AMENDMENT
OF BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A DELAWARE CORPORATION)**

On October 17, 2017, the Board of Directors of Neurocrine Biosciences, Inc. approved the amendment of Section 3.2 of the Bylaws of the corporation to read as follows:

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of eight (8) members. The number of directors may be changed by an amendment to this bylaw, duly adopted by the board of directors or by the stockholders, or by a duly adopted amendment to the certificate of incorporation. The directors shall be divided into three classes, with the term of office of the first class (Class I Directors), which class shall initially consist of two (2) directors, to expire at the 2018 annual meeting of stockholders; the term of office of the second class (Class II Directors), which class shall initially consist of three (3) directors, to expire at the 2019 annual meeting of stockholders; the term of office of the third class (Class III Directors), which class shall initially consist of three (3) directors, to expire at the 2020 annual meeting of stockholders; and thereafter for each such term to expire at each third succeeding annual meeting of stockholders held after such election.

**CERTIFICATE OF AMENDMENT
OF BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A DELAWARE CORPORATION)**

On February 1, 2020, the Board of Directors of Neurocrine Biosciences, Inc. approved the amendment of Section 3.2 of the Bylaws of the corporation to read as follows:

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of nine (9) members. The number of directors may be changed by an amendment to this bylaw, duly adopted by the board of directors or by the stockholders, or by a duly adopted amendment to the certificate of incorporation. The directors shall be divided into three classes, with the term of office of the first class (Class I Directors), which class shall initially consist of three (3) directors, to expire at the 2021 annual meeting of stockholders; the term of office of the second class (Class II Directors), which class shall initially consist of three (3) directors, to expire at the 2022 annual meeting of stockholders; the term of office of the third class (Class III Directors), which class shall initially consist of three (3) directors, to expire at the 2020 annual meeting of stockholders; and thereafter for each such term to expire at each third succeeding annual meeting of stockholders held after such election.

**CERTIFICATE OF AMENDMENT
OF BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A DELAWARE CORPORATION)**

On August 28, 2020, the Board of Directors of Neurocrine Biosciences, Inc. approved the amendment of Article X of the Bylaws of the corporation to read as follows:

ARTICLE X

FORUM FOR ADJUDICATION OF DISPUTES

10.1. Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have subject matter jurisdiction, another state court located within the State of Delaware or, if no state court located within the State of Delaware has subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall be the sole and exclusive forum for the following claims or causes of action under Delaware statutory or common law: (a) any derivative claim or cause of action brought on behalf of the corporation; (b) any claim or cause of action for breach of a fiduciary duty owed by any current or former director, officer or other employee of the corporation, to the corporation or the corporation's stockholders; (c) any claim or cause of action against the corporation or any current or former director, officer or other employee of the corporation, arising out of or pursuant to any provision of the General Corporation Law of Delaware (the "DGCL"), the certificate of incorporation or the bylaws of the corporation; (d) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of the certificate of incorporation or the bylaws of the corporation (including any right, obligation, or remedy thereunder); (e) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (f) any claim or cause of action against the corporation or any current or former director, officer or other employee of the corporation, governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. This Section 10.1 shall not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act of 1933, as amended (the "1933 Act"), or the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction.

10.2. Unless the corporation consents in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the 1933 Act.

10.3. Any person or entity holding, owning or otherwise acquiring any interest in any security of the corporation shall be deemed to have notice of and consented to the provisions of this Article.

**CERTIFICATE OF AMENDMENT
OF BYLAWS OF
NEUROCRINE BIOSCIENCES, INC.
(A DELAWARE CORPORATION)**

On April 15, 2021, the Board of Directors of Neurocrine Biosciences, Inc. approved the amendment of Section 3.2 of the Bylaws of the corporation to read as follows:

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of nine (9) members. The number of directors may be changed by an amendment to this bylaw, duly adopted by the board of directors or by the stockholders, or by a duly adopted amendment to the certificate of incorporation. The directors shall be divided into three classes, with the term of office of the first class (Class I Directors), which class shall initially consist of three (3) directors, to expire at the 2021 annual meeting of stockholders; the term of office of the second class (Class II Directors), which class shall initially consist of three (3) directors, to expire at the 2022 annual meeting of stockholders; the term of office of the third class (Class III Directors), which class shall initially consist of three (3) directors, to expire at the 2023 annual meeting of stockholders; and thereafter for each such term to expire at each third succeeding annual meeting of stockholders held after such election.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT NEUROCRINE BIOSCIENCES, INC. TREATS AS PRIVATE OR CONFIDENTIAL

COLLABORATION AGREEMENT

dated June 15, 2010

by and between

Abbott International Luxembourg S.à r.l.

and

Neurocrine Biosciences, Inc.

CONFIDENTIAL

EXHIBIT INDEX

A – *Elagolix*

B – Follow-on Compounds

C – Neurocrine Patent Rights

D – Third Party Development Contracts

E – Third Party Manufacturing Contracts

F – Transition Plan

G – Collaborative Development Plan

H – Alternative Dispute Resolution

I – Press Release

COLLABORATION AGREEMENT

COLLABORATION AND LICENSE AGREEMENT (the "**Agreement**") dated as of June 15, 2010 ("**Effective Date**") by and between Abbott International Luxembourg S.à r.l., a corporation organized and existing under the laws of Luxembourg, with offices at 26, Boulevard Royal, L-2449 Luxembourg ("**Abbott**") and Neurocrine Biosciences, Inc., a corporation organized and existing under the laws of Delaware with offices at 12780 El Camino Real, San Diego, California 92130 ("**Neurocrine**").

WHEREAS, Neurocrine has a proprietary research and development program in the field of Non-peptide GnRH Antagonists (as defined below) and in connection therewith has identified proprietary drug candidates for development and commercialization.

WHEREAS, Abbott is engaged in research, development and commercialization of pharmaceuticals and would like to collaborate with Neurocrine in the field of Non-peptide GnRH Antagonists.

WHEREAS, the Parties would like to set forth the terms and conditions pursuant to which the Parties will collaborate in connection with the research, development and commercialization of Products in the Territory (as both terms are defined below), and with respect to certain other matters as described herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties agree as follows:

ARTICLE ONE - DEFINITIONS

Capitalized terms not otherwise defined herein will have the definitions set forth below.

- 1.1 "**Abbott Patent Rights**" means the Patent Rights covering Abbott Technology.
- 1.2 "**Abbott Quarter**" means the calendar quarters ending March 31, June 30, September 30 and December 31 each year.
- 1.3 "**Abbott Technology**" means Technology reasonably necessary or directly useful to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Compounds and Products in the Field of Use, including synthetic processes to manufacture Compounds and all related chemical and biological data: (i) Controlled by Abbott during the Term but, excluding Program Technology, and is actually utilized by Abbott, in Abbott's sole discretion, in the Development or Commercialization of Compounds or Products.
- 1.4 "**Abbott Year**" means the twelve (12) month period commencing on January 1 of any calendar year.
- 1.5 "[...***...]" means [...***...].
- 1.6 "**Affiliate**" means any entity directly or indirectly controlled by, controlling, able to control, or under common control with, a Party to this Agreement, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of an entity

(whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least fifty percent (50%) of the voting securities (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. Neither of the Parties to this Agreement shall be deemed to be an "Affiliate" of the other solely as a result of their entering into this Agreement.

- 1.7 "**Assigned Third Party Development Contracts**" means those contracts set forth on Exhibit D assigned to Abbott as set forth in Section 6.5 (*Assignment of Third Party Development Contracts*).
- 1.8 "**Assigned Third Party Manufacturing Contracts**" means those contracts set forth on Exhibit E assigned to Abbott as set forth in Section 6.6 (*Assignment of Third Party Manufacturing Contracts*).
- 1.9 "**Bankruptcy Code**" means 11 U.S.C. §§ 101-1532, as amended.
- 1.10 "[...***...]" means [...***...].
- 1.11 "**Change of Control**" means (i) a merger, consolidation or reorganization of Neurocrine with a Third Party which results in the voting securities of Neurocrine outstanding immediately prior thereto ceasing to represent more than fifty percent (50%) of the voting power of the then combined entity, (ii) a Third Party(ies) becoming the beneficial owner(s) of more than fifty percent (50%) of the combined voting power of the outstanding securities of Neurocrine or (iii) the sale or transfer to a Third Party of all or substantially all of the assets of Neurocrine. Notwithstanding the foregoing, the merger, consolidation or reorganization of Neurocrine with another entity in which [...***...] is the surviving entity and with respect to which [...***...], will not constitute a Change of Control.
- 1.12 "**Collaboration**" means the collaboration between Neurocrine and Abbott related to the Transition Program and Collaborative Development Program.
- 1.13 "**Collaborative Development Program**" means the collaborative development program to be conducted by Abbott and Neurocrine as set forth in Article Seven, as further described in the Collaborative Development Plan.
- 1.14 "**Collaborative Development Plan**" means the plan describing the overall plan, budget, goals and activities to be undertaken by the Parties in the Collaborative Development Program, as agreed to by the Parties in writing concurrently with the execution of this Agreement and set forth on Exhibit G, and as may be updated from time to time pursuant to Section 7.2(b) (*Collaborative Development Plan and Budget, Amendments*).
- 1.15 "**Combination Product(s)**" means any product which contains, in addition to a Product, one or more other therapeutically active ingredients that are proprietary to Abbott and not within the scope of the Neurocrine Patent Rights and/or Program Patent Rights.
- 1.16 "**Commercialization**" or "**Commercialize**" means any and all activities directed to the offering for sale and sale of a Product, after Regulatory Approval has been obtained, including activities related to marketing, promoting, distributing, importing, selling and offering to sell Product and/or conducting post-marketing human clinical studies with respect to any Indication with respect to

which Regulatory Approval has been received or for a use that is subject of an investigator-initiated study program, and interacting with Regulatory Authorities regarding the foregoing. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization and "Commercialized" has a corresponding meaning.

1.17 "**Commercially Reasonable Efforts**" means with respect to activities of a Party in the discovery, Development or the Commercialization of a particular Product, the efforts and resources typically used by that Party in the development of product candidates or the commercialization of products of comparable market potential taking into account all relevant factors including, as applicable and without limitations, stage of development, mechanism of action, efficacy and safety relative to competitive products in the marketplace, actual or anticipated labeling, the nature and extent of market exclusivity (including patent coverage and regulatory exclusivity), cost, actual or projected profitability (provided [...***...]) and likelihood of obtaining marketing approval. Commercially Reasonable Efforts will be determined on a market-by-market and indication-by-indication basis, and it is anticipated that the level of effort will be different for different markets and will change over time reflecting changes in the status of the Product and the markets involved.

1.18 "**Compound(s)**" means (a) *Elagolix*, (b) the Follow-on Compounds, (c) all complexes, mixtures or other combinations, prodrugs, esters, metabolites, solvates, enantiomers, salt forms, polymorphs, racemates and stereoisomers of the foregoing; and (d) all derivatives of the foregoing containing one or more atoms substituted with an isotope.

1.19 "**Confidential Information**" means with respect to each Party, all materials, trade secrets or other information or data in connection with and pursuant to this Agreement, including without limitation, any data, proprietary information and materials (whether or not patentable, or protectable as a trade secret) regarding a Party's Technology, products, business information or objectives, which is disclosed orally, visually in writing or other form by a Party to the other Party. Confidential Information does not include such materials, trade secrets or other information or data which the receiving Party can demonstrate by competent evidence:

- a) was known by the receiving Party or its Affiliates or Sublicensees prior to its date of disclosure to the receiving Party; or
- b) is in the public domain by use and/or publication before its receipt from the disclosing Party or thereafter enters the public domain through no fault of the receiving Party or its Affiliates or Sublicensees; or
- c) either before or after the date of the disclosure to the receiving Party or its Affiliates or Sublicensees is lawfully disclosed to the receiving Party by a Third Party(ies) not in violation of any obligation to the disclosing Party; or
- d) is independently developed by or for the receiving Party or its Affiliates or Sublicensees without reference to or reliance upon the Confidential Information.

All confidential information disclosed prior to the Effective Date by one Party to the other Party under or pursuant to the confidentiality agreements between the Parties dated [...***...], that is not excluded by subsections (a)-(d) above shall be deemed "Confidential Information" of the disclosing Party.

1.20 "**Control**" or "**Controlled**" means with respect to Technology or Patent Rights, ownership by the applicable Party or possession (whether by license, covenant not to sue or otherwise) of the ability

to grant licenses, sublicenses or access, other than pursuant to this Agreement, without [...] the violation of the terms of any agreement or other arrangement with, or rights of, any Third Party existing on or after the Effective Date and during the Term.

- 1.21 **“Default”** means with respect to a Party that (i) any representation or warranty of such Party set forth herein shall have been untrue in any material respect when made or (ii) such Party shall have failed to perform any material obligation set forth in this Agreement.
- 1.22 **“Development”** or **“Develop”** means, with respect to each Product, all non-clinical and clinical activities designed to obtain Regulatory Approval of such Product in accordance with this Agreement up to and including the obtaining of Regulatory Approval of such Product, including regulatory toxicology studies, statistical analysis and report writing, clinical trial design and operations, preparing and filing Regulatory Filings, and all regulatory affairs related to the foregoing. When used as a verb, “Developing” means to engage in Development and “Developed” has a corresponding meaning.
- 1.23 **“Diagnostic Use”** means use solely for diagnosis, prediction, detection or imaging of any disease, disorder, state, or condition where: the Product (i) is packaged, labeled and sold solely for diagnosis, prediction, detection or imaging of any disease, disorder, state or condition and (ii) does not on its own or in combination with another product(s) rely on the pharmacodynamic effect of a Non-peptide GnRH Antagonist for its use or application.
- 1.24 **“Effective Date”** means the date first written above.
- 1.25 **“Elagolix”** means the compound known as NBI-56418, as further described and set forth on Exhibit A.
- 1.26 **“EMA”** means European Medicines Agency or any successor agency(ies) or authority having substantially the same function.
- 1.27 **“End of Phase II Meeting(s)”** means the meeting(s) between the sponsor of an investigational drug and the FDA following completion of a key set of Phase II clinical studies in which it is determined whether it is safe to proceed to Phase III, Phase III program and protocols are evaluated and additional information necessary to support a marketing application for the uses under investigation are decided.
- 1.28 **“Endometriosis”** means the condition in which endometrial glands and stroma are present in a location outside of the uterus, including its signs and symptoms, which include, but are not limited to, pain associated with such condition.
- 1.29 **“FDA”** means the U.S. Food and Drug Administration of the United States Department of Health and Human Services or any successor agency(ies) or authority having substantially the same function.
- 1.30 **“Field of Use”** means all Therapeutic Uses and Diagnostic Uses.
- 1.31 **“First Commercial Sale”** means with respect to each Product granted Regulatory Approval for commercial sale by applicable Regulatory Authorities, the first transfer by Abbott, its Affiliates or Sublicensees of the Product to a Third Party in exchange for cash or some equivalent to which value can be assigned. A sale by Abbott to an Affiliate or Sublicensee will not constitute a First Commercial Sale unless the Affiliate or Sublicensee is the last entity in the distribution chain and provided further that any sale on a cost reimbursement basis for use in a clinical trial will not constitute a First Commercial Sale.

- 1.32 **“Follow-on Compound”** means any of (i) [...***...], and [...***...] as set forth on Exhibit B (ii) and all non-peptide synthetic organic chemical compounds which are encompassed, generically or specifically, by (a) [...***...].
- 1.33 **“Force Majeure”** means any occurrence beyond the reasonable control of a Party that prevents or substantially interferes with the performance by the Party of any of its obligations hereunder, if such occurs by reason of any act of God, flood, fire, explosion, earthquake, strike, lockout, labor dispute, casualty or accident; or war, revolution, civil commotion, acts of terrorism, acts of public enemies, blockage or embargo; or any injunction, Law, order, proclamation, regulation, ordinance, demand or requirement of any Governmental Authority; or breakdown of plant, inability to procure or use materials, labor, equipment, transportation, or energy sufficient to meet manufacturing needs without the necessity of allocation; or any other cause whatsoever, whether similar or dissimilar to those above enumerated, beyond the reasonable control of such Party, if and only if the Party affected shall have used reasonable efforts to avoid such occurrence and to remedy it promptly if it shall have occurred.
- 1.34 **“FTE”** means a full time equivalent Neurocrine employee consisting of a total of approximately [...***...] hours per year of work in accordance with Neurocrine’s time allocation practices (including normal vacations, sick-days and holidays for Neurocrine employees).
- 1.35 **“Generic Product(s)”** means any pharmaceutical product that (i) is sold by a Third Party that is not a licensee or Sublicensee of Abbott or its Affiliates, or any of their licensees or Sublicensees under a marketing authorization granted by a Regulatory Authority to such Third Party, and (ii) contains the same Compound as an active pharmaceutical ingredient as the relevant Product and (x) for purposes of the United States, is approved in reliance on the prior approval of a Product as determined by the FDA, or (y) for purposes of a country outside the United States, is approved in reliance on the prior approval of a Product as determined by the applicable Regulatory Authority. On a country by country basis, a Product licensed or produced by Abbott (e.g. an authorized generic product) will not constitute a Generic Product.
- 1.36 **“Generic Competition”** means, on a country by country and Product by Product basis, that the following conditions are met: (x) one or more Third Parties is selling a Generic Product in a country during [...***...], and (y) the [...***...] of such Generic Products sold in such country by the Third Party(ies) in such [...***...] is [...***...] sold in that country by Abbott, its Affiliates and Sublicensees. Unless otherwise agreed by the Parties, the [...***...] of each Generic Product sold during [...***...] shall be deemed to be the volume of sales of the Generic Product in such country in that [...***...] as reported by IMS America Ltd. of Plymouth Meeting, Pennsylvania (“**IMS**”) or any successor to IMS or any other independent sales auditing firm reasonably agreed upon by the Parties.
- 1.37 **“GnRH Receptor”** means [...***...].
- 1.38 **“Governmental Authority”** means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.
- 1.39 **“IND”** means an investigational new drug application filed with the FDA pursuant to 21 CFR 312 or the foreign equivalent for authorization to commence human clinical trials of a product, including all supplements and amendments that may be filed with respect to the foregoing.

- 1.40 “**Indication**” means an individual, separate and distinct disease or clinical condition with respect to which at least one adequate and well controlled study is required to support inclusion of such disease or condition in the indication statement of a Regulatory Authority approved package insert for a Product. The Parties agree that: (i) prevention of a disease or medical condition shall not be a separate indication from treatment of the same disease or medical condition; (ii) the treatment and prevention of separate varieties of the same disease or medical condition shall not be a separate indication; and (iii) the treatment or prevention of the same disease or medical condition in a different population shall not be a separate indication (e.g., adult and pediatric) unless in each of (i)-(iii) above, at least one adequate and well controlled study is required to support inclusion of such disease or condition in the indication statement of a Regulatory Authority approved package insert for a Product. Furthermore, a label enhancement or elaboration or expansion of an approved Indication is not a separate Indication even if one or more studies are performed to receive such enhancement or elaboration.
- 1.41 “**Initiation**” means, with respect to a human clinical trial, dosing of the first subject in a Phase I, Phase II or Phase III clinical study, as applicable, pursuant to a clinical protocol of the specified clinical trial.
- 1.42 “**Invention**” means any information, composition of matter, or article of manufacture that is discovered, developed, generated, made, conceived and/or reduced to practice by or on behalf of a Party (or its Affiliate) through performance of activities conducted pursuant to the Collaboration. Inventorship of Inventions will be determined in accordance with United States patent laws and ownership shall be determined in accordance with this Agreement.
- 1.43 “**Law**” or “**Laws**” means all laws, statutes, rules, codes, regulations, orders, decrees, judgments and/or ordinances of any Governmental Authority.
- 1.44 “**MAA**” means a Marketing Authorization Application covering a Product filed with the EMA, required for marketing approval of a pharmaceutical product.
- 1.45 “**Major European Country**” means [...***...].
- 1.46 “**Milestones**” means those payments to be made by Abbott to Neurocrine upon the occurrence of certain events as set forth in Article Four.
- 1.47 “**NDA**” means a New Drug Application covering a Product filed with the FDA pursuant to 21 CFR 314, required for marketing approval of a pharmaceutical product and/or a supplemental NDA (sNDA).
- 1.48 “**Net Sales**” means the total amount billed or invoiced on sales of Product by Abbott, its Affiliates and/or Sublicensees in the Territory to Third Parties (for example, wholesalers or distributors) in bona fide arm’s length transactions, less the following deductions (specifically excluding any royalty payments made by Abbott, its Affiliates and/or Sublicensees to Licensor), in each case related specifically to the Product and actually allowed and taken by such Third Parties and not otherwise recovered by or reimbursed to Abbott, its Affiliates and/or Sublicensees:
- a) trade, cash and quantity discounts;
 - b) price reductions or rebates, retroactive or otherwise, imposed by, negotiated with or otherwise paid to Governmental Authorities;

- c) taxes on sales (such as sales, value added or use taxes) to the extent added to the sale price and set forth separately as such in the total amount invoiced;
- d) freight, insurance and other transportation charges to the extent added to the sale price and set forth separately as such in the total amount invoiced, as well as any fees for services provided by wholesalers and warehousing chains related to the distribution of the Product;
- e) amounts repaid or credited by reason of rejections, defects, one percent (1%) return goods allowance, recalls or returns, or because of retroactive price reductions, including, but not limited to, rebates or wholesaler charge backs;
- f) the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers and/or Medicare Prescription Drug Plans relating specifically to the Product; and
- g) any consideration actually paid or payable for any Delivery System related to a billed or invoiced sale of a Product, where for purposes of this Net Sales definition, a “Delivery System” means any delivery system comprising equipment, instrumentation, one or more devices or other components designed to assist in the administration of a Product.

Net Sales shall include the amount or fair market value of all other consideration received by Abbott, its Affiliates and/or Sublicensees in respect of the Product, whether such consideration is in cash, payment in kind, exchange or other form. For purposes of determining Net Sales, Net Sales shall not include transfers or dispositions for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes. Net sales shall not include sales between or among Abbott, its Affiliates and/or Sublicensees.

Subject to the above, Net Sales shall be calculated in accordance with the standard internal policies and procedures of Abbott, its Affiliates and/or Sublicensees, which must be in accordance with generally accepted accounting principles (“**GAAP**”).

For purposes of calculating Net Sales, all Net Sales shall be converted into United States Dollars using Abbott, its Affiliates and/or Sublicensees’ standard conversion methodology consistent with GAAP. The standard conversion methodology is based on monthly averages (the spot rate at the end of the month immediately prior to the reporting month plus the spot rate at the end of the reporting month, divided by two) using open market rates.

In the event that a Product is sold in the form of a Combination Product, the Net Sales for such Combination Product will be [...***...]:

- a) [...***...].
- b) [...***...].
- c) [...***...].
- d) [...***...].

1.49 “**Neurocrine Patent Rights**” means the Patent Rights covering Neurocrine Technology, as set forth on Exhibit C.

- 1.50 **“Neurocrine Technology.”** means all Technology Controlled by Neurocrine: (i) on the Effective Date or during the Term, that is reasonably necessary or directly useful to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Compounds (including Compounds contained in Product(s)) in the Field of Use, including synthetic processes to manufacture Compounds and all related chemical and biological data and/or (ii) on the Effective Date, that is reasonably necessary or directly useful to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Products in the Field of Use that is not otherwise covered by (i). Neurocrine Technology will specifically not include [...***...].
- 1.51 **“Non-peptide GnRH Antagonists”** means [...***...]. “Non-peptide GnRH Antagonists” excludes [...***...].
- 1.52 **“Patent Rights”** means the rights and interest in and to all issued patents and pending patent applications in any country, including, all divisionals, continuations, renewals, continuations-in-part, patents of addition, substitutions, reexaminations, supplementary protection certificates and the like, extensions, registration or confirmation patents and reissues thereof.
- 1.53 **“Phase I”** means a human clinical trial in any country of a product in any country, the principal purpose of which is a preliminary determination of safety or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to applicable law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(a).
- 1.54 **“Phase II”** means a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b) conducted to study the effectiveness and establish the dose range of a Product for a particular Indication in patients with the disease or condition under study, including Phase IIa studies.
- 1.55 **“Phase IIb”** means a Phase II study in any country, the principal purpose of which is to explore the dose relationship of a Product against some efficacy measure for the Indication in patients with the disease or Indication under study.
- 1.56 **“Phase III”** means an expanded human clinical study in any country on a sufficient number of subjects that is designated to establish that such product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions, if any, that are associated with such product in the dosage range to be prescribed, which trial is designed to result in Regulatory Approval of such product, including all tests, studies, or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to applicable law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(c).
- 1.57 **“PMDA”** means Japan’s Pharmaceuticals and Medical Devices Agency or any successor agency(ies) or authority having substantially the same function.
- 1.58 **“Product(s)”** means a product or product candidate that contains one or more Compounds, including all formulations and dosages of such Compound, all processes and delivery systems that incorporate such Compound, and any Combination Product. For the purposes of this Agreement, [...***...] will constitute a single Product.
- 1.59 **“Program Patent Rights”** means the Patent Rights covering the Program Technology.

- 1.60 **“Program Technology”** means any and all Technology conceived, reduced to practice, made or developed, [...***...], by employees of [...***...] and/or others acting on behalf of [...***...] in performance of the Collaborative Development Program or Transition Program that is necessary or useful to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Compounds and Products in the Field of Use.
- 1.61 [...***...] means [...***...].
- 1.62 **“Regulatory Approval”** means all the technical, medical and scientific licenses, registrations, authorizations and approvals (including, approvals of NDAs and equivalents, supplements and amendments, pre- and post- approvals, pricing and third party reimbursement approvals where required, and labeling approvals) of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority, necessary for the manufacture, distribution, marketing, promotion, offer for sale, use, import, export or sale of Product(s) in a regulatory jurisdiction.
- 1.63 **“Regulatory Authorities”** means any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a product in the Territory, including the FDA, EMA and PMDA.
- 1.64 **“Regulatory Filings”** means, collectively, INDs, MAAs, NDAs and/or any other related, equivalent or comparable filings as may be required by Regulatory Authorities to obtain Regulatory Approvals relating to the Products.
- 1.65 **“Royalties”** means those royalties payable by Abbott to Neurocrine pursuant to Article Four of this Agreement.
- 1.66 **“Rest of World Territory”** means worldwide excluding the United States Territory.
- 1.67 “[...***...]” means [...***...].
- 1.68 **“Sublicensee”** means any Third Party to whom Abbott has granted a sublicense of the license rights granted to Abbott under this Agreement.
- 1.69 **“Technology”** means all proprietary data, information, and materials (including Inventions, know-how, trade secrets, experimental data, formula, market research data, expert opinions, experimental procedures, pre-clinical and clinical data, regulatory data and filings and other confidential and/or proprietary information, molecules, assays, reagents, compounds, compositions, human or animal tissue, samples or specimens).
- 1.70 **“Territory”** means United States Territory and Rest of World Territory.
- 1.71 **“Therapeutic Use”** means use(s) for any disease, disorder, state or condition in humans or animals, other than a Diagnostic Use.
- 1.72 **“Third Party(ies)”** means any person or party other than Neurocrine, Abbott and their respective Affiliates.

- 1.73 **“Third Party Development Contracts”** means all contracts in effect on the Effective Date between Neurocrine and Third Party contractors pursuant to which Neurocrine has contracted for pre-clinical and/or clinical services for Products as set forth on Exhibit D, true and complete copies of which have been made available to Abbott prior to the date hereof.
- 1.74 **“Third Party License Payments”** means [...***...] payments payable by Abbott, its Affiliates or Sublicensees to a Third Party (or multiple Third Parties) [...***...] to obtain rights under the Third Party Patent Rights to make, have made, use, offer for sale, sell and/or import such Products.
- 1.75 **“Third Party Manufacturing Contracts”** means all contracts in effect on the Effective Date between Neurocrine and Third Party contract manufacturers pursuant to which Neurocrine has contracted for manufacturing services for Products as set forth on Exhibit E, true and complete copies of which have been made available to Abbott prior to the date hereof.
- 1.76 **“Trademarks”** means any proprietary names selected by Abbott for commercialization of Products in the Territory.
- 1.77 **“Transition Plan”** means the plan describing the Development activities to be conducted by Neurocrine including (i) the timetable for transferring to Abbott various assets related to the Compounds and the Products, including the Development and manufacture thereof, and (ii) the activities to be undertaken by Neurocrine in the Transition Program, as agreed to by the Parties in writing concurrently with the execution of this Agreement and set forth on Exhibit F as may be updated from time to time pursuant to Section 6.1(c) (*Transition Program; Transition Plan*).
- 1.78 **“Transition Program”** means the Product development, regulatory and manufacturing activities to be conducted by Neurocrine pursuant to Article Six, as described in further detail in the Transition Plan.
- 1.79 **“United States Territory”** means the United States of America.
- 1.80 **“Uterine Fibroids”** means the condition in which a benign (non-cancerous) tumor originates from the smooth muscle layer (myometrium) and the accompanying connective tissue of the uterus, including its signs and symptoms, which include, but are not limited to, heavy bleeding during menstruation, dysmenorrhea, dyspareunia, pressure related symptoms, and urinary frequency and urgency.
- 1.81 **“Valid Claim”** means a claim of any issued and unexpired patent included within the Neurocrine Patent Rights and/or Program Patent Rights whose enforceability has not been effected by one or more of any of the following: (1) irretrievable lapse, revocation or abandonment and/or (2) holding of unenforceability or invalidity by a decision of a court or other appropriate body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and/or (3) disclaimer or admission of invalidity or unenforceability through reissue or re-examination or opposition, nullity action or invalidation suit response or otherwise.

1.82 **Additional Definitions.** Each of the following definitions is set forth in the Section of this Agreement indicated below:

DEFINITION	SECTION
Agreement	Preamble
Abbott	Preamble
Neurocrine	Preamble
GAAP	"Net Sales"
Exclusivity Period	2.3
License Fee	4.1
JDC	5.3
Alliance Manager	5.5
Assigned Third Party Development Contracts	6.5
Assigned Third Party Manufacturing Contracts	6.6
Manufacturing Technology Transfer	8.4
Paragraph IV Notice	12.5
Neurocrine Indemnified Party	10.1
Liability	10.1
Abbott Indemnified Party	10.2
Indemnified Party	10.3
Indemnifying Party	10.3
Term	11.1(a)
Notifying Party	11.4(a)
Adverse Ruling	11.4(a)(1)
Insolvent Party	11.5

1.83 **Construction.** In construing this Agreement, unless expressly specified otherwise:

- (a) references to Articles, Sections, Exhibits and Schedules are to articles and sections of, and exhibits and schedules to, this Agreement;
- (b) except where the context otherwise requires, use of either gender includes the other gender, and use of the singular includes the plural and vice versa;
- (c) any list or examples following the word "including" shall be interpreted without limitation to the generality of the preceding words;

(d) except where the context otherwise requires, the word “or” is used in the inclusive sense; and

(e) all references to “dollars” or “\$” herein means United States of America Dollars.

ARTICLE TWO - REPRESENTATIONS AND WARRANTIES AND COVENANTS

2.1 **Mutual Representations and Warranties.** Neurocrine and Abbott each hereby represents and warrants, to the other as of the Effective Date of this Agreement, as follows:

- a) Organization. It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation and has all requisite power and authority, corporate and otherwise, to execute, deliver and perform this Agreement.
- b) Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate (a) such Party’s certificate of incorporation or by-laws, (b) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (c) any requirement of applicable Law, or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party.
- c) Binding Agreement. Assuming due authorization, execution and delivery on the part of the other Party, this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium and similar Laws relating to or affecting creditors generally or by general equitable principles (regardless of whether such enforceability is considered in a proceeding in equity or at Law).
- d) No Inconsistent Obligation. It is not under any obligation, contractual or otherwise, to any Third Party that conflict with or is inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

2.2 **Additional Neurocrine Representations and Warranties.** Neurocrine hereby represents and warrants as of the Effective Date as follows:

- a) The status of all Neurocrine Patent Rights listed on Exhibit C are properly stated as to their filing status or issuance and, to Neurocrine’s knowledge, no issued patents which are part of Neurocrine Patent Rights listed on Exhibit C are invalid or unenforceable. All Neurocrine Patent Rights that (a) contain one or more claims that cover any Compound or Product (including its manufacture or its formulation or a method of its delivery or of its use); and (b) to the best of Neurocrine’s knowledge are necessary for Abbott to exercise the licenses granted to it pursuant to Article Three and (c) that are existing on the Effective Date, are listed on Exhibit C.

- b) There are no claims, judgment or settlements against Neurocrine pending, or to Neurocrine's knowledge, threatened that invalidate or seek to invalidate the Neurocrine Patent Rights.
- c) Except as required [...***...], Neurocrine has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Neurocrine Patent Rights in manner inconsistent with the terms hereof.
- d) Except as required by [...***...], to Neurocrine's knowledge, it is the sole and exclusive owner of the Neurocrine Patent Rights all of which are free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to the Neurocrine Patent Rights.
- e) To Neurocrine's knowledge and except [...***...], Neurocrine has complied with all requirements of [...***...], where applicable, with respect to Neurocrine Patent Rights.
- f) Neurocrine has disclosed or made available to Abbott all material information known to Neurocrine regarding the Neurocrine Patent Rights and Neurocrine Technology.
- g) To Neurocrine's knowledge, Neurocrine has sufficient legal and/or beneficial title under the Neurocrine Patent Rights and Neurocrine Technology necessary to grant the rights contained in and to carry out its obligations under this Agreement.
- h) Subject to Sections 6.2(b) and 7.3(b), Neurocrine shall maintain all Third Party Development Contracts, Third Party Manufacturing Contracts, and the [...***...] in full force and effect and will not, without Abbott's prior written consent, terminate or otherwise modify the terms of such Third Party Development Contracts, Third Party Manufacturing Contracts, or the [...***...].

2.3 Exclusive Collaborative Effort. Subject to Abbott's sublicensing rights hereunder, and except where the Parties shall mutually agree otherwise (in which event, for avoidance of doubt, such activities to which the Parties shall have agreed will be considered part of the Collaboration), Neurocrine and Abbott shall not, and shall cause their respective Affiliates and Sublicensees not to, other than pursuant to this Agreement, independently, or in collaboration with any Third Parties, engage in [...***...] prior to the earlier of (a) [...***...] or (b) [...***...] (the "**Exclusivity Period**"); provided, however, that nothing in this Agreement shall (i) restrict [...***...], or (ii) preclude either Party [...***...], provided that the Party making such [...***...]. If either Party (or its Affiliates) breaches this Section 2.3 due to an acquisition of or merger with all or substantially all of the business or assets of a Third Party, such acquiring Party shall not be in breach of this Section 2.3 so long as such acquiring Party (or its Affiliate) [...***...] after the closing of such acquisition or merger.

2.4 Commercially Reasonable Efforts. Abbott will use Commercially Reasonable Efforts to Develop and Commercialize [...***...]. Neurocrine and Abbott shall each use Commercially Reasonable Efforts to perform their respective obligations hereunder. In addition, Abbott agrees to comply with the [...***...], if and as applicable, in relation to this Agreement.

2.5 Conduct of Activities. Each Party will conduct, and shall use Commercially Reasonable Efforts to cause its Affiliates to conduct, those activities allocated to such Party under this Agreement in compliance in all material respects with applicable Laws of the country in which such activities are conducted.

2.6 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY HEREBY DISCLAIMS, ANY OTHER REPRESENTATION OR WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING, ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT, INCLUDING WITHOUT LIMITATION NEUROCRINE PATENT RIGHTS AND NEUROCRINE TECHNOLOGY. ADDITIONALLY, EXCEPT AS EXPRESSLY PROVIDED HEREIN, NEUROCRINE MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT THE MANUFACTURE, USE OR SALE OF ANY PRODUCT WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

ARTICLE THREE - LICENSE GRANTS; RETAINED RIGHTS

3.1 License. Subject to the terms of this Agreement, Neurocrine and its Affiliates hereby grants to Abbott, and Abbott hereby accepts, an exclusive worldwide license, with the right to sublicense through multiple tiers, under the Neurocrine Technology and Neurocrine Patent Rights, in each case, to research, develop, make, have made, use, sell, offer for sale, import and/or otherwise exploit Compounds and Products in the Field of Use in the Territory.

3.2 License Grant to Neurocrine for the Collaboration. Abbott hereby grants to Neurocrine a non-exclusive license, without the right to sublicense, under Patent Rights and Technology Controlled by Abbott solely for use in connection with Neurocrine's conduct of the Collaboration. Nothing set forth herein will limit Abbott's right to use for all purposes, any Abbott Technology or Abbott Patent Rights.

3.3 Retention of Rights. Notwithstanding the exclusive licenses granted to Abbott pursuant to Section 3.1 (*License*), Neurocrine retains the right to practice under the Neurocrine Technology and Neurocrine Patent Rights to perform (and to sublicense Third Parties to perform) its obligations under this Agreement (including the manufacture and supply of Compound and Product to Abbott). Subject to Section 2.3, Neurocrine also retains: (i) a [...] license in the [...***...], to use the Neurocrine Technology (including Neurocrine Patent Rights) for [...] and (ii) exclusive rights for all purposes outside the scope of the licenses granted in Section 3.1; provided that any activity Neurocrine would undertake in relation to the retention of rights hereunder that [...***...], shall require Abbott's prior written consent before undertaking such activity.

3.4 License Grant to Neurocrine under Program Technology. Subject to Section 2.3, Abbott grants Neurocrine a [...] license [...***...], to use the Program Technology (including Program Patent Rights) [...] for: (i) [...] and (ii) for any purpose outside the scope of the licenses granted in Section 3.1; provided that any activity Neurocrine would undertake in relation to the grant of rights hereunder that [...***...], shall require Abbott's prior written consent before undertaking such activity.

3.5 No Implied Licenses. Except as expressly set forth in this Agreement, neither Party grants any license under its intellectual property rights to the other Party.

3.6 **Exclusions.** For avoidance of doubt, the licenses granted to Abbott under this Agreement shall not include any rights for Abbott to research, develop, make, have made, use, sell, offer for sale and/or import any proprietary compound of Neurocrine that is not a Compound. Notwithstanding anything to the contrary in this Agreement, for the Term of Royalty set forth in Section 4.6, Neurocrine shall not, alone or with or through (i) its Affiliates or (ii) any Third Party: Develop, Commercialize, offer for sale, sell and/or otherwise commercially exploit Compounds or Products in the Field of Use in the Territory.

ARTICLE FOUR - ROYALTIES, MILESTONES AND PAYMENT PROVISIONS

4.1 **License Fee.** In consideration of the licenses granted to Abbott hereunder and the disclosure to Abbott of Neurocrine Technology, Abbott shall pay to Neurocrine a non-refundable, non-creditable license fee equal to seventy five million dollars (\$75 MM) (“ *License Fee* ”). The License Fee shall be paid to Neurocrine within [...***...] days after the Effective Date of this Agreement.

4.2 **Milestones.** Abbott will pay to Neurocrine [...***...] Milestones for achievement of the events set forth below. Abbott will notify Neurocrine within [...***...] days of achievement of each Milestone event and the related Milestone payment will be made to Neurocrine within [...***...] days of achievement of the event.

a) *Elagolix.* In consideration for the license rights granted by Neurocrine to Abbott, on an [...***...], Abbott will pay to Neurocrine the Milestones set forth below for *Elagolix* :

ELAGOLIX EVENT*	[...***...]	[...***...]
Acceptance of [...***...]	[...***...]	[...***...]
Initiation of [...***...]	[...***...]	[...***...]
Initiation of [...***...]	[...***...]	[...***...]
Initiation of [...***...]	[...***...]	[...***...]
Acceptance of [...***...]	[...***...]	[...***...]

First Regulatory Approval of [...***...]

[...***...]

[...***...]

First filing of [...***...]

[...***...]

[...***...]

First Regulatory Approval of [...***...]

[...***...]

[...***...]

First filing of [...***...]

[...***...]

[...***...]

First Regulatory Approval of [...***...]

[...***...]

[...***...]

Total Milestones payable under this Section 4.2(a) shall not exceed [...***...].

In the event that a Product is discontinued in the course of development for [...***...], only those Milestones that have not been paid at the time the Product has been discontinued shall be payable for a future Product achieving the Milestone Event.

* Once a Product achieves a Milestone for [...***...], it will be deemed to have achieved all earlier Milestones [...***...] and any Milestone payment for such earlier Milestone will become due and payable to the extent it has not already been paid. Specifically, (i) should the Initiation of [...***...] be achieved prior to or in the absence of the Acceptance of [...***...], the Acceptance of [...***...] shall be paid when the Initiation of [...***...] is achieved and (ii) should a [...***...] not be required or a previously conducted clinical study be accepted in place of such a study, the Initiation of [...***...] will be paid upon the earlier of (A) receipt of [...***...] or (B) first filing of [...***...].

** Should another [...***...] as the [...***...] to advance through Development, the Milestone events enumerated in the [...***...] stream above shall apply to that [...***...][...***...] shall apply to [...***...].

*** If Regulatory approval of a MAA [...***...] is granted, such Milestone event shall be paid [...***...]. If approved by [...***...], without regard to order or combination.

b) Follow-On Compounds. On the first occurrence of the events set forth below for a Follow-on Compound, Abbott shall pay Neurocrine the following Milestones for Follow-on Compounds on [...] (each Milestone stream would be payable one time only regardless of how many Products advance through development):

FOLLOW-ON EVENT*	[...***...]	[...***...]
Initiation of [...***...]	[...***...]	[...***...]
Initiation of [...***...]	[...***...]	[...***...]
Initiation of [...***...]	[...***...]	[...***...]
Initiation of [...***...]	[...***...]	[...***...]
Acceptance of [...***...]	[...***...]	[...***...]
First Regulatory Approval of [...***...]	[...***...]	[...***...]
First Regulatory Approval of [...***...]	[...***...]	[...***...]
First Regulatory Approval of [...***...]	[...***...]	[...***...]

Total Milestones payable under this Section 4.2(b) shall not exceed [...***...].

In the event that a Product is discontinued in the course of development for [...***...], only those Milestones that have not been paid at the time the Product has been discontinued would be payable for a future Product achieving the Milestone Event.

* Once a product achieves a Milestone for a [...***...], it will be deemed to have achieved all earlier Milestones [...***...] and any Milestone payment for such earlier Milestone will become due and payable to the extent it has not already been paid.

** In the event that Follow-on Compound [...***...] is the same Follow-on Compound [...***...], the [...***...] Milestone shall be paid upon the achievement of the Initiation of [...***...].

*** If Regulatory Approval of a MAA [...***...] is granted, such Milestone event shall be paid [...***...]. If approved by a [...***...], without regard to order or combination.

4.3 Royalties. Subject to Section 4.4 (*Royalty Adjustments*) and Section 4.6 (*Royalty Term*), Abbott will pay to Neurocrine Royalties on Net Sales in an Abbott Year, of each Product [...***...] containing *Elagolix* and the Follow-on Compounds, on a Product [...***...] by Product [...***...] and United States

Territory and Rest of World Territory basis (as the case may be), commencing upon the First Commercial Sale in the United States Territory or Rest of World Territory, as applicable, as follows:

For Products containing [...***...]:

	United States Territory Royalty (% Net Sales)	Rest of World Territory Royalty (% Net Sales)
Abbott Year Net Sales		
Less than [...***...]	[...***...]	[...***...]
Greater than or equal to [...***...] and less than [...***...]	[...***...]	[...***...]
Greater than or equal [...***...]	[...***...]	[...***...]

For Products containing [...***...]:

	United States Territory Royalty (% Net Sales)	Rest of World Territory Royalty (% Net Sales)
Abbott Year Net Sales		
Less than [...***...]	[...***...]	[...***...]
Greater than or equal to [...***...]	[...***...]	[...***...]

The Royalties set forth above are marginal rates and shall only apply to that portion of Net Sales opposite each applicable Royalty rate. For the purposes of Royalty payments, [...***...] will be considered to be the same Product, regardless of the indications for which such Product [...***...] may be used.

Notwithstanding anything to the contrary in this Agreement, the Parties shall, prior [...***...] negotiate in good faith on commercially reasonable terms, and execute an amendment to this Agreement duly executed by authorized representatives of both Parties, setting forth [...***...] of the applicable [...***...] sold by Abbott or its Affiliates or Sublicensees. If the Parties are unable to agree [...***...] after good faith negotiations, then the Parties shall submit the issue under Section 13.2 (*Dispute Resolution*).

4.4 Royalty Adjustments. Except as otherwise set forth in this Agreement, Royalties due hereunder are subject to adjustment on a Product by Product, [...***...] basis as a result of the events set forth below (such adjustments to be prorated for the then-current [...***...] in which the reduction becomes

applicable) provided, however, that the Royalties payable under Section 4.3 (*Royalties*) shall not be reduced by more than [...] of the amounts set forth in Section 4.3 (*Royalties*) by reason of the adjustments set forth below.

- a) Royalty Adjustment for Third Party License Payments. Neurocrine shall be responsible for and pay all amounts due under the [...***...]. If Abbott, its Affiliates or Sublicensees, in their reasonable judgment, is required to pay any Third Party License Payments, then the amount of Royalties payable under Section 4.3 (*Royalties*) shall be reduced by [...***...] of the amount of such Third Party License Payments paid to such Third Party.
- b) Royalty Adjustment for Non-Patent Products. If the making, having made, using, offering for sale, sale, and/or importation of a Product would not infringe a Valid Claim within the [...***...], Royalties payable to Neurocrine will be reduced by [...***...] of the Royalty rate(s) set forth in Section 4.3 (*Royalties*).
- c) Royalty Adjustment for Generic Competition. If there is Generic Competition, the Royalties payable to Neurocrine shall be reduced by [...***...] of the Royalty rates set forth in Section 4.3 (*Royalties*).

4.5 Sales Milestones. Within [...] days following the last day of the Abbott Year of the first achievement of each event of annual combined Net Sales of all Products as detailed below, Abbott shall make the following one-time payments:

Event	Sales Milestone
Abbott Year Net Sales of Product(s) exceeds [...***...]	[...***...]
Abbott Year Net Sales of Product(s) exceeds [...***...]	[...***...]
Abbott Year Net Sales of Product(s) exceeds [...***...]	[...***...]

4.6 Term of Royalty. Notwithstanding the foregoing, Abbott's Royalty obligations pursuant to Section 4.3 (*Royalties*) shall expire, on a Product by Product and country by country basis, following the later of: (i) the last to expire of all Valid Claims in the Neurocrine Patent Rights or Program Patent Rights covering the making, having made, using, offering to sell, selling, and importing of Product in such country or (ii) [...] following the First Commercial Sale in such country. Notwithstanding the foregoing, if, after the aforementioned Royalty term, Neurocrine is required to make royalty payments [...***...].

4.7 Reports and Payments.

- a) Inter-Company Sales. Sales between or among Abbott, its Affiliates or Sublicensees shall not be subject to Royalties under this Section 4. Abbott shall be responsible for the payment of Royalties on Net Sales by its Affiliates or Sublicensees.
- b) Cumulative Royalties. The obligation to pay Royalties under this Article 4 shall be imposed only once (i) with respect to any sale of the same unit of Product and (ii) with respect to a single unit of Product, in each case, regardless of how many Valid Claims in the Neurocrine Patent Rights or Program Patent Rights cover the Compound included in such Product.
- c) Statements and Payments. Following commencement of Abbott's obligation to pay Royalties pursuant to Section 4.3, Abbott shall deliver to Neurocrine (a) within [...***...] days after the end of each [...***...] report setting forth [...***...] and (b) within [...***...] days after

the end of each [...***...], a report certified by Abbott as accurate to the best of its ability based on information then available to Abbott, setting forth for such [...***...] the following information on a Product by Product basis [...***...]. The total Royalty due for the sale of Products during [...***...] shall be remitted within [...***...] days after the end of each [...***...].

d) Taxes and Withholding.

- 1) VAT. It is understood and agreed between the Parties that any payments made by Abbott under this Agreement are inclusive of any value added or similar tax imposed upon such payments.
- 2) Tax Cooperation. Where any sum due to be paid to either Party hereunder is subject to any withholding or similar tax, the Parties shall use their commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable them to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, the payor shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount due to payee and secure and send to payee the best available evidence of such payment. On the Effective Date, each Party shall provide the other with a completed and signed Form W-8BEN.
- 3) Withholding Tax Matters. In addition, in the event any of the payments made by Abbott to Neurocrine under this Agreement become subject to withholding taxes under the Laws of any jurisdiction, Abbott shall deduct and withhold the amount of such taxes for the account of Neurocrine to the extent required by Law, such payment to Neurocrine shall be reduced by the amount of taxes deducted and withheld, and Abbott shall pay the amount of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Neurocrine an official tax certificate or other evidence of such tax obligations, together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable Neurocrine to claim such payment of taxes. Any such withholding taxes required under applicable Law to be paid or withheld shall be an expense of, and borne solely by, Neurocrine. Abbott will provide Neurocrine with reasonable assistance, at Neurocrine's expense, to enable Neurocrine to recover such taxes as permitted by Law.

e) Currency. All amounts payable and calculations hereunder shall be in United States dollars. Conversion of sales recorded in local currencies to U.S. dollars will be at the monthly rate of exchange used by Abbott in its worldwide accounting system prevailing on the third to last business day of the month preceding the month in which such sales are recorded by Abbott. If governmental regulations prevent remittances from a foreign country with respect to sales made in that country, the Royalties shall continue to accrue but the obligation of Abbott to pay Royalties on sales in that country shall be delayed until such remittances are possible. Neurocrine shall have the right, upon giving written notice to Abbott, to receive payment in that country in local currency.

f) Late Payments. If Neurocrine does not receive payment of any sum due it hereunder on or before the due date set forth herein, simple interest thereon shall accrue on the sum from the due date until the date of payment at the rate equal to [...***...]; provided, that with respect to any disputed payments, no interest payment shall be due until such dispute is resolved and

the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

- g) **Maintenance of Records; Audit.** For a period [...***...], Abbott shall maintain and shall cause its Affiliates and Sublicensees to maintain complete and accurate books and records in connection with the sale of Products hereunder, as necessary to allow the accurate calculation of Royalties due hereunder including any records required to calculate any Royalty adjustments hereunder. Once per calendar year, Neurocrine shall have the right to engage an registered public accounting firm of nationally recognized standing selected by Neurocrine and reasonably acceptable to Abbott, at Neurocrine's expense, which shall have the right to examine in confidence the relevant Abbott records as may be reasonably necessary to determine and/or verify the amount of Royalty payments due hereunder for any year ending not more than [...***...] months prior to the date of such request. Such examination shall be conducted during Abbott's normal business hours, after at least [...***...] days prior written notice to Abbott and shall take place at the Abbott facility(ies) where such records are maintained. In the event the report reflects an under-payment by Abbott hereunder, Abbott shall promptly (but in no event later than [...***...] days after Abbott's receipt of the independent auditor's report) make payment to Neurocrine of any short-fall. In the event that there was an over-payment by Abbott hereunder, Neurocrine shall promptly (but in no event later than [...***...] days after Neurocrine's receipt of the independent auditor's report so correctly concluding) refund to Abbott the excess amount. In the event any payment by Abbott shall prove to have been incorrect by more than [...***...] to Neurocrine's detriment, Abbott will pay the reasonable fees and costs of Neurocrine's independent auditor for conducting the audit.
- h) **No Other Compensation.** Each party hereby agrees that the terms of this Agreement, fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by one party to the other Party in connection with the transactions contemplated herein. Neither Party previously has paid or entered into any other commitment to pay, whether orally or in writing, any of the other Party's employees, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transaction contemplated herein.

ARTICLE FIVE - MANAGEMENT OF COLLABORATION

5.1 **Goal of the Collaboration.** The goals of the Collaboration are to conduct the Transition Program in accordance with the Transition Program Plan and conduct the Collaborative Development Program in accordance with the Collaborative Development Plan.

5.2 **Meetings of Senior Executives.** Upon agreement of the JDC for the necessity of a meeting(s) with senior executives, the Chief Executive Officer of Neurocrine and Senior Vice President, Pharmaceuticals Research & Development of Abbott shall meet and review the progress of the Collaboration and shall discuss any current issues of the Collaboration with the intent of proposing resolutions for such issues. Meetings may be in person or may be held telephonically or by videoconference.

5.3 Joint Development Committee.

- a) Formation. Within thirty (30) days following the Effective Date, the Parties shall establish a joint development committee (the “ **JDC** ”). The JDC shall consist of senior representatives from each Party with decision making authority in such number as mutually agreed on by the Parties not to exceed [...] from each Party. Each Party shall have the right at any time to substitute individuals, on a permanent or temporary basis, for any of its previously designated representatives to the JDC by giving written notice to the other Party. The JDC shall be chaired by a representative member from Abbott.
- b) Responsibility. The JDC will be responsible for coordination and oversight of all activities conducted under the Transition Program and the Collaborative Development Program in accordance with this Agreement. The Parties shall cause their respective representatives on the JDC to use diligent efforts, acting in good faith, to resolve all matters presented to them as expeditiously as possible.
- c) Decision Making and Dispute Resolution. All decisions of the JDC will be by consensus whereby each of Neurocrine and Abbott shall have one (1) vote on all matters before the JDC. If for any reason the JDC cannot resolve any matter properly before it, the matter shall be [...***...].
- d) Withdrawal; Disbandment. Subject to Neurocrine’s other obligations herein, Neurocrine may irrevocably withdraw from participation in the JDC upon written notice to Abbott and subject to Abbott’s consent, not to be unreasonably withheld, conditioned or delayed. The JDC shall disband upon completion of the Transition Program and Collaborative Development Program.

5.4 JDC Meetings. The JDC chairperson shall call meetings [...***...], or as otherwise mutually agreed. Meetings may be held in person, by telephone, or by video conference call, and the location of each meeting shall be selected by the chairperson, unless otherwise agreed. In addition to the foregoing, either Party may call a special meeting of the JDC up to [...***...] per year upon [...***...] days notice to the other Party. Meetings will be minuted and signed by the chairperson and distributed to both Parties. Upon the other Party’s consent, additional participants of a Party may be invited by any representative to attend meetings when and where appropriate. If feasible, prior to each JDC meeting, the Parties will distribute to each other written copies (or corresponding electronic files) of materials intended to be discussed at such meeting. In the event that after receipt of any such report, either Party shall request additional data or information, the Party to whom such request is made shall use reasonable efforts to promptly provide to the other Party such data or information.

5.5 Alliance Managers. In addition to the JDC set forth above, Neurocrine and Abbott each acknowledge and agree that it would be beneficial to the Collaboration for each to have a senior representative with a general understanding of the non-clinical and pharmaceutical development (API and drug product), clinical, regulatory, and manufacturing issues relating to Products to act as an alliance manager (“ **Alliance Manager** ”), and will appoint such a person to the extent each Party in its sole discretion determines it is practical. It is envisioned that the Alliance Managers will serve as a single point of contact within each Party with responsibility for facilitating communication and collaboration between the Parties. The Alliance Managers may attend JDC meetings as appropriate and will be provided access to decision making representatives of both Parties.

5.6 Abbott Authority. Subject to the oversight of the JDC as provided in Section 5.3 (*Joint Development Committee*) and except as provided elsewhere herein, Abbott shall have sole responsibility and authority with regard to (a) Development activities related to Products, including the timing and staging of Development work on the various Indications and the determination of which Indications to

pursue, (b) manufacturing and commercial supply of Products, including holding title to commercial inventory and responsibility for invoicing, credit and collection, and (c) Commercialization of Products, including pricing of Products, all pricing and reimbursement approvals and all other terms of sale.

5.7 **Reporting.** After the JDC has been disbanded, on [...] basis until [...], Abbott will provide to Neurocrine a written report setting forth [...]; provided however, in the event of a Change of Control, Abbott will provide to Neurocrine, on [...] basis, a written report setting forth [...] only. If following receipt of [...] report or [...], Neurocrine shall reasonably request additional information about [...], Neurocrine may make such request through the Alliance Managers of the Parties and Abbott will provide such information within a reasonable time after the request; provided however, in the event of a Change of Control, Abbott shall not be obligated to provide any such information.

ARTICLE SIX - TRANSITION PROGRAM

6.1 **Transition Program.**

- a) **Term.** The activities under the Transition Program as outlined in the Transition Plan will terminate on the date set forth in the Transition Plan, provided that, prior to the end of the Transition Term, (i) all Regulatory Filings in existence on the Effective Date will have been assigned to, and accepted by, Abbott, (ii) all Assigned Third Party Development Contracts will have been assigned to, and accepted by Abbott, and (iii) all Assigned Third Party Manufacturing Contracts will have been assigned to, and accepted by, Abbott. The Parties shall use Commercially Reasonable Efforts to perform the activities set forth in the Transition Plan and complete the Transition Program, in accordance with the timelines set forth in the Transition Plan. The Parties currently agree that the Transition Program will be initiated on [...] and will be substantially completed and will terminate on [...], it being understood that such date is an estimate based on the current state of the Transition Program and may be changed by the JDC even if the Parties are exerting Commercially Reasonable Efforts to complete the Transition Program by such date.
- b) **Goal; Diligence.** The goal of the Transition Program will be to (1) [...] and (2) [...]. Specifically, the Transition Program may include, but is not limited to, all activities under the Third Party Development Contracts and Third Party Manufacturing Contracts during the term of the Transition Program. Each Party shall use Commercially Reasonable Efforts in carrying out its activities under the Transition Program and Transition Plan and shall conduct the Transition Program in compliance with all applicable Laws.
- c) **Transition Plan.** Subject to oversight of the JDC, Neurocrine shall (i) perform Product manufacturing, clinical, and regulatory activities set forth in the Transition Plan, in accordance with the terms of the Transition Plan, and (ii) transfer to Abbott the data and other assets set forth in the Transition Plan, in accordance with the terms of the Transition Plan. The Transition Plan will be updated by the JDC as needed and will specifically include detailed plans for staffing levels and activities, timelines and transition dates. In particular, the Transition Plan will address the timelines for the transfer of data and Technology to Abbott, and for the assignment to Abbott of Regulatory Filings, Third Party Manufacturing Contracts and Third Party Development Contracts, and the specific Development activities

(and corresponding timelines) to be performed by Neurocrine. Each amendment and update to the Transition Plan shall be prepared jointly by the Parties through the JDC in accordance with the limitations on total numbers of FTEs in any given period and allocation across functional areas set forth on Exhibit F. The Transition Plan may be amended by the JDC to accelerate, decelerate, add or remove activities thereunder including reducing or eliminating Neurocrine's responsibilities for an activity thereunder provided that, the number of Neurocrine FTEs funded and the allocation of Neurocrine FTEs across functional areas (e.g., CMC, pre-clinical, clinical) may not be reduced or increased or altered without Neurocrine's consent.

- d) Transfer of Data, Information, Technology and Assets. From and after the Effective Date, all data, information, Technology and assets related to the Compounds and Products that are reasonably requested by Abbott shall be made available to Abbott through a secure electronic document sharing service. Additionally, hardcopy forms of data, information, Technology and assets related to the Compounds and Products that are reasonably requested by Abbott shall be transferred to a site selected by Abbott, and electronic forms of data, information, Technology and assets related to the Compounds that are reasonably requested by Abbott shall be transferred to an Abbott electronic system per Abbott's instructions. These transfers of data, information, Technology and assets shall occur at scheduled intervals as mutually agreed upon by the Parties and will be categorized as high priority, low priority and upon request to determine the expedience of such transfer. The Parties agree that the method of transfer of such data, information, Technology and assets will be of a secure nature, with an agreed upon applied data integrity method (such as a checksum utility), if applicable.

6.2 Transition Budget. Notwithstanding anything to the contrary in this Agreement, Abbott's total funding responsibility for the Transition Program shall not exceed [...***...] without Abbott's prior written permission.

- a) Internal Costs. Abbott will initially provide funding for Neurocrine FTEs devoted to the conduct of the Transition Program in accordance with the Transition Plan, at a rate of [...***...] per FTE per year (such rate will be prorated for any partial year), and provided such funding shall not exceed [...***...] without Abbott's prior written permission. The contemplated allocation of Neurocrine FTEs devoted to the conduct of the Transition Program in accordance with the Transition Plan, as of the Effective Date, is [...***...]. Neurocrine FTEs in [...***...] will be allocated by the JDC in accordance with the Transition Plan and Section 6.1(c) from time to time based on the progress of the activities under the Transition Plan. Within [...***...] days after the end of each Abbott Quarter after the Effective Date, Neurocrine will provide to Abbott an invoice setting forth the amount of funding for Neurocrine FTEs allocated to Transition Plan activities in such preceding Abbott Quarter as well as a FTE report for the preceding Abbott Quarter, which FTE report details the FTEs committed to the Transition Program by department and/or functional area, and a brief summary of the work performed (which summary may be limited to references to the reports to the JDC). Invoices will be payable by Abbott within [...***...] days of receipt of the invoice.

- b) External and Third Party Costs.

- 1) Abbott agrees that Abbott will be responsible for all Third Party and external costs and expenses for the activities set forth on Exhibit F on or after [...***...] and accrued and properly expensed under generally accepted accounting principles for activities undertaken on or after [...***...], as set forth in the Transition Plan, or otherwise

approved by the JDC, provided such amounts do not exceed the budget set forth in the Transition Plan by more than [...] without Abbott's prior written permission. Within [...] days after the end of each Abbott Quarter during the term of the Transition Program, Neurocrine will provide to Abbott a report and invoice setting forth the external and Third Party costs arising out of the Transition Program in such Abbott Quarter, including copies of original invoices for such Third Party costs. Neurocrine's quarterly invoice to Abbott will be payable by Abbott within [...] days of receipt of the report.

- 2) All expenses under the Third Party Development Contracts and Third Party Manufacturing Contracts relating to activities conducted by Neurocrine pursuant to the Transition Plan on or after [...] (including termination fees, if applicable, as contemplated by the Transition Plan) are included in the budget in the Transition Plan and will be reimbursed by Abbott as Third Party external costs and expenses hereunder.
- 3) The budget included in the Transition Plan sets forth all the expenditures that will be incurred in the course of the Transition Program with respect to activities performed by Neurocrine and Third Parties. The Parties acknowledge and agree that, notwithstanding the Parties' efforts to fully budget all cost items of the Transition Program, costs may change over time and/or unbudgeted items may be identified. As such, the JDC will review the Transition Program budget on a quarterly basis and reforecast such budget based on the then current costs and expenses on the basis of whether such expenditure is reasonably necessary to maintain timelines and beyond the reasonable control of the Parties.

6.3 Regulatory Filings. In accordance with the Transition Plan, Neurocrine will assign to Abbott all Regulatory Filings and thereafter all Regulatory Filings shall be the property of Abbott and Abbott shall be responsible for, and pay all cost and expenses relating to, Regulatory Filings in the Territory. Each of the Parties shall take all reasonable steps to ensure an orderly transfer of the Regulatory Filings to Abbott as provided herein and in the Transition Plan, and in accordance with the timelines for transfer set forth in the Transition Plan.

6.4 Adverse Events and Safety Information. Within ninety (90) days after the date of this Agreement, the Parties shall enter into an agreement to initiate a process for the exchange of adverse event safety data in a mutually agreed format, including but not limited to, postmarketing spontaneous reports received by the Party or its Affiliates in order to monitor the safety of the product and to meet reporting requirements with any applicable regulatory authority.

6.5 Assignment of Third Party Development Contracts. If and to the extent applicable, Neurocrine will use Commercially Reasonable Efforts to obtain necessary consents from Third Parties to assign to Abbott all Third Party Development Contracts the JDC requests be assigned to Abbott. Neurocrine will assign to Abbott, and Abbott will accept assignment of, the assignable Third Party Development Contracts identified by the JDC prior to the end of the Transition Program (the "**Assigned Third Party Development Contracts**"). Upon assignment to Abbott of each Assigned Third Party Development Contract, Abbott will be responsible for all future performance under such Assigned Third Party Development Contract and will make all decisions regarding such Assigned Third Party Development Contract and any other future Development contracts Abbott elects. Subject to Section 6.2(b), Neurocrine remains responsible for all rights, duties and obligations of such Assigned Third Party Development Contracts prior to the date of assignment to Abbott. Any Third Party Development Contracts not included in the Assigned Third Party Development Contracts will not be assigned to Abbott and Abbott shall have no rights or obligations under such unassigned Third Party Development Contracts (it being understood that Abbott has certain obligations to Neurocrine with respect to such unassigned Third Party Development Contracts pursuant to Section 6.2(b)).

6.6 **Assignment of Third Party Manufacturing Contracts.** If and to the extent applicable, Neurocrine will use Commercially Reasonable Efforts to obtain necessary consents from Third Parties to assign to Abbott all Third Party Manufacturing Contracts the JDC requests be assigned to Abbott. Neurocrine will assign to Abbott, and Abbott will accept assignment of, all assignable Third Party Manufacturing Contracts identified by the JDC prior to the end of the Transition Program (the “ **Assigned Third Party Manufacturing Contracts** ”). Upon assignment to Abbott of each Assigned Third Party Manufacturing Contract, Abbott will be responsible for all future performance under such Assigned Third Party Manufacturing Contract and will make all decisions regarding such Assigned Third Party Manufacturing Contract and any future manufacturing or Product supply contracts Abbott elects. Subject to Section 6.2(b), Neurocrine remains responsible for all rights, duties and obligations of such Assigned Third Party Development Contracts prior to the date of assignment to Abbott. Any Third Party Manufacturing Contracts not included in the Assigned Third Party Manufacturing Contracts will not be assigned to Abbott and Abbott shall have no rights or obligations under such unassigned Third Party Manufacturing Contracts (it being understood that Abbott has certain obligations to Neurocrine with respect to such unassigned Third Party Manufacturing Contracts pursuant to Section 6.2(b)).

6.7 **Use of Third Parties.** Neurocrine shall be entitled to utilize the services of Third Parties to perform its share of Transition Program activities, only upon Abbott’s prior written consent, which [...***...]. Notwithstanding the foregoing, Neurocrine shall remain at all times fully liable for its responsibilities under the Transition Program and this Agreement; provided, further, that Neurocrine shall not subcontract any such obligations unless the written agreement pursuant to which it engages any Third Party: (i) is consistent in all material respects with this Agreement, and (ii) contains terms obligating such Third Party to comply with the confidentiality, intellectual property, and all other relevant provisions no less stringent than those set forth in this Agreement.

ARTICLE SEVEN - COLLABORATIVE DEVELOPMENT PROGRAM

7.1 **Collaborative Development Program.**

- a) **Goal.** The Parties will collaborate in a Collaborative Development Program to achieve [...***...], as more expressly set forth in the Collaborative Development Plan.
- b) **Term.** The term of the Collaborative Development Program will begin on [...***...] and will end [...***...], unless otherwise agreed by the Parties.
- c) **Efforts.** The Parties will use Commercially Reasonable Efforts to perform the activities set forth in the Collaborative Development Plan in accordance with the timelines set forth in the Collaborative Development Plan. Both parties will participate in [...***...] and, as appropriate, [...***...] as Transition Program or Collaborative Development Program activities, as the case may be.

7.2 **Collaborative Development Plan and Budget.**

- a) **Activities.** The Collaborative Development Program, subject to JDC approval and oversight, may include any of the types of activities contemplated in the Collaborative Development Plan set forth as Exhibit G. The Parties understand and agree that Exhibit G is not intended

to represent a final Collaborative Development Plan. In addition, while Exhibit G includes estimated numbers of Neurocrine FTEs that will be required to conduct development activities, it is understood that these numbers are estimates only and may change depending on timing of the activities and final study designs for selected activities. Within [...] days following the Effective Date, the JDC will finalize a Collaborative Development Plan for the term of the Collaborative Development Program. The Collaborative Development Plan will allocate to Neurocrine activities equivalent to the Neurocrine FTE Funding Commitment (as defined in Section 7.3(a) in accordance with the limitations on total numbers of FTEs in any given period and allocation across functional areas set forth on Exhibit G. The initial Collaborative Development Plan will focus on the activities to be conducted in the [...***...]. Thereafter the Collaborative Development Plan will be updated by the JDC quarterly as needed and will specifically include detailed plans for staffing levels and activities, timelines and transition dates and outline all Neurocrine FTE funding and external costs and expenses. The Parties acknowledge and agree that, notwithstanding the Parties' efforts to fully budget all cost items of the Collaborative Development Program, costs may change over time and/or unbudgeted items may be identified. As such, the JDC will review the budget set forth in the Collaborative Development Plan on a quarterly basis and reforecast such budget based on the then current costs and expenses on the basis of whether such expenditure is reasonably necessary to maintain timelines and beyond the reasonable control of the Parties.

- b) Amendments. The Collaborative Development Plan and each amendment and update thereto shall be prepared jointly by the Parties through the JDC. The JDC shall have the authority to amend the Collaborative Development Plan with [...] days prior written notice to Neurocrine, including accelerating, decelerating, extending, adding or removing activities thereunder; provided that, (i) the amendment is consistent with the goals of the Collaborative Development Program and (ii) the number of Neurocrine FTEs funded pursuant to Section 7.3(a), the limitations on total numbers of FTEs in any given period and the allocation of Neurocrine FTEs across functional areas (e.g., CMC, pre-clinical, clinical) may not be decreased or extended or activities added that result in an increase, in either case except as set forth in Section 7.3(a) or with Neurocrine's written approval, (iii) the Third Party activities set forth in the Third Party Development Contracts and Third Party Manufacturing Contracts will not be terminated except in accordance with their terms (and any associated expenses being payable pursuant to Section 7.3(b)).

7.3 Collaborative Development Program Funding.

- a) Internal Costs. Abbott will provide funding for Neurocrine FTEs devoted to the conduct of the Collaborative Development Program in accordance with the Collaborative Development Plan at a rate of [...] per year (such rate will be prorated for any partial year), in an amount equal to [...] over the term of the Collaborative Development Program (the "*Neurocrine FTE Funding Commitment*"). The Neurocrine FTE Funding Commitment will not exceed [...] without Abbott's prior written permission.
- b) External and Third Party Costs. Abbott will be responsible for all Third Party and external costs and expenses approved in advance by Abbott for the Collaborative Development Program activities.
- c) Invoices. During the term of the Collaborative Development Program, within [...] days after the end of each Abbott Quarter, Neurocrine will provide to Abbott an invoice

setting forth the amount of funding for Neurocrine FTEs allocated to Collaborative Development Plan activities and Third Party external costs and expenses incurred by Neurocrine pursuant to the Collaborative Development Plan for such preceding Abbott Quarter, as well as a FTE report for the preceding Abbott Quarter, which FTE report details the FTEs committed to the Collaborative Development Program by department and/or functional area, and a brief summary of the work performed (which summary may be limited to references to the reports to the JDC). Invoices will be payable by Abbott within [...***...] days of receipt of the invoice.

7.4 **Use of Third Parties.** The provisions set forth in Section 6.7 (*Use of Third Parties*) apply *mutatis mutandis* for the Collaborative Development Program.

ARTICLE EIGHT - MANUFACTURING

8.1 **Manufacturing Responsibility.** Product manufacturing shall be the responsibility of Abbott and Abbott, at its sole discretion, may (1) modify or terminate Assigned Third Party Manufacturing Agreements, subject to the terms of such agreements; (2) negotiate with Neurocrine or its designee an agreement for the manufacture and supply Compound or Product to Abbott, its Affiliates or Sublicensees which agreement will contain standard manufacturing commercial terms, conditions and payments mutually acceptable to Neurocrine and Abbott (for avoidance of doubt Neurocrine will not be obligated to enter into such a manufacturing agreement if it mutually acceptable terms cannot be negotiated); (3) transfer some or all of the manufacture of the Product to locations selected by Abbott, (4) modify the manufacturing process for Products, (5) modify the quality assurance process for the manufacture or release of Product, and (5) take such other actions related to the manufacture of Products that Abbott deems appropriate.

8.2 **Clinical Supply.** Neurocrine will arrange for the transfer to Abbott of all *Elagolix* clinical trial material owned by Neurocrine on the Effective Date. Neurocrine will invoice Abbott for all costs incurred by Neurocrine in the manufacture, testing, formulation, packaging, storage, and release of the *Elagolix* clinical trial material as well as shipment costs to Abbott, provided however such cost shall not exceed [...***...] without Abbott's prior written consent. Abbott shall only be responsible to pay for such clinical trial material that conforms to the applicable Product specifications in effect on the Effective Date, and (b) which has been manufactured in compliance with cGMP and all applicable laws and regulations; and (c) which is not adulterated or misbranded within the meaning of the U.S. Food, Drug & Cosmetics Act or other applicable law. Abbott may request that Neurocrine assume responsibility for *Elagolix* clinical supply production after the Effective Date as a Collaborative Development Program activity.

8.3 **Inspections.** Abbott shall be responsible for the management of any governmental or regulatory review, audit or inspection of facilities or processes relating to the manufacture of Products and all communications to governmental or regulatory authorities on such matters shall be made by Abbott.

8.4 **Manufacturing Technology Transfer.** All manufacturing Neurocrine Technology transfer activities will be Transition Program or Collaborative Development Program activities, as the case may be. Upon receipt of written notice from Abbott, Neurocrine shall use Commercially Reasonable Efforts to make available or to cause to be made available to Abbott or its designee, all manufacturing Neurocrine Technology, including, product manufacturing, packaging and sterilization specifications, utilities and process equipment information, and other technical information, relating to the manufacture of the

Products, then within Neurocrine's possession or Control, and shall thereafter render such assistance to Abbott or its designee as would allow Abbott or its designee to manufacture the Products (such transfer, the "**Manufacturing Technology Transfer**"). If any manufacturing Neurocrine Technology is within the control or possession of a Third Party pursuant to a Third Party Manufacturing Contract, Neurocrine shall use Commercially Reasonable Efforts to obtain the cooperation and assistance of such Third Party in such Manufacturing Technology Transfer. The Manufacturing Technology Transfer shall include the successful completion of installation qualification, operational qualification, performance qualification and process validation of the manufacturing process at the facility designated by Abbott. In connection with the Manufacturing Technology Transfer, Neurocrine and/or its Third Party manufacturer shall (i) deliver a comprehensive manual in English setting forth in detail the techniques, processes, documentation and know-how that are reasonably necessary or directly useful in the manufacture of Products then within either Neurocrine's possession or control and (ii) make available to Abbott at a site designated by Abbott the services of such personnel of Neurocrine's as Abbott may reasonably request in order to assist Abbott in establishing the manufacturing facility.

ARTICLE NINE - CONFIDENTIAL INFORMATION

9.1 **Treatment of Confidential Information.** During the Term and for a period of [...***...] years thereafter, each Party shall maintain Confidential Information of the other Party in confidence, and shall not disclose, divulge or otherwise communicate such Confidential Information to any Third Party, or use it for any purpose other than as permitted under this Agreement or in connection with the development, manufacture, marketing, promotion, distribution or sale of the Products pursuant to this Agreement, and each Party agrees to exercise its reasonable efforts to prevent and restrain the unauthorized disclosure of such Confidential Information by any of its directors, officers, employees, or permitted Third Parties.

If, in the opinion of the receiving Party's counsel, any of the disclosing Party's Confidential Information is required to be disclosed pursuant to law, regulation, or court order, the receiving Party shall give the disclosing Party prompt, written notice and, to the extent practical and consistent with the receiving Party's legal obligations (as determined in good faith by counsel to the receiving Party) withhold disclosure to allow the disclosing Party to take whatever action it reasonably deems necessary to protect its Confidential Information. In the event that (i) no protective order or other remedy is obtained, or (ii) the disclosing Party waives compliance with the terms of this Article 9 (*Confidential Information*), or (iii) in the good faith opinion of counsel to the receiving Party, disclosure of the disclosing Party's Confidential information can or should not be withheld to allow (i) or (ii) above, then in each case the receiving Party will furnish only that portion of the Confidential Information which receiving Party is advised by counsel is legally required.

Notwithstanding the foregoing, the receiving Party may disclose the disclosing Party's Confidential Information to the extent that such:

- a) is disclosed to governmental or other regulatory agencies in order to obtain and/or maintain patents pursuant to and in accordance with Article 12 (*Intellectual Property*) or to gain or maintain Regulatory Approvals in accordance with a Party's rights to do so under this Agreement, but such disclosure, in each case, may only be to the extent reasonably necessary to obtain and/or maintain patents or Regulatory Approvals and reasonable measures shall be taken to assure confidential treatment of such information;
- b) is deemed reasonably necessary by a Party to be disclosed to agents, consultants, Sublicensees and/or other Third Parties for the research, development, manufacturing and/or marketing of

Products (or for such entities to determine their interest in entering into applicable agreements to perform such activities with or for such Party) in accordance with this Agreement provided such Third Parties agree to be bound by confidentiality and non-use provisions no less stringent than those contained in this Agreement for terms of not less than [...] years; or

- c) is deemed necessary by counsel to the receiving Party to be disclosed to (1) such Party's directors, attorneys, auditors and advisors for the sole purpose of enabling such parties to provide advice to the receiving Party, or (2) [...***...], provided such Third Parties agree to be bound by confidentiality and non-use provisions no less stringent than those contained in this Agreement for terms of not less than [...] years; or
- d) is required to be disclosed by the receiving Party defend or prosecute litigation pursuant to and in accordance with Article 12 (*Intellectual Property*), provided that the receiving Party provides prior notice of such disclosure to the other Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure; or
- e) is required to be disclosed by the receiving Party to comply with applicable Laws including disclosure required by the U.S. Securities and Exchange Commission, subject to the second paragraph above and Section 9.3.

9.2 Publications. The Parties, through the JDC, will develop a publication plan for the Collaboration, as well as a Joint Publication Practices, Processes, and Policies document that is consistent with the Parties' respective policies and procedures for publication and disclosure of results of clinical trials. During the term of the Transition Program and Collaborative Development Program, each Party will submit to the other Party through the JDC for review and approval all peer-reviewed academic, scientific and medical publications relating to the Development of Compounds or Products. The submitting Party will also provide all data (eg, final protocol, statistical analysis plan, relevant statistical tables generated from the plan, figures, and reports) needed to prepare the publication. Neurocrine agrees that it will, and will cause its Affiliates to, not publish any such publications without the prior written consent of Abbott. The non-publishing Party shall have at least [...] days to review each proposed publication. The review period may be extended for up to [...] days in the event the non-publishing Party can demonstrate to the JDC a reasonable need for such extension including, but not limited to, the preparation and filing of patent applications. Such period may be further extended by the JDC. In the event that the two Parties differ in their opinion or interpretation of data in the publication, the parties shall resolve such differences in good faith through appropriate scientific debate. The Parties agree to, and will cause their respective Affiliates to, comply with the ICMJE criteria for authorship of scientific publications and acknowledgement of contributions of other Parties in any publications relating to research or Development of Products. Notwithstanding the foregoing, the Parties shall endeavor as far as possible, for ease and convenience, to agree on a universal basis joint authorship in respect of such publications. After the expiration of the Transition Program and Collaborative Development Program, Neurocrine agrees that it will, and will cause its Affiliates to, not publish any such publications relating to the Compounds or Products without the prior written consent of Abbott.

9.3 Public Announcements.

- a) **Coordination.** The Parties agree on the importance of coordinating their public announcements respecting this Agreement and the subject matter thereof (other than academic, scientific or medical publications that are subject to the publication provision set forth above). Neurocrine and Abbott will, from time to time, and at the request of the other Party discuss and agree on the general information content relating to this Agreement and/or Products which may be publicly disclosed.

- b) **Announcements.** The Parties agree that the public announcement of the execution of this Agreement shall be in the form of the press release attached as Exhibit I. Any other publication, news release or other public announcement relating to this Agreement or to the performance hereunder, may only be made by Neurocrine or Abbott with the review and prior written approval of the other Party, [...***...]. The party wishing to make a publication, news release or other public announcement hereunder shall provide written notice to the other Party regarding the same. If a publication, news release or other public announcement is agreed upon by both Parties, the other Party shall be allowed to review and comment on the publication, news release or other public announcement. The aforementioned approval procedure and review period in total shall not exceed [...***...] days. In no event shall such statements or disclosures disclose, if previously undisclosed, the stage of development of Products and/or the financial terms of the transaction; provided, however, that any disclosure which is required by applicable law, including disclosures required by the U.S. Securities and Exchange Commission or made pursuant to the requirements of the national securities exchange or other recognized stock market on which such Party's securities are traded, as advised by the disclosing Party's counsel, may be made without the prior consent of the other Party, although, to the extent practicable and in opinion of counsel to the disclosing Party consistent with such Party's disclosure obligations, the other Party shall, as far in advance as reasonably practicable but in no event less than [...***...] days provide advance notice of any such legally required disclosure to comment and reasonably consider such comments provided by such Party on the proposed disclosure. Notwithstanding the foregoing, with respect to [...***...], and is thus [...***...], the Parties agree: [...***...].
- c) Notwithstanding anything to the contrary in this Agreement, but subject to the provisions of Article 9 (*Confidential Information*) and Section 13.19 (*Use Of Names, Logos Or Symbols*), Abbott shall have the right to publicly disclose research, development and commercial information regarding the Compound(s) and Product(s).

ARTICLE TEN - INDEMNIFICATION AND INSURANCE

10.1 **Indemnification by Abbott.** Abbott will indemnify, defend and hold harmless Neurocrine, its licensees, sublicensees and Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "**Neurocrine Indemnified Party**") from and against any and all liability, loss, damage, expense (including reasonable attorneys' fees and expenses) and cost (collectively, a "**Liability**") which the Neurocrine Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of: (i) any claims of any nature arising out of (y) the conduct of the Product Development or Commercialization by, on behalf of or under authority of, Abbott (other than by a Neurocrine Indemnified Party) or (z) research, Development and/or Commercialization of Products by, on behalf of or under authority of, Abbott (other than by Neurocrine Indemnified Party) and/or (ii) any Abbott representation or warranty set forth herein being untrue in any material respect when made; except in each case, to the extent caused by the negligence or willful misconduct of Neurocrine or any Neurocrine Indemnified Party. Notwithstanding the foregoing, Abbott shall have no obligation to defend, indemnify or hold harmless any Neurocrine Indemnified Party from and against any Liability arising out of or resulting from the infringement of a Third Party Patent Right provided such indemnify does fall within the foregoing indemnification requirements.

10.2 **Indemnification by Neurocrine.** Neurocrine will indemnify, defend and hold harmless Abbott, its licensees, Sublicensees and Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "**Abbott Indemnified Party**") from and against and all Liability which the

Abbott Indemnified Party may be required to pay to one or more Third Parties arising out of (i) any claims of any nature arising out of (x) the conduct of Product Development or Commercialization of by, on behalf of or under authority of, Neurocrine (other than by an Abbott Indemnified Party) or (y) research, Development and/or Commercialization of Products by, on behalf of or under authority of, Neurocrine (other than by an Abbott Indemnified Party) and/or (ii) any Neurocrine representation or warranty set forth herein being untrue in any material respect when made; except in each case, to the extent caused by the negligence or willful misconduct of Abbott or any Abbott Indemnified Party. Notwithstanding the foregoing, Neurocrine shall have no obligation to defend, indemnify or hold harmless any Abbott Indemnified Party from and against any Liability arising out of or resulting from the infringement of a Third Party Patent Right provided such indemnify does fall within the foregoing indemnification requirements.

10.3 Procedure. Each Party will provide prompt written notice to the other in the event it becomes aware of a claim for which indemnification may be sought hereunder. In case any proceeding (including any governmental investigation) shall be instituted involving any Party in respect of which indemnity may be sought pursuant to this Article 10, such Party (the “ **Indemnified Party** ”) shall promptly notify the other Party (the “ **Indemnifying Party** ”) in writing. Within [...***...] days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party claim with counsel reasonably satisfactory to the Indemnified Party and control the disposition or settlement thereof (including all decisions relative to litigation, appeal, and settlement subject to this Article). The Indemnified Party shall cooperate fully with the Indemnifying Party in such defense. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense; provided the Indemnified Party shall bear the expense if the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. All such fees and expenses shall be reimbursed as they are incurred, and provided reasonable documentation along with an invoice is provided. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its prior written consent, but if settled with such prior written consent or if there be a final judgment for the plaintiff, the Indemnifying Party agrees to indemnify the Indemnified Party from and against any Liability by reason of such settlement or judgment. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnified Party is, or arising out of the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless [...***...].

10.4 Insurance. Each Party acknowledges that they each maintain and shall, maintain adequate insurance for liability insurance adequately covering such Party’s obligations under this Agreement. During the Term Abbott shall maintain comprehensive general liability insurance, including products liability insurance, with reputable and financially secure insurance carriers, or shall provide an explanation of self insurance, in a minimum amount of \$[...***...] per occurrence and \$[...***...] aggregate prior to first commercial sale and \$[...***...] aggregate on and after first commercial sale (exclusive of deductible amounts) as respects personal injury, bodily injury and property damage arising out of a Abbott’s Development and Commercialization of Products. Abbott shall provide Neurocrine with evidence of such insurance, upon request. Such insurance shall include Neurocrine as a named insured and shall require prior notice to the Neurocrine before cancellation. Notwithstanding the foregoing, either Party may self-insure in whole or in part the insurance requirements described above, provided such Party continues to be investment grade determined by reputable and accepted financial rating agencies. This Section shall apply *mutatis mutandis* to Neurocrine, in the event Neurocrine obtains a license to Compounds and Products pursuant to Section 11.2(b), 11.3, 11.4, 11.5 and 11.7.

10.5 **Survival.** All obligations of indemnification and insurance imposed under this Article 10 (*Indemnification and Insurance*) shall expire [...***...] years following the longer of termination or expiration of this Agreement or, with respect to a particular Party, last sale of a Product sold under this Agreement by a Party.

ARTICLE ELEVEN - TERM AND TERMINATION

11.1 **Term; Effect of Expiration.**

- a) Unless earlier terminated by mutual agreement of the Parties, or pursuant to the provisions of this Article 11, this Agreement shall commence on the Effective Date and will continue in full force and effect, on a country by country and Product by Product basis, until the final obligation to pay Royalties with respect to the sale of such Product in a country expires as provided in Article 4 and Abbott's obligations [...***...] expire, at which time this Agreement shall expire in its entirety in such country for such Product (" **Term** ").
- b) On a country by country and Product by Product basis, upon expiration of this Agreement with respect to a Product in a country pursuant to this Section 11.1(a) (**Term**), the license set forth in Section 3.1 (**License**) shall be deemed to be irrevocable, unrestricted, perpetual and fully paid-up with respect to such Product in such country.

11.2 **Termination for Convenience; Effects.**

- a) **Termination for Convenience.** Notwithstanding anything contained herein to the contrary, Abbott shall have the right to terminate this Agreement at any time in its sole discretion by giving Neurocrine one hundred eighty (180) days prior written notice.
- b) **Effects of Termination.** If Abbott terminates this Agreement pursuant to Section 11.2(a), (i) Abbott will pay all amounts due and owing to Neurocrine as of the termination effective date; and (ii) Abbott shall continue to be obligated during the termination notice period to perform all of its obligations under this Agreement, including its obligation to pay all expenses associated with the Transition Program and Collaborative Development Program. In addition, if Abbott terminates this Agreement pursuant to Section 11.2(a):
- 1) All of Abbott's licenses and rights to the Neurocrine Technology and Neurocrine Patent Rights will terminate;
 - 2) All Neurocrine Confidential Information provided to Abbott in tangible form and all substances or compositions provided by Neurocrine to Abbott will be returned to Neurocrine or destroyed, except that Abbott may retain one copy of the Neurocrine Confidential Information solely for legal archive purposes;
 - 3) All Abbott Confidential Information provided to Neurocrine in tangible form and all substances or compositions delivered or provided to Neurocrine by Abbott shall be returned to Abbott or destroyed, except that Neurocrine may retain one copy of the Abbott Confidential Information solely for legal archive purposes;

- 4) Abbott will transfer to Neurocrine such [...] and information reasonably necessary to allow Neurocrine to [...], including, at Neurocrine's option, exercisable within [...] days following the effective date of such termination, transfer to Neurocrine of any [...];
- 5) Abbott will transfer to Neurocrine any [...];
- 6) Abbott will transfer and assign ownership to Neurocrine of all [...] as well as (1) a copy of the [...], (2) copies of [...], and access to the [...], (3) copies of all documents [...], (4) access to [...] (5) copies of correspondence with [...] and (6) access to information Abbott determines is relevant to [...];
- 7) At Abbott's option, Abbott will either [...], provided, if Abbott [...]; and
- 8) Abbott will grant to Neurocrine an [...] license under the Abbott Technology, Abbott Patent Rights, [...] and [...] to make, have made, use, import, offer for sale and sell Compounds and Products.
- 9) The [...] pursuant to subsections 7 and 8 above, shall be [...]. Subject to [...], if there is a termination [...] pursuant to [...], then the parties shall negotiate in good faith [...], whereby the Parties shall take into consideration: [...].

11.3 **Termination if Abbott** [...]. In the event Abbott, Abbott's Affiliates or Sublicensees [...], Neurocrine shall have the right to terminate this Agreement upon [...] days written notice to Abbott. Any such termination shall only become effective if Abbott or its Affiliate or Sublicensees, as applicable, has not [...] before the end of the above notice period and the provisions of Section 11.2(b) shall apply *mutatis mutandis* to termination pursuant to this Section.

11.4 **Termination for Cause.**

- a) **Termination for Cause.** If either Party (the "**Notifying Party**") believes that the other Party (the "**Other Party**") is in Default of this Agreement, then the Notifying Party may deliver notice of such breach to the Other Party.
 - 1) If the Other Party disputes that it is in Default of this Agreement, the matter shall be handled pursuant to Section 13.2 (*Dispute Resolution*). If the neutral renders a ruling that the Other Party is in Default of this Agreement (the "**Adverse Ruling**"), such ruling shall also specify the actions to be taken by the Other Party to cure such Default, which actions must be completed within [...] days after such ruling (or [...] days if such Default relates [...]). If the Other Party has failed to comply with the terms of the Adverse Ruling within such [...] or [...] day period, as applicable, or if such compliance cannot be fully achieved within such [...] day or [...] day period, the Other Party has failed to commence compliance and/or has failed to use diligent efforts to achieve full compliance as soon thereafter as is reasonably possible, then the Notifying Party shall have the following rights:
 - a) where [...] is the Other Party and where the basis for such Default is [...] failure to abide by a material obligation under this Agreement with respect to [...] may terminate this Agreement with respect [...] by delivering written notice to [...] of such termination; and

- b) notwithstanding (A) above, where [...] is the Other Party and where the basis for such breach is [...] may terminate this Agreement by delivering written notice to [...] of such termination; and
- c) where [...] is the Other Party, [...] may terminate this Agreement by delivering written notice to [...] of such termination.

2) If the Other Party does not dispute that it has committed a material breach of this Agreement, then if the Other Party fails to cure such breach, or take steps as would be considered reasonable to effectively cure such breach, within [...] (or [...] days if such Default relates to [...]), after receipt of notice as provided above, the the provisions of Section 11.4(1)(a)(b) or (c) shall apply.

b) Effect of Termination for Cause. If a Party terminates this Agreement pursuant to Section 11.4(a), the Parties shall have the rights set forth below, each measured from the date written notice of such termination is given to the Other Party.

(i) Neurocrine. Where Neurocrine is the Other Party and Abbott terminated [...] pursuant to 11.4(a), Abbott may in its sole discretion: (i) [...] and (ii) [...]. Except as set forth in this clause (a): all rights and obligations under this Agreement shall survive such termination and continue unaffected, subject to [...], as determined in accordance with Section 13.2 (*Dispute Resolution*).

(ii) Abbott. Where Abbott is the Other Party and Neurocrine terminated [...] pursuant to 11.4(a), the provisions of Section 11.2(b) shall apply provided however, that if this Agreement is terminated only with respect to [...], the provisions of Section 11.2(b) shall apply *mutatis mutandis* to termination by Neurocrine pursuant to this Section but only with respect to [...].

11.5 Bankruptcy. Each Party may, in addition to any other remedies available to it by Law or in equity, exercise the rights set forth below by written notice to the other Party (the “ **Insolvent Party** ”), in the event the Insolvent Party shall have become insolvent or bankrupt, or shall cease conducting business in the ordinary course, or shall have made an assignment for the benefit of its creditors, or there shall have been appointed a trustee or receiver of the Insolvent Party or for all or a substantial part of its property, or any case or proceeding shall have been commenced or other action taken by or against the Insolvent Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or Law of any jurisdiction now or hereafter in effect, or there shall have been issued a warrant of attachment, execution, distraint or similar process against any substantial part of the property of the Insolvent Party, and any such event shall have continued for sixty (60) days undismissed, unbonded and undischarged.

All rights and licenses granted under or pursuant to this Agreement by Neurocrine and Abbott are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code or its foreign equivalent, licenses of rights to “intellectual property” as defined under Section 101

of the Bankruptcy Code or its foreign equivalent. The Parties agree that the Parties as licensees of such rights under this Agreement shall retain and may fully exercise all of their rights and elections under the Bankruptcy Code or its foreign equivalent. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the Bankruptcy Code or its foreign equivalent, the other Party shall 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 the same, if not already in the other Party's possession, shall be promptly delivered to other Party (i) upon any such commencement of a bankruptcy proceeding upon its written request therefore, unless the Party subject to such proceeding elects to continue to perform all of their obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefore by the other Party.

- a) Neurocrine. In the event Neurocrine is the Insolvent Party, in addition to any other remedies available to Abbott at Law or in equity, Abbott may in its sole discretion (i) [...***...]. Except as set forth in this clause (a), all rights and obligations under this Agreement shall survive such termination and continue unaffected upon Neurocrine becoming an Insolvent Party, unless this Agreement is terminated by Abbott pursuant to Section 11.2(a).
- b) Abbott. In the event Abbott is the Insolvent Party, in addition to any other remedies available to Neurocrine at Law or in equity, Neurocrine may terminate this Agreement and the provisions of Section 11.2(b) shall apply to termination by Neurocrine pursuant to this Section.

11.6 **Change of Control**. In the event of a Change of Control of Neurocrine, Abbott may in its discretion within [...***...] days following the Change of Control elect some or all of the following:

- a) with no less than [...***...] prior written notice [...***...] and thereafter [...***...];
- b) with no less than [...***...] prior written notice, terminate [...***...];
- c) Abbott may elect to require Neurocrine and the Change of Control party to adopt [...***...];
- d) Abbott may elect to terminate the [...***...];
- e) All other rights and obligations under this Agreement shall continue unaffected upon a Change of Control, unless this Agreement is terminated pursuant to this Agreement.

11.7 **Divestiture by** [...***...]. If in connection with any proposed acquisition, merger, or agreement, [...***...] determines that in order to [...***...], it would be advisable, in [...***...] business judgment, [...***...] shall notify [...***...] thereof [...***...].

If [...***...] in good faith believes, based on a determination made by [...***...], that it is capable of [...***...] shall have [...***...] days from [...***...] to (i) [...***...] and (ii) [...***...]. Upon receipt of [...***...] notice hereunder, [...***...] shall [...***...]. [...***...] shall be free at any and all times to [...***...]; provided however, [...***...] shall provide to [...***...] notice of [...***...] and [...***...] shall have [...***...] days following receipt of such notice to [...***...].

11.8 **Debarment and Exclusion.**

- a) Neurocrine represents and warrants that prior to the Effective Date neither it, nor any of its employees, nor [...***...] each of its consultants, or independent contractors or any other person working on its behalf that provided services in connection with an NDA for a Product, were at the time the services were performed a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, or after the services were performed, [...***...] became a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual due to actions related to the services in connection with an NDA for a Product.
- b) Neurocrine covenants that with respect to work conducted pursuant to the Transition Plan and Collaborative Development Plan neither it, nor any of its employees, nor [...***...] each of its consultants, or independent contractors and any other person working on its behalf that provide services in connection with an NDA for a Product (i) will be at the time services are performed a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual or (ii) [...***...] are currently the subject of a proceeding that could lead to it or such employees, consultants, independent contractors, becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual.
- c) Abbott covenants that neither it, nor any of its employees, nor [...***...] each of its consultants, or independent contractors or any other person working on its behalf that provide services in connection with an NDA for a Product, (i) will be at the time services are performed a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual or (ii) [...***...] are currently the subject of a proceeding that could lead to it or such employees, consultants, independent contractors, becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual.
- d) Each Party covenants, represents and warrants that if, during the Term, it, or any of its employees, consultants, independent contractors, or any other person working on its behalf that provided services or are providing services in connection with an NDA for a Product becomes, as applicable, a Debarred Entity, or Debarred Individual, an Excluded Entity or Excluded Individual, a Convicted Entity, or Convicted Individual, it shall immediately notify the other Party. The parties shall serve said written notice in accordance with Section 13.4 (Notices).
- e) Upon breach of this Section 11.7, the [...***...].

For purposes of this provision, the following definitions shall apply

- a) A “Debarred Individual” is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug or biological product application.
- b) A “Debarred Entity” is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

- c) An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).
- d) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

11.9 **Liabilities.** Termination of this Agreement shall not release either Party from any obligation or liability which shall have accrued at the time of termination, or preclude either Party from pursuing all rights at Law and in equity with respect to any Default under this Agreement.

11.10 **LIMITATION ON LIABILITY.** NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, EXCEPT FOR THE WILLFUL MISCONDUCT OF A PARTY OR ITS AFFILIATES, OR A MATERIAL BREACH OF THE CONFIDENTIALITY AND INTELLECTUAL PROPERTY PROVISIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER UNDER CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR CONSEQUENTIAL DAMAGES EXCEPT SUCH DAMAGES OWED TO THIRD PARTIES EXPRESSLY PROVIDED IN THIS AGREEMENT.

11.11 **Survival.** Upon expiration or termination of this Agreement the following provisions shall expressly survive any such expiration or termination: Articles 1, 12, and 13 and Sections 2.6, 3.5, 3.6, 11.1(c), 11.2(b), 11.4(b), 11.5(a) and 11.5(b), 11.8, 11.9, 11.10, and this 11.11 and the following provisions shall expressly survive any such expiration or termination for the period stated therein: Articles 9, 10, and Section 4.7(g).

ARTICLE TWELVE - INTELLECTUAL PROPERTY

12.1 **Ownership, Filing, Prosecution and Maintenance.**

- a) **Abbott Patent Rights.** Abbott shall solely own and shall, at its expense, be solely responsible for the preparation, filing, all prosecution matters, including all inter parte and ex parte patent office submissions, procedural decisions and patent office adversarial proceedings, for example, requests for, or filing or declaration of, interference or opposition, or reexamination (collectively, "Prosecution") and maintenance of Abbott Patent Rights. Abbott shall have no obligation to continue the Prosecution and/or maintenance of any Abbott Patent Right in any country and shall be free to abandon such Abbott Patent Rights at its sole discretion.

b) Program Patent Rights. Abbott shall solely own and shall, at its expense, be solely responsible for the preparation, filing, Prosecution and maintenance of Program Patent Rights. Neurocrine agrees that it will, and will cause its Affiliates to, (i) execute and file those notices and other filings as Abbott shall request be made, from time to time, with the United States Patent and Trademark Office (or any successor agency) or any analogous patent office in the Territory with respect to the rights granted under this Agreement, and (ii) execute and deliver to Abbott all assignments and other instruments as Abbott shall request to effect the ownership, filing, Prosecution and maintenance of Program Patent Rights. Abbott will keep Neurocrine reasonably informed of the status of the Program Patent Rights and will provide Neurocrine with copies of all substantive documentation submitted to, or received from, the patent offices in connection therewith. With respect to any substantive submissions that Abbott is required to or otherwise intends to submit to a patent office, Abbott shall provide a draft of such submission to Neurocrine at least [...] days prior to the deadline or intended filing date, whichever is earlier, for submission of such documentation. Neurocrine shall have the right to review and comment upon any such submission by Abbott to a patent office, and will provide such comments, if any, no later than [...] days prior to the applicable deadline or intended filing date provided that Abbott shall not be obligated to incorporate comments provided by Neurocrine. Abbott shall have the right to cease the Prosecution and/or maintenance of, or not to pursue, or cease to pay the expenses of Prosecution or maintenance of, any Program Patent Right in any country in which such Program Patent Right has been filed. In all cases, Abbott shall have final decision-making authority with respect to the filing, Prosecution, and maintenance of Program Patent Rights.

c) Neurocrine Patents.

(i) Neurocrine shall solely own the Neurocrine Patent Rights and shall be responsible for, through [...] counsel reasonably acceptable to Abbott, the preparation, filing, Prosecution (except as provided in Article 12.1(c)(ii)) and maintenance of Neurocrine Patent Rights. [...] Neurocrine will keep Abbott fully informed of all significant steps to be taken in the preparation and Prosecution of all patent applications and any subsequent actions to be taken with respect to issued patents within the Neurocrine Patents and Neurocrine shall furnish Abbott with copies of any such applications, amendments thereto and other related [...] correspondence to and from patent offices and patent associates to allow for review by and consultation with Abbott reasonably in advance of any submission to a patent office which could [...] affect the scope or validity of the patent coverage that may result. Copies of all such applications filed prior to the Effective Date shall be provided to Abbott promptly after the Effective Date. With respect to any substantive submissions that Neurocrine is required to or otherwise intends to submit to a patent office, Neurocrine shall provide a draft of such submission to Abbott at least [...] days prior to the deadline or intended filing date, whichever is earlier, for submission of such documentation. Abbott shall have the right to review and comment upon any such submission by Neurocrine to a patent office, and will provide such comments, if any, no later than [...] days prior to the applicable deadline or intended filing date. Neurocrine shall also act on recommendations Abbott may make with respect to issued patents within the Neurocrine Patent Rights.

(ii) Notwithstanding the foregoing, Neurocrine shall promptly inform Abbott of any adversarial patent office proceeding, including, but not limited to a request for, or filing or declaration of, any interference, opposition, or reexamination relating to Neurocrine Patent Rights. Abbott and Neurocrine shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding and Neurocrine shall incorporate all comments provided by Abbott. Neurocrine shall not initiate any reexamination, interference or reissue proceeding relating to Neurocrine Patent Rights without the prior written consent of Abbott.

(iii) In the event that Neurocrine disagrees with any comment or suggestion provided by Abbott under Section 12.1(i) or Section 12.1(ii), Neurocrine shall provide Abbott with a written explanation detailing the basis for such disagreement. If Abbott does not accept Neurocrine's explanation, Abbott shall have final decision-

making authority with respect to the matter in dispute.

- d) **Abandonment of Patent Rights.** Abbott may elect to discontinue payment for the costs and expenses of preparation, filing, Prosecution, validation or maintenance of any Program Patent Right pursuant to Section 12.1(b) or Neurocrine Patent Right pursuant to Section 12.1(c) on a country-by-country and application-by-application or patent-by-patent basis, at any time and in its sole discretion. If Neurocrine thereafter chooses to resume the preparation, filing, Prosecution, validation or maintenance of any Program Patent Rights [...] or Neurocrine Patent Right, the licenses to Abbott hereunder with respect to such applications or patents shall terminate and Neurocrine will own sole right, title and interest in and to such applications or patents.
- e) **Trademarks.** Abbott shall solely own and shall, at its expense, be solely responsible for the development, selection, filing prosecution, enforcement, and maintenance of the Trademarks. Abbott shall have no obligation to continue the prosecution and/or maintenance of any Trademark in any country and shall be free to abandon such Trademark at its sole discretion. Neurocrine agrees, at its own expense, to cooperate with Abbott in the protection of the Trademarks by executing documents, and by taking any other action reasonably requested by Abbott to effectuate the intent of this Section 12.1(e). Neurocrine also agrees not to take any action detrimental to Abbott's interest in the Trademarks. Neurocrine agrees to notify Abbott immediately if Neurocrine becomes aware of any infringement of the Trademarks. Abbott shall have the sole right but no obligation to initiate any legal proceedings alleging infringement of the Trademarks.

12.2 **Extension of Patent Rights.** At the time of the granting of approval of an NDA or equivalent in any country in respect of a Product, Abbott shall have the exclusive right, but not the obligation, to seek, in Neurocrine's name if so required, patent term extensions or supplemental patent protection in any country in the Territory in respect of a Neurocrine Patent Right, Program Patent Right or Abbott Patent Right. Abbott shall use Commercially Reasonable Efforts to obtain such patent term extensions or supplement protection, where applicable. Neurocrine and Abbott shall cooperate in connection with all such activities, and Abbott, its agents and attorneys will give due consideration to all suggestions and comments of Neurocrine regarding any such activities, but in the event of a disagreement between the parties, Abbott will have the final decision-making authority. In the case where Abbott determines to seek such patent term extensions or supplement patent protection in respect of a Neurocrine Patent Right, Neurocrine shall appoint Abbott or its designee as Neurocrine's agent for the sole purpose of submitting an application to extend the term of such patent, an application for a Supplementary Protection Certificate, or an equivalent thereof. Neurocrine shall co-operate with Abbott or its designee in connection with any such application.

12.3 **Enforcement and Defense of Patent Rights.**

- a) **Notification.** Each Party shall promptly notify each other of any infringement, alleged infringement or non-patent office adversarial proceeding challenging the validity or enforceability of the Neurocrine Patent Rights or Program Patent Rights. In the event of a

notification under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii) (IV) concerning Neurocrine Patent Rights or Program Patent Rights, then the Party receiving the notice shall provide a copy of such notice to the other Party within [...***...] days after its receipt thereof.

- b) Abbott shall have the sole right, but not the obligation, in its own name, to (i) enforce Neurocrine Patent Rights and Program Patent Rights against any Third Party suspected of infringing a claim of such a Patent Right in the Territory, and (ii) defend Neurocrine Patent Rights and Program Patent Rights against any Third Party asserting that a claim of such a Patent Right is invalid or unenforceable. Neurocrine, upon request of Abbott, shall reasonably cooperate with Abbott in any such litigation, or file such action in Neurocrine's name, if required, at Abbott's expense and shall join in any such litigation at Abbott's request and expense. Abbott shall have exclusive control over the conduct of any such proceedings, including the right to not bring an action, settle or compromise such proceedings. Any award or recovery paid to Abbott by a Third Party as a result of such patent infringement or defense proceedings (whether by way of settlement or otherwise) shall first be applied toward reimbursement of legal fees, costs and expenses incurred by Abbott, and from the remainder, if any, [...***...]. Any excess shall be [...***...].

- c) In the event Abbott shall not elect to enforce or defend any such Patent Right in the Territory pursuant to 12.3(b), it may grant, in its sole discretion, such right to Neurocrine and Neurocrine shall have the sole right, but not the obligation, in its own name, to (i) enforce Neurocrine Patent Rights and Program Patent Rights against any Third Party suspected of infringing a claim of such a Patent Right in the Territory, and (ii) defend Neurocrine Patent Rights and Program Patent Rights against any Third Party asserting that a claim of such a Patent Right is invalid or unenforceable. Abbott, upon request of Neurocrine, shall reasonably cooperate with Neurocrine in any such litigation, or file such action in Abbott's name, if required, at Neurocrine's expense and shall join in any such litigation at Neurocrine's request and expense. Neurocrine shall have exclusive control over the conduct of any such proceedings, including the right to not bring an action, settle or compromise such proceedings. Any award or recovery paid to Neurocrine by a Third Party as a result of such patent infringement proceedings (whether by way of settlement or otherwise) shall first be applied toward reimbursement of legal fees, costs and expenses incurred by Neurocrine, and the excess, if any shall be [...***...].

- 12.4 **Infringement Defense.** Abbott will be responsible for defending and controlling any suit against any of Abbott, Abbott's Affiliates or Sublicensees, alleging infringement of any patent or other intellectual property right of a Third Party arising out of the manufacture, use, sale, offer to sell or importation of a Product by Abbott, Abbott's Affiliates or Sublicensees in the Territory. Abbott shall be responsible for the costs and expenses, including legal fees and costs, associated with any suit or action. Upon Abbott's request, Neurocrine will consult with Abbott and co-operate in the defense of any such action. If Abbott finds it necessary or desirable to join Neurocrine as a party to any such action, Neurocrine will execute all papers and perform such acts as shall be reasonably required, at Abbott expense.
- 12.5 **Inventorship.** Inventorship with respect to all Patent Rights under this Agreement shall be determined according to United States Law.
- 12.6 **Hold Harmless.** The Parties hereby agree to hold each other harmless in respect of their good faith activities hereunder to file, prosecute, maintain, enforce and defend Patent Rights under this Article 12.6.13.

ARTICLE THIRTEEN - MISCELLANEOUS

- 13.1 **Governing Law.** This Agreement (and any claims or disputes arising out of or related thereto or to the transactions contemplated thereby or to the inducement of a Party to enter therein, whether for breach of contract, tortious conduct, or otherwise and whether predicated on common law, statute or otherwise) shall be governed by and interpreted in accordance with the internal laws of [...***...], including all matters of construction, validity and performance, and in each case without regard to its conflicts of laws rules that might lead to the application of the laws of any other jurisdiction. Notwithstanding the foregoing, questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted.
- 13.2 **ADR.** If a dispute arises between the Parties, the Parties will follow the procedures set forth in Exhibit H.
- 13.3 **Waiver.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party or Parties waiving such term or condition. Neither the waiver by any Party of any term or condition of this Agreement nor the failure on the part of any Party, on one or more instances, to enforce any of the provisions of this Agreement or to exercise any right or privilege, shall be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.
- 13.4 **Notices.** All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address below and shall be: (a) delivered personally; (b) sent by registered or certified mail, return receipt requested, postage prepaid; (c) sent via a reputable nationwide overnight courier service; or (d) sent by facsimile transmission. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if

delivered by hand, three (3) business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) business day after it is sent via a reputable nationwide overnight courier service, or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is on a business day; otherwise, on the next business day following such transmission).

Notices to Abbott shall be addressed to:

Abbott International Luxembourg S.à r.l.
26, Boulevard Royal
L-2449 Luxembourg
Luxembourg
Attention: Treasurer, Logistics

With a copy to:

Abbott International Luxembourg S.à r.l.
c/o Abbott Laboratories
Pharmaceutical Products Group
100 Abbott Park Road
Abbott Park, IL 60064-3500
Attention: Executive Vice President
Facsimile No.: [...***...]

Abbott Laboratories
Pharmaceutical Products Group Legal Operations
Bldg. AP6A-2
100 Abbott Park Road
Abbott Park, IL 60064-3500
Attention: DVP & Associate General Counsel
Fax: [...***...]

Notices to Neurocrine shall be addressed to:

Neurocrine Biosciences, Inc.
12780 El Camino Real
San Diego, California 92130

Attention: Chief Executive Officer and President

Fax: [...***...]

with a copy to: General Counsel

Fax: [...***...]

Either Party may change its address by giving notice to the other Party in the manner provided above.

- 13.5 **Entire Agreement.** This Agreement (including Exhibits and Schedules), contains the complete understanding of the Parties with respect to the subject matter hereof and supersedes all prior agreements or understandings between the Parties with respect to the subject matter hereof, including the Confidential Disclosure Agreement between the Parties, dated [...***...]. None of the terms of this Agreement shall be amended, supplemented or modified except in writing signed by duly authorized representatives of the Parties hereto.

- 13.6 **Headings; References.** Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. References to Articles, Sections, Exhibits and Schedules are to Articles, Sections, Exhibits and Schedules of this Agreement unless otherwise specified.
- 13.7 **Severability.** If and solely to the extent that any provision of this Agreement shall be invalid or unenforceable, or shall render this entire Agreement to be unenforceable or invalid, such offending provision shall be of no effect and shall not effect the validity of the remainder of this Agreement or any of its provisions; provided , however , the Parties shall use their respective reasonable efforts to renegotiate the offending provisions to best accomplish the original intentions of the Parties.
- 13.8 **Registration and Filing of the Agreement.** To the extent, if any, that counsel of a Party concludes in good faith that it is required under applicable Laws to file or register this Agreement or a notification thereof with any Governmental Authority, including without limitation the US Securities and Exchange Commission, or the US Federal Trade Commission, in accordance with applicable Laws, such Party may do so and shall provide the other Party to this Agreement with a written copy of all proposed filings or registrations to allow for a reasonably sufficient time for review and comment by the other Party. The other Party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith. If confidential treatment of sensitive provisions of the Agreement is available, the Parties will request such treatment and file a redacted copy of this Agreement mutually agreed to promptly following the Effective Date. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall cooperate to respond to any request for further information therefrom.
- 13.9 **Assignment.** Except as expressly set forth herein, this Agreement may not be assigned or transferred, nor may any right or obligation hereunder be assigned or transferred without the prior written consent of the other Party.
- a) Abbott may assign this Agreement, in whole or in part, to an Affiliate of Abbott or in whole to a Third Party in connection with the transfer or sale of all or substantially all of business unit which relates to this Agreement, or to a Third Party in the event of its merger, consolidation, change in control or similar transaction.
 - b) Neurocrine may assign this Agreement to the surviving entity in a merger, consolidation, reorganization or similar transaction of Neurocrine with another person that does not constitute a Change of Control, provided the management and Board of Directors of the surviving entity are predominantly comprised of the Neurocrine management and Board of Directors immediately preceding the transaction.
 - c) Subject to Section 11.6 (*Change of Control*), Neurocrine may assign this Agreement to a Change of Control party.

Any attempted assignment not in accordance with this Section 13.9 shall be void.

- 13.10 **Successors and Assigns.** This Agreement will be binding on and inure to the benefit of successors and permitted assigns.

- 13.11 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which, when executed, shall be deemed an original and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.
- 13.12 **Force Majeure.** The Parties agree that, if either of them find themselves wholly or partially unable to fulfill their respective obligations in this Agreement by reasons of Force Majeure, the Party affected will advise the other Party in writing of its inability to perform giving a detailed explanation of the occurrence of the event which excuses performance as soon as possible after the cause or event has occurred. If said notice is given, the performance of the Party giving the notification, except for the payment of funds and except as otherwise expressly provided in this Agreement, shall be abated, and any time deadlines shall be extended, for so long as performance may be prevented by such event of Force Majeure. Except as otherwise expressly provided in this Agreement and except for the payment of funds that are due and payable, neither Party shall be required to make up any performance that was prevented by Force Majeure.
- 13.13 **Non-Solicitation of Employees.** Commencing on the Effective Date and for a period of [...***...] thereafter, neither Party shall, directly or indirectly, actively recruit, or solicit any employee of the other Party with whom such Party has come into contact or interacted for the purposes of performing this Agreement, without the prior consent of the other Party For purposes of this Section, "solicit" shall be deemed not to include: (a) circumstances where an employee of one Party or any of its Affiliates initially contacts the other Party, or any of such Party's Affiliates, seeking employment or (b) general solicitations of employment not specifically targeted at such employees.
- 13.14 **Third Party Beneficiaries.** Except as provided in Article 10 (*Indemnification and Insurance*), None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including, any creditor of either Party hereto. Except as provided in Article 10 (*Indemnification and Insurance*), no such Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.
- 13.15 **Relationship of the Parties.** Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party shall be that of independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.
- 13.16 **Further Assurances.** Following the date hereof, Neurocrine and Abbott shall, and shall cause each of their respective Affiliates to, from time to time, execute and deliver such additional instruments, documents, conveyances or assurances and take such other actions as shall be

necessary or otherwise reasonably requested by Abbott or Neurocrine, to confirm and assure the rights and obligations provided for in this Agreement, and render effective the consummation of the transactions contemplated thereby provided however that neither Party will be required under this Section 13.16 to deliver instruments, documents, conveyances or assurances of any third Party.

- 13.17 **Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.
- 13.18 **Cumulative Remedies.** No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Law.
- 13.19 **Use Of Names, Logos Or Symbols.** No Party shall use the name, trademarks, logos, physical likeness, employee names or owner symbol of the other Party for any promotional or publicity purpose without the other Party's prior written consent. The restrictions imposed by this Section 13.19 shall not prohibit either Party from making any disclosure identifying the other Party that is required by Law or the requirements of a national securities exchange or similar regulatory body, provided the procedures set forth in Section 9.3(b) (*Announcements*) are followed. Nothing contained in this Agreement shall be construed as granting either Party any rights or license to use any of the other Party's trademarks or trade names without separate, express written permission of the owner of such trademark or trade name or name.
- 13.20 **Exhibits; Schedules.** In the event of inconsistencies between this Agreement and any exhibits, schedules or attachments hereto, the terms of this Agreement shall control.

[The remainder of this page is intentionally blank]

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the date first written above.

ABBOTT INTERNATIONAL LUXEMBOURG S.À R.L

/s/ William J. Chase

By: William J. Chase

Title: Vice President, Corporate Licensing and Acquisitions

NEUROCRINE BIOSCIENCES, INC.

/s/ Kevin C. Gorman

By: Kevin C. Gorman

Title: President and Chief Executive Officer

Exhibit A

Elagolix

[...***...]

Exhibit B
Follow-On Compounds

[...***...]

Exhibit C
Neurocrine Patent Rights

[...***...]

Exhibit D
Third Party Development Contracts

[...***...]

Exhibit E

Third Party Manufacturing Contracts

[...***...]

Exhibit F
Transition Plan

[...***...]

Exhibit G
Collaborative Development Plan

[...***...]

Exhibit H
ALTERNATIVE DISPUTE RESOLUTION

[...***...]

Exhibit I
PRESS RELEASE

ABBOTT PARK, Ill. and SAN DIEGO, June 16 /PRNewswire-FirstCall/ — Abbott (NYSE: ABT) and Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that they have entered into a collaboration agreement to develop and commercialize elagolix for the treatment of endometriosis-related pain. Elagolix is a novel, first-in-class oral gonadotropin-releasing hormone (GnRH) antagonist, which has recently completed a phase IIb study in endometriosis. In addition to endometriosis, elagolix will be evaluated for the treatment of uterine fibroids.

“Extensive preclinical and clinical experience with elagolix suggests this drug could be an important advance for women with endometriosis and uterine fibroids, highly prevalent conditions where there is a need for new treatments,” said John Leonard, M.D., senior vice president, pharmaceuticals, research and development, Abbott. “This agreement enhances Abbott’s late stage pipeline, with the potential for additional compounds in earlier stage development.”

Under the terms of the agreement, Abbott will receive worldwide exclusive rights to develop and commercialize elagolix and all next-generation GnRH antagonists for women’s and men’s health. Abbott will make an upfront payment of \$75 million and will fund all ongoing development activities. Neurocrine is eligible to receive additional milestone payments of approximately \$500 million from Abbott for the achievement of certain development, regulatory and commercial milestones; funding for certain internal collaboration expenses; plus royalty payments on any future product sales.

“We are pleased to have one of the world’s most admired companies as our partner in developing our entire GnRH portfolio for both women’s and men’s health indications,” said Kevin Gorman, president and chief executive officer, Neurocrine Biosciences. “Abbott shares our long-term vision for elagolix, and, together, we look forward to bringing this important new treatment option to endometriosis and uterine fibroid sufferers.”

About GnRH and Elagolix

Elagolix inhibits gonadotropin releasing hormone (GnRH) receptors in the pituitary gland and ultimately reduces circulating sex hormone levels. Elagolix has a unique profile that allows partial estrogen suppression. It maintains estradiol in the low-normal range, providing symptom reduction while avoiding significant bone loss or other adverse effects that can sometimes be associated with excessive suppression of estrogen. In Phase II studies, elagolix has been found to be effective in reducing the pain associated with endometriosis. To date, elagolix has been studied in 18 clinical trials totaling more than 1,000 subjects.

About Endometriosis and Uterine Fibroids

Endometriosis is associated with a multitude of symptoms, some of the most common of which include pain related both to menstruation (dysmenorrhea) as well as chronic pelvic pain

throughout the menstrual cycle, and infertility. The World Endometriosis Research Foundation estimates that there are approximately 100 million women worldwide who suffer from endometriosis. With annual healthcare costs and endometriosis-related productivity losses of approximately \$4,000 per patient, the annual direct and indirect costs of endometriosis are estimated to exceed \$20 billion in the United States alone.

Uterine fibroids are benign tumors that form on the wall of the uterus. They are the most common type of growth found in a woman's pelvis and are most common in women aged 30-40 years. While many women do not have symptoms, depending on the size, location and number, uterine fibroids can cause heavy menstrual bleeding, can put pressure on the bladder and rectum, and can cause pain and nausea. Symptoms can also include miscarriages and infertility. Depending on the symptoms, treatment sometimes requires surgery.

About Neurocrine Biosciences

Neurocrine Biosciences is a biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including endometriosis, anxiety, depression, pain, diabetes, irritable bowel syndrome, insomnia, and other neurological and endocrine related diseases and disorders. Neurocrine Biosciences news releases are available through the Company's website at <http://www.neurocrine.com>.

About Abbott Laboratories

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs approximately 83,000 people and markets its products in more than 130 countries. Abbott's news releases and other information are available on the company's website at www.abbott.com.

Neurocrine Biosciences Forward Looking Statement

In addition to historical facts, this press release may contain forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with Neurocrine's business and finances in general, as well as risks and uncertainties associated with the Company's GnRH program and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's GnRH program include, but are not limited to, risk that the elagolix clinical trials will fail to demonstrate that elagolix is safe and effective; risk that elagolix will not proceed to Phase III clinical trials; risk associated with the Company's dependence on Abbott for Phase III development, commercial manufacturing and marketing and sales activities. With respect to its pipeline overall, the Company faces risk that it will be unable to raise additional funding required to complete development of all of its product candidates; risk relating to the Company's dependence on contract manufacturers for clinical drug supply; risks associated with the Company's dependence on corporate collaborators for commercial manufacturing and marketing and sales

activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2009 and reports on Form 10-Q for the quarter ended March 31, 2010. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

Abbott Forward Looking Statement

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. Abbott cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Economic, competitive, governmental, technological and other factors that may affect Abbott's operations are discussed in Item 1A, "Risk Factors," to our Annual Report on Securities and Exchange Commission Form 10-K for the year ended Dec. 31, 2009, and in Item 1A, "Risk Factors," to our Quarterly Report on Securities and Exchange Commission Form 10-Q for the period ended March 31, 2010, and are incorporated by reference. Abbott undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT NEUROCRINE BIOSCIENCES, INC. TREATS AS PRIVATE OR CONFIDENTIAL.

First Amendment (“First Amendment”) to the Collaboration And License Agreement dated as of June 15, 2010 (the “Collaboration Agreement”) by and between Abbott International Luxembourg S.à r.l., a corporation organized and existing under the laws of Luxembourg, with offices at 26, Boulevard Royal, L-2449 Luxembourg (“Abbott”) and Neurocrine Biosciences, Inc., a corporation organized and existing under the laws of Delaware with offices at 12780 El Camino Real, San Diego, California 92130 (“Neurocrine”) is made this thirty-first day of August, 2011 (“First Amendment Effective Date”).

WHEREAS, the Collaboration Agreement governs the collaboration between Abbott and Neurocrine in the field of Non-peptide GnRH Antagonists; and

WHEREAS, Abbott and Neurocrine would like to amend the Collaboration Agreement as set forth below;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties agree as follows:

1. Capitalized Terms; First Amendment Effective Date. Unless otherwise defined herein, any capitalized terms used in this First Amendment shall have the meanings ascribed to them in the Collaboration Agreement. This First Amendment shall be effective as of the First Amendment Effective Date.
2. Amendment of Section 1.41. Section 1.41, the definition of “Initiation” is hereby deleted and replaced in its entirety with the following:
“Initiation” means, with respect to a human clinical trial, execution of an informed consent by the first subject in a Phase I, Phase II or Phase III clinical study, as applicable.
3. Amendment of Section 4.2 (a). The table appearing in Section 4.2(a) of the Collaboration Agreement (the “Elagolix Development Milestones Table”) shall be amended as follows:

The words appearing as the first item in the Elagolix Development Milestones Table currently reading,

“Acceptance of [...***...]”

shall be replaced in their entirety by the following:

“[...***...]”

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

4. No other Amendment. Save as specifically amended by this First Amendment the Collaboration Agreement shall continue in full force and effect in all respects.

5. Counterparts. This First Amendment may be executed in any number of counterparts, each of which, when executed, shall be deemed an original and all of which together shall constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

IN WITNESS WHEREOF, the Parties have signed this First Amendment as of the First Amendment Effective Date.

Abbott International Luxembourg S.à r.l.

By: /s/ William J. Chase

Title: Vice President, Licensing and Acquisitions

Neurocrine Biosciences, Inc.

By: /s/ Kevin C. Gorman

Title: President and Chief Executive Officer

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT NEUROCRINE BIOSCIENCES, INC. TREATS AS PRIVATE OR CONFIDENTIAL.

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

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.

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

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’-

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,

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

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) [...***...]

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

(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) [...***...].

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:

(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

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.

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

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

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 of 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

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,

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

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.

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

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
[...***...]	

[...***...]	<p>i) \$[...***...]</p> <p>and</p> <p>ii) \$[...***...]</p>
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(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:

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

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

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

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

(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.

(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

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

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

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.

(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.

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

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

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. TERMAND 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.

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;

(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.

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.

(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: [...***...]

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]

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

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT NEUROCRINE BIOSCIENCES, INC. TREATS AS PRIVATE OR CONFIDENTIAL.**

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this “**Agreement**”) is made and entered into as of February 9, 2017 (the “**Effective Date**”)

by and between

BIAL – PORTELA & CA, S.A., a Portuguese corporation having a principal place of business at À Avenida da Siderurgia Nacional, 4745-457 Coronado (S. Romão e S. Mamede), Portugal (hereinafter referred to as “**BIAL**”)

and

NEUROCRINE BIOSCIENCES, INC., a Delaware corporation having a principal place of business at 12780 El Camino Real, San Diego, CA 92130, USA (hereinafter referred to as “**NBIX**”).

Each of NBIX and BIAL may be referred to herein as a “**Party**” or collectively as the “**Parties**”.

WITNESSETH

WHEREAS, BIAL Controls (as defined below) the BIAL Patents and BIAL Know-How (each as defined below), which relate to the compound BIA 9-1067 (as defined below) and its use in the treatment of human diseases and conditions, including Parkinson’s disease; and

WHEREAS, NBIX wishes to acquire licenses under the BIAL Patents, BIAL Know-How and Trademarks (as defined below) for the purpose of using, developing, marketing, distributing, importing, commercializing, offering for sale and selling the Licensed Products (as defined below) under the Trademark within the Field and Territory (each as defined below); and

WHEREAS, BIAL is willing to grant such licenses to NBIX under the terms and conditions of this Agreement; and

WHEREAS, BIAL is willing to manufacture and supply Licensed Products to NBIX for using, developing, marketing, distributing, importing, commercializing, offering for sale and selling the Licensed Products under the Trademark within the Field and Territory under the terms and conditions of this Agreement and a Supply Agreement (as defined below) to be entered into between the Parties; and

NOW, THEREFORE, in reliance on the foregoing recitals and in consideration of the mutual covenants and promises set forth herein, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

- 1.1. “**Affiliate**” means any person or entity that, as of the Effective Date or at any time during the Term, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with a Party. For purposes of this definition, “control” means (i) the ownership of at least fifty percent (50%) of the voting securities of the entity or such lesser percentage which is the maximum allowed by applicable law; or (ii) the ability to otherwise direct the management and operations of the entity.
- 1.2. “**Agency**” means the FDA (as defined below), Health Canada or any other governmental entity(ies), and its or their successor bodies, whose authorization is required to market and sell any pharmaceutical product in Territory.
- 1.3. “**Agency Interactions**” has the meaning set forth in Section 7.2(e).
- 1.4. “**Agreed Sales Forecast**” has the meaning set forth in Section 8.3(d).
- 1.5. “**Alleged Infringement**” has the meaning set forth in Section 12.2(a).
- 1.6. “**Alleged Manufacturing Infringement**” has the meaning set forth in Section 12.2(b).
- 1.7. “**Alleged Manufacturing Infringement Costs**” has the meaning set forth in Section 12.2(d).
- 1.8. “**Alliance Manager**” has the meaning set forth in Section 5.8(a).
- 1.9. “**Alternative Trademarks**” has the meaning set forth in Section 2.3(d).
- 1.10. “**Annual Commercialization Plan**” has the meaning set forth in Section 8.2(a).
- 1.11. “**Approval**” means the marketing authorization issued by an Agency for the commercialization of a Licensed Product within the Field and Territory.
- 1.12. “**Assumptions**” has the meaning set forth in Section 8.3(e).
- 1.13. “**BIA 9-1067**” means [...***...].
- 1.14. “**BIA 9-1067 API**” means the active pharmaceutical ingredient of BIA 9-1067.

1.15. “**BIA 9-1067 IND**” means the IND No.[...***...].

1.16. “**BIAL Indemnitees**” has the meaning set forth in Section 16.2.

1.17. “**BIAL Know-How**” means any and all research and development information, unpatented inventions, trade secrets, proprietary materials, or any other type of proprietary or confidential technical data or information, including without limitation, products, methods, techniques, processes, specifications, recipes, formulae, designs, plans, drawings, data, protocols, or non-clinical and clinical data (including, without limitation, Data), which are Controlled by BIAL or its Affiliates as of the Effective Date or during the Term and are either (i) reasonably necessary for the use, development marketing, distribution, importation, commercialization, manufacture (other than the Manufacturing Know-How), offer for sale or sale of the Licensed Products, or (ii) useful for the use, development marketing, distribution, importation, commercialization, manufacture (other than the Manufacturing Know-How), offer for sale or sale of the Licensed Products, and in such case (i) or (ii) to the extent that BIAL or its Affiliates have developed or used such know-how in connection with the Licensed Products. The term “BIAL Know-How” includes, without limitation, all proprietary and confidential information included in INDs/NDAs and any other regulatory filings and correspondence related to any Licensed Product and all Data and information to be submitted in support of such filings or correspondence, and information relating to marketing and commercialization, to the extent Controlled by BIAL or its Affiliates during the Term and related to Licensed Products, and BIAL’s interest in Development Intellectual Property jointly owned by the Parties; provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any know-how of such Third Party in existence as of the effective date of such merger or acquisition shall not be included in BIAL Know-How so long as it is not used and was not generated in connection with the development, manufacture or commercialization of any Licensed Product. For greater certainty, the term “BIAL Know-How” does not include the Manufacturing Know-How.

1.18. “**BIAL Logo**” means the logo included in **Exhibit 2.4**, which BIAL may, at its own discretion, update from time to time.

1.19. “**BIAL Patents**” means (i) all US and Canadian Patents Controlled by BIAL or its Affiliates as of the Effective Date or during the Term, claiming or covering or which would be practiced by the use, development, marketing, distribution, import, commercialization, offer for sale and sale of the Licensed Products, including, without limitation, the BIAL Patents listed in **Exhibit 2.1** ; (ii) any US and Canadian provisional, divisional, substitution, continuation or continuation-in-part applications based on, directly or indirectly, relying for priority on, or having identical disclosure as, any of the US or Canadian Patents in (i); (iii) any US and Canadian Patent issuing from any of the Patents in (i) or (ii); and (iv) any extensions, patent term adjustments, reissues, supplemental examinations or reexaminations of any of the Patents in (i), (ii) and/or (iii). BIAL Patents also include any Patents covering any Development Intellectual Property owned solely by BIAL or one of its Affiliates or jointly by BIAL and its Affiliates. BIAL agrees to update Exhibit 2.1 from time to time with additional BIAL Patents;

provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any Patent of such Third Party in existence as of the effective date of such merger or acquisition shall not be included in BIAL Patents, so long as it does not cover any subject matter that is directly used or directly generated in connection with the development or commercialization of any Licensed Product.

1.20. “**BIAL Representatives**” has the meaning set forth in Section 2.10(iii).

1.21. “**BIAL Representatives Costs**” has the meaning set forth in Section 2.10(iii).

1.22. “**BIAL Studies**” means the studies set out in **Exhibit 6.4**.

1.23. “**Blocking BIAL IP**” means any Patent or other Intellectual Property outside the Territory that is Controlled by BIAL (by ownership, license or otherwise) and which would be infringed by the use, manufacture, development, marketing, distribution, importation, commercialization, offer for sale or sale of any product or process that is claimed, covered or would be practiced by such Patent or Intellectual Property.

1.24. “**Business Day**” means any of the days Monday through Friday less (i) public holidays in Porto, Portugal, (ii) public holidays in San Diego, California, United States of America, (iii) first two (2) weeks of August of each Calendar Year, and (iv) the period between 24th December of a Calendar Year and 1st January of the subsequent Calendar Year.

1.25. “**Calendar Quarter**” means each period of three (3) months ending on 31st March, 30th June, 30th September and 31st December.

1.26. “**Calendar Year**” means each twelve (12) months period starting on 1st January and ending on 31st December.

1.27. “**Change of Control**” means, with respect to NBIX, any of the following events: (i) a Third Party (or group of Third Parties acting in concert) directly or indirectly, acquires more than fifty percent (50%) of the then outstanding capital stock entitled to vote for the election of NBIX’s directors; or (ii) a consolidation, reorganization or merger involving NBIX in which more than fifty percent (50%) of the then outstanding capital stock of the surviving entity entitled to vote for the election of directors is not held by the parties holding at least fifty percent (50%) of the outstanding shares of NBIX preceding such consolidation or merger; or (iii) NBIX conveys, transfers or sells all or substantially all of its assets relating to Licensed Products.

1.28. “**Change of Control Entity**” has the meaning set forth in Section 15.2(d)(i).

1.29. “**Change of Control Notice**” has the meaning set forth in Section 2.11.

1.30. “**Claim**” has the meaning set forth in Section 16.1.

- 1.31. “**Clinical Trials**” means Phase I Clinical Trials, Phase II Clinical Trials and/or Phase III Clinical Trials.
- 1.32. “**Co-Promotion Agreement**” has the meaning set forth in Section 2.10(c).
- 1.33. “**Co-Promotion Option**” has the meaning set forth in Section 2.10(a).
- 1.34. “**Co-Promotion Plan**” has the meaning set forth in Section 2.10(b).
- 1.35. “**Co-Promotion Steering Committee**” has the meaning set forth in Section 2.10(c)(vii).
- 1.36. “**Combination Product**” means [...***...].
- 1.37. “**Commercial Year**” has the meaning set forth in Section 8.3(d).
- 1.38. “**Commercially Reasonable Efforts**” means, with respect to a Party’s obligations under this Agreement, with respect to each Licensed Product, the level of efforts required to carry out a task in a diligent and sustained manner without undue interruption, pause or delay, which level is at least commensurate with the level of efforts that a similarly situated biopharmaceutical company, of similar size and resources, would devote to a product of similar commercial and market potential and at a similar stage of development or commercialization and having similar commercial and scientific advantages and disadvantages resulting from such company’s own research efforts (*i.e.* . explicitly ignoring the upfront, milestone, and royalty payments, but including payments for product supply and other payments related to the Co-Promotion Agreement due to BIAL under this Agreement), taking into account all relevant factors, including (without limitation) Patent coverage, safety, efficacy, product profile, competitiveness of the marketplace, proprietary position and profitability. Commercially Reasonable Efforts requires (without limitation) that NBIX **(i)** promptly assigns responsibility for its obligations to specific employee(s) who are held accountable for progress and monitor such progress on an ongoing basis, **(ii)** continues to seek to achieve specific and meaningful objectives for carrying out such obligations and **(iii)** makes and/or implements decisions and allocates resources designed to make progress with respect to such objectives.
- 1.39. “**Competing Product**” means [...***...].
- 1.40. “**COMT**” means catechol-O-methyl transferase.
- 1.41. “**Confidential Information**” has the meaning set forth in Section 13.1(a).

1.42. “**Confidentiality Agreement**” has the meaning set forth in Section 13.1(a).

1.43. “**Controlled**” means, with respect to any Intellectual Property (as defined below), the possession by a Party of the right, whether directly or indirectly, whether by ownership, license or otherwise, to grant a license, sublicense or other right to or under such Intellectual Property, as provided for in this Agreement, without violating the terms of any agreement, contract or any other arrangement with any Third Party. For the avoidance of doubt, Third Party Intellectual Property shall only be considered “Controlled” by a Party, if the Party has right to assign or grant a license, sublicense or otherwise grant rights to the other Party as provided for in this Agreement, at no additional cost (unless the other Party agrees to assume such cost) and without prior Third Party approval. The term “**Control**” or “**Controls**” used in this context will also have a correlative meaning.

1.44. “**Data**” means any and all scientific, technical or test data pertaining to Licensed Product(s) (provided, that if any such scientific, technical and/or test data pertains to Licensed Product(s) and something other than Licensed Product(s), then only such scientific, technical and test data that pertains to Licensed Product(s) and not to something else) that is generated by or under the authority of NBIX or its Affiliates and contractors, or by or under the authority of BIAL or BIAL’s Affiliates and contractors (provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any data of such Third Party in existence as of the effective date of such merger or acquisition shall not be included as Data) or by or under the authority of any Third Party licensee in respect of BIA 9-1067 and/or Licensed Products of BIAL outside the Territory, including, without limitation, research data, non-clinical data, clinical data and/or all submissions made in association with an IND or application for a Marketing Authorization filed in or outside the Territory with respect to such Licensed Product(s), in each case to the extent such data either (a) is Controlled by BIAL or its Affiliates on the Effective Date or (b) comes within a Party’s or its Affiliates’ Control during the Term (provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any data of such Third Party in existence as of the effective date of such merger or acquisition shall not be included as Data unless BIAL Controls such Data prior to the effective date of such merger or acquisition or BIAL subsequently includes such data in regulatory filings in connection with the Licensed Product outside the Territory). Data shall not include any Manufacturing Know-How.

1.45. “**Data Update Filings**” has the meaning set forth in Section 7.2(f).

1.46. “**Detail**” means, with respect to a Licensed Product in the Territory, a face-to-face contact between a sales representative of NBIX (or of BIAL or its Affiliate or its contractor in the case the Parties have executed a Co-Promotion Agreement and are co-promoting) and a physician or other medical professional licensed to prescribe drugs, during which promotional, scientific and/or medical information about the Licensed Products is discussed at length with such person in either a first position detail (as defined in the Annual Commercialization Plan) or a second position detail (as defined in the Annual Commercialization Plan), in each case as measured by each Party’s internal recording of such

activity; *provided* that such meeting is consistent with and in accordance with the requirements of applicable law and this Agreement and the Co-Promotion Agreement. A Detail shall not include discussions at medical congress or meetings or any other form of communication that is not face to face and shall not include a reminder call in which the Licensed Products are not discussed at length or a Licensed Product sample drop if the sole purpose of the face to face contact was a sample drop. “Detailing” shall be construed accordingly. When used as a verb, “ **Detail** ” means to engage in a Detail.

1.47. “**Development and Regulatory Plan**” has the meaning set forth in Section 6.2(a).

1.48. “**Development Intellectual Property**” means any inventions or discoveries (whether or not patentable) made solely by or on behalf of one Party or its Affiliates or jointly by or on behalf of both Parties or their respective Affiliates in the performance of this Agreement, but only to the extent related to BIA 9-1067 or any Licensed Product. Development Intellectual Property does not include any Manufacturing Know-How or Patents to the extent that they claim or cover the manufacture of BIA 9-1067 API.

1.49. “**Development License**” has the meaning set forth in Section 2.2.

1.50. “**Development Studies**” means any Nonclinical Studies, Clinical Trials, Post-Approval Commitment (PAC) (or post-marketing requirement) Studies and Phase IV Studies in respect of BIA 9-1067 or Licensed Products carried out by or on behalf of NBIX in accordance with this Agreement.

1.51. “**Difference**” has the meaning set forth in Section 8.3(g).

1.52. “**Dispute**” has the meaning set forth in Section 17.1(a).

1.53. “**Divestiture**” has the meaning set forth in Section 2.8(b).

1.54. “**EMA**” means the European Medicines Agency and its successor bodies.

1.55. “**Excluded Claim**” has the meaning set forth in Section 17.1(k).

1.56. “**Exclusivity Rights**” means a marketing or data exclusivity right conferred by any Agency, including rights conferred in the United States under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity), or rights similar thereto in Canada.

1.57. “**Executive Officer**” means (a) with respect to NBIX, [...***...] and (b) with respect to BIAL, an individual (i) [...***...] or (ii) [...***...].

1.58. “**Existing Licensees**” has the meaning set forth in Section 9.2(c).

- 1.59. “**Extension Party**” has the meaning set forth in Section 11.4(e).
- 1.60. “**FDA**” means the United States of America Food and Drug Administration.
- 1.61. “**Field**” means [...***...]. For certainty, Field includes the Initial Indication and any Subsequent Indications (both as defined below).
- 1.62. “**First Development and Regulatory Plan**” has the meaning set forth in Section 6.3(a).
- 1.63. “**First Tentative Supply Price**” has the meaning set forth in Paragraph 1.1(b)(ii) of Exhibit 4.
- 1.64. “**For Cause Audit**” has the meaning set forth in Sections 7.6(b) and 7.6(d).
- 1.65. “**Force Majeure**” has the meaning set forth in Section 17.3.
- 1.66. “**Fully Burdened Manufacturing Cost**” means [...***...]. Such costs shall be calculated in accordance with International Financial Reporting Standards and using BIAL’s or its Affiliates normal cost accounting and allocation methods and procedures, consistently applied historically and across all of BIAL’s and its Affiliates’ investigational medicinal products and commercial products.
- 1.67. “**GAAP**” means US generally accepted accounting principles.
- 1.68. “**GCPs**” or “**Good Clinical Practices**” means a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and the rights, integrity, and confidentiality of the trial subjects are protected, as defined in ICH E6: Good Clinical Practice, April 1996, as amended.
- 1.69. “**Generic Product**” means a Third Party pharmaceutical product that [...***...].

1.70. “Global Brand Identity” means the designs and colors of Licensed Products’ trademark(s) and logos used by BIAL or its Affiliates or licensees outside the Territory and related guidance for their use and placement in promotional materials with respect to the Licensed Products.

1.71. “GLPs” or “Good Laboratory Practices” means a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported., as defined in the Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice, as amended.

1.72. “GMPs” or “Good Manufacturing Practices” means the then current Good Manufacturing Practices pursuant to the EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines, containing guidance documents for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human use laid down in Commission Directive 2003/94/EC, as may be amended from time to time. “GMP” also includes adherence to the then-current requirements of the European Pharmacopoeia and the relevant current ICH Quality Guidelines.

1.73. “GVPs” or “Good Pharmacovigilance Practices” means a set of guidelines for the conduct of pharmacovigilance in the EU, drawn up based on Article 108a of Directive 2001/83/EC, by the European Medicines Agency in cooperation with competent authorities in Member States and interested parties, and applying to marketing authorization holders in the EU or the Territory.

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

1.75. “IMP” or “Investigational Medicinal Product” means [...***...].

1.76. “IND” or “Investigational New Drug Application” means an investigational new drug application, clinical study application, clinical trial exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.77. “IND Filings” has the meaning set forth in Section 7.2(c).

1.78. “Indemnification Claim Notice” has the meaning set forth in Section 16.3.

1.79. “Indemnified Party” has the meaning set forth in Section 16.3.

1.80. “Indemnifying Party” has the meaning set forth in Section 16.3.

1.81. “Indemnitees” has the meaning set forth in Section 16.3.

1.82. “Initial BIAL Patent” means the US patent [...***...] and any patent term extension thereof.

1.83. “Initial Indication” means [...***...], as filed by BIAL with the European Medicines Agency, or any indication substantially similar thereto as recommended, required or approved by an Agency.

1.84. “Initial Product” means a capsule formulation in fully finished and final packaged consumer form ready for sale and administration, [...***...]. The definition of Initial Product may also include a capsule formulation in fully finished and final packaged consumer form ready for sale and administration, containing [...***...] and in fully finished and final packaged consumer form, provided that [...***...].

1.85. “Intellectual Property” means any Patents (including, without limitation, the BIAL Patents and NBIX Patents), Development Intellectual Property, copyrights, designs, database rights, trademarks (including, without limitation, the Trademarks), know-how (including, without limitation, the BIAL Know-How and the NBIX Know-How), trade secrets, proprietary information or data (including, without limitation, any regulatory filings and related data), or any application for any of the foregoing, or any other forms of comparable property rights protected by applicable law.

1.86. “Interaction Agenda” has the meaning set forth in Section 7.2(e).

1.87. “Joint Patent” means a Patent covering Development Intellectual Property jointly owned by the Parties.

1.88. “JSC” has the meaning set forth in Section 5.2.

1.89. “Kick-Off Meeting” has the meaning set forth in Section 2.6(a).

1.90. “Knowledge of BIAL” means BIAL’s and its Affiliates’ actual understanding and knowledge in good faith as possessed by its Executive Officers.

1.91. “Label Related Documents & Materials” has the meaning set forth in Section 7.2(a).

1.92. “**LCIA**” means the London Court of International Arbitration.

1.93. “**Licensed Products**” means the Initial Product, any Subsequent Products and any Investigational Medicinal Product.

1.94. “**Losses**” has the meaning set forth in Section 16.1.

1.95. “**Manufacturing Know-How**” means manufacturing information, unpatented inventions, trade secrets, proprietary materials, or any other type of proprietary or confidential technical data or information, including, without limitation, methods, techniques, processes, specifications, recipes, formulae, designs, plans, drawings, data, or protocols, which are Controlled by BIAL or its Affiliates as of the Effective Date or during the Term and are either (i) reasonably necessary for the manufacture of the BIA 9-1067 API, or (ii) reasonably useful for the manufacture of BIA 9-1067 API to the extent that BIAL or its Affiliates have developed or used such know-how in connection with the BIA 9-067 API as of the Effective Date or during the Term; provided however that in the event that any Third Party becomes a BIAL Affiliate by merger with or by acquisition of BIAL or any of its Affiliates, any manufacturing know-how of such Third Party in existence as of the effective date of such merger or acquisition shall not be included in Manufacturing Know-How, unless such manufacturing know-how was Controlled by BIAL or its Affiliates prior to the effective date of such merger or acquisition, or it is used thereafter and Controlled by BIAL or its Affiliates in connection with the manufacture of the BIA 9-1067 API. For greater certainty, the Manufacturing Know-How is not included in the BIAL Know-How.

1.96. “**Marketing Authorization**” means all approvals from the relevant Regulatory Authority necessary to import, market and sell a pharmaceutical product (including, without limitation, as and when applicable, all drug pricing and governmental reimbursement approvals, and Approval).

1.97. “**Milestone Event**” has the meaning set forth in Section 3.1(b).

1.98. “**Milestone Payments**” has the meaning set forth in Section 3.1(b).

1.99. “**Minimum Detail Effort**” has the meaning set forth in Section 2.10(c)(i).

1.100. “**Minimum Sales**” has the meaning set forth in Section 8.3(f).

1.101. “**Minimum Supply Price**” has the meaning set forth in Paragraph 1.1(a) of Exhibit 4.

1.102. “**NBIX Indemnitees**” has the meaning set forth in Section 16.1.

1.103. “**NBIX Know-How**” means (a) research and development or commercialization information, unpatented inventions, trade secrets, proprietary materials, or any other proprietary or confidential technical data or information, Development Intellectual Property, including without limitation, products, methods, techniques, processes, specifications, recipes, formulae, designs, plans,

drawings, data, protocols or non-clinical and clinical studies (including, without limitation Data), which are generated by or under the authority of NBIX or its Affiliates and contractors or otherwise Controlled by NBIX during the Term (including without limitation any of the foregoing arising from any Development Studies), and are either **(i)** reasonably necessary for the manufacture, use, development, marketing, distribution, importation, commercialization, offer for sale or sale of BIA 9-1067 or any Licensed Product, or **(ii)** useful for the manufacture, development, marketing, distribution, importation, commercialization, offer for sale or sale of any Licensed Products to the extent that NBIX has developed or otherwise uses such know-how in connection with BIA 9-1067 or any Licensed Products. The term “NBIX Know-How” includes all information included in INDs/NDAs and any other regulatory filings and correspondence related to BIA 9-1067 or any Licensed Product and all Data and information submitted in support of such filings or correspondence, and information relating to marketing and commercialization, to the extent Controlled by NBIX during the Term and which relate to BIA 9-1067, the Initial Product or any other Licensed Products, and NBIX’s interest in Development Intellectual Property jointly owned by the Parties; provided however that in the event that any Third Party becomes an Affiliate of NBIX by merger with or by acquisition of NBIX or any of its Affiliates, any know-how of such Third Party in existence as of the effective date of such merger or acquisition shall not be included in NBIX Know-How so long as it is not used and was not generated in connection with the development, manufacture or commercialization of any Licensed Product.

1.104. “NBIX License” has the meaning in Section 2.7(b).

1.105. “NBIX Patents” means any and all Patents which are Controlled by NBIX and which: **(i)** claim or cover or would be practiced by using, manufacturing, developing, marketing, distributing, importing, commercializing, offering for sale or selling BIA-9-1067 or the Licensed Products; or **(ii)** claim or cover Development Intellectual Property Controlled by NBIX.

1.106. “NDA” means a New Drug Application or similar application or submission for Approval of a pharmaceutical product filed with Regulatory Authority to obtain marketing approval for such product.

1.107. “Net Sales” means the gross amounts invoiced by NBIX or its Affiliates (the “Selling Party”) on account of sales of the Licensed Products to the first Third Party in the distribution chain in the Territory, less the following deductions to the extent actually allowed and specifically allocated to the Licensed Products by the Selling Party in accordance with GAAP:

[...***...]

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

In no event shall any particular amount, identified above, be deducted more than once in calculating Net Sales (i.e., no “double counting” of reductions). Sales of the Licensed Products between the Selling Party and its Affiliates shall be excluded from the computation of Net Sales, but the subsequent resale of such the Licensed Products to the first Third Party in distribution chain shall be included within the computation of Net Sales. Any amounts hereunder shall be determined from the books and records of the Selling Party maintained in accordance with GAAP, consistently applied to all products of the Selling Party.

Notwithstanding the foregoing, “Net Sales” shall not include any amounts invoiced for sales of Licensed Products supplied for use in clinical trials conducted by or on behalf of NBIX (including investigator initiated studies where NBIX does not charge for Licensed Product), or under any early access, named patient, indigent access, patient assistance or other programs whereby patients received free Licensed Product, or as samples or donations.

In the event that the Parties agree that NBIX commercializes a Combination Product, the Parties will, in connection with the negotiation under Section 2.9, determine a reasonable allocation of Net Sales to BIA 9-1067 and the other active pharmaceutical ingredient(s) therein.

1.108. “Net Sales Estimation” has the meaning set forth in Section 8.3(e).

- 1.109. “**Net Sales Volume**” means, for each applicable period, [...***...].
- 1.110. “**Net Selling Price**” means, for each applicable period, [...***...].
- 1.111. “**Nonclinical Study**” means any study of a product or active pharmaceutical ingredient which is not conducted in humans and which may be conducted in animals (*in vivo*) or in a test tube (*in vitro*).
- 1.112. “**Non-Extension Party**” has the meaning set forth in Section 11.4(e).
- 1.113. “**Opposition Contest**” has the meaning set forth in Section 11.2.
- 1.114. “**Outside Territory KOL**” means healthcare providers outside of the Territory that have administered a Licensed Product in clinical trials, have published academic articles relating to a Product, or are otherwise regarded by BIAL, its Affiliates and licensees or NBIX, as the case may be, as a key opinion leader (“ **KOL** ”) for a Licensed Product or products in the same therapeutic class outside of the Territory.
- 1.115. “**Patent**” means any and all patents, patent applications and patents issued from such patent applications, including, without limitation, divisions, continuations, continuations-in-part, reissues, renewals, extensions, supplementary protection certificates, and the like of any such patents and patent applications and foreign equivalents thereof.
- 1.116. “**Phase I Clinical Trial**” means a clinical trial in humans the principal purpose of which is determining safety and/or metabolism, and/or pharmacokinetic properties and/or clinical pharmacology of such product, as described in 21 C.F.R. § 312.21(a), as amended from time to time.
- 1.117. “**Phase II Clinical Trial**” means a clinical trial in humans of a product for an indication, the principal purpose of which is a determination of safety and efficacy for such indication in the target patient population over a range of doses and/or to obtain sufficient information about such product’s efficacy to permit the design of further clinical trials, as described in 21 C.F.R. § 312.21(b), as amended from time to time.
- 1.118. “**Phase III Clinical Trial**” means a clinical trial in humans of a product for an indication on a sufficient number of subjects that is prospectively designed to statistically demonstrate that the product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with the product in the dosage range to be prescribed, and to support regulatory approval of the product for such indication or label expansion of the product, as described in 21 C.F.R. § 312.21(c), as amended from time to time.

1.119. “Phase IV Studies” means both post-marketing and pharmacoeconomic studies that are initiated by NBIX after Approval and are not requested, mandated or required by an Agency to support or maintain an Approval. Phase IV Studies does not include investigator initiated studies or Post-Approval Commitment Studies in the Territory.

1.120. “Post-Approval Commitment Studies” means any study or data collection effort in respect of the Licensed Products which is requested, mandated or required by an Agency following an Approval for the Licensed Products in the Territory.

1.121. “Process Modification Costs” has the meaning set forth in Section 12.2(d).

1.122. “Product Specifications” means the specifications for the Initial Product, as such specifications shall be defined in the Quality Agreement , as may be amended or modified by BIAL from time to time in accordance with the terms of the Quality Agreement.

1.123. “Publishing Party” has the meaning set forth in Section 9.3(b).

1.124. “Quality Agreement” means a quality agreement between the Parties relating to the IMP and/or the Licensed Products.

1.125. “Recall Costs” has the meaning set forth in Section 7.8(b).

1.126. “Reconciliation Payment” has the meaning set forth in paragraph 1.2(a) of Exhibit 4.

1.127. “Regulatory Authority” means any governmental and/or regulatory authority involved in granting approvals for the marketing, reimbursement and/or pricing of a pharmaceutical product including, without limitation, as and when applicable, the EMA in the European Union, and an Agency in the Territory.

1.128. “Representatives” has the meaning set forth in Section 13.3(a).

1.129. “Re-Manufacturing” has the meaning set forth in Section 7.9.

1.130. “Right to Object”, with respect to a Development and Regulatory Plan, has the meaning set forth in Section 6.3(h), and with respect to any Label Related Documents & Materials, has the meaning set forth in Section 7.2(b).

1.131. “SDEA” or “Safety Data Exchange Agreement” has the meaning set forth in Section 7.5(a).

1.132. “Subsequent Indication” means any indication within the Field other than the Initial Indication.

- 1.133. “**Subsequent Product**” means: (a) [...***...]; and (b) any Combination Product.
- 1.134. “**Subsequent Product Development**” has the meaning set forth in Section 2.9(a).
- 1.135. “**Subsequent Tentative Supply Price**” has the meaning set forth in paragraph 1.1(b)(ii) of Exhibit 4.
- 1.136. “**Supply Agreement**” has the meaning set forth in Section 4.1(b).
- 1.137. “**Supply Price**” means the supply price for the Initial Product as set forth in Paragraph 1.1(a) of Exhibit 4.
- 1.138. “**Supply Price Report**” has the meaning set forth in paragraph 1.2(a) of Exhibit 4.
- 1.139. “**Supply Related Filings**” has the meaning set forth in Section 7.2(f).
- 1.140. “**Tentative Supply Price**” has the meaning set forth in paragraph 1.1(b)(ii) of Exhibit 4.
- 1.141. “**Term**” has the meaning set forth in Section 15.1(a).
- 1.142. “**Termination Event**” has the meaning set forth in Section 15.2.
- 1.143. “**Territory**” means the United States of America (“US”) and Canada.
- 1.144. “**Territory KOL**” means healthcare providers in the Territory that have administered a Licensed Product in clinical trials, have published academic articles relating to a Licensed Product, or are otherwise regarded by BIAL, its Affiliates and licensees or NBIX, as the case may be, as a key opinion leader for a Licensed Product or products in the same therapeutic class in the Territory.
- 1.145. “**Third Party**” means any person or entity who or which is neither a Party nor an Affiliate of a Party.
- 1.146. “**Third Party License**” has the meaning set forth in Section 12.2(c).
- 1.147. “**Trademark**” means the US and Canadian trademarks or trademark applications Controlled by BIAL and listed in **Exhibit 2.3** , for use in conjunction with the Licensed Products within the Field and Territory, or any trademark that is selected by the Parties pursuant to the terms of Section 2.3(c). For the avoidance of doubt, the term “Trademarks” does not encompass the INN Opicapone, the BIAL Logo or any marks, brand names and/or other indicators of source not specifically listed in Exhibit 2.3.

1.148. “**Transfer Plan**” has the meaning set forth in Section 2.6(b).

1.149. “**Unit**” means each single tablet, capsule or other pharmaceutical finished form of the Licensed Products as specifically applied to each dosage strength.

1.150. “**US**” means the United States of America, including its territories and possessions.

1.151. **Interpretation.** In this Agreement (except where the context otherwise requires):

(a) any reference to a Recital, Section or Exhibit is a reference to the relevant recital, section or exhibit of or to this Agreement, and the Exhibits and Recitals form part of this Agreement;

(b) the table of contents and section headings are included for convenience only and shall not affect the interpretation of this Agreement;

(c) use of the singular includes the plural and vice versa;

(d) use of any gender includes the other genders;

(e) any reference to “persons” includes natural persons, firms, partnerships, companies, corporations, associations, organizations, governments, governmental agencies and departments, states, foundations and trusts (in each case whether or not having separate legal personality);

(f) any reference to an English legal term for any action, remedy, method of judicial proceeding, legal document, legal status, court, official or any legal concept or thing shall, in respect of any jurisdiction other than England, be deemed to include a reference to what most nearly approximates in that jurisdiction to the English legal term;

(g) the words “include”, “includes”, “including” and “such as” and “in particular” are to be construed as if they were immediately followed by the words “without limitation”; and

(h) references to any statute or statutory provision shall include (i) any subordinate legislation made under it, (ii) any provision which it has modified or re-enacted (whether with or without modification) and (iii) any provision which subsequently supersedes it or re-enacts it (whether with or without modification).

ARTICLE 2

GRANT OF RIGHTS

2.1 Sole Commercialization License: BIAL grants to NBIX during the Term a sole and non-sublicensable license under the BIAL Patents and BIAL Know-How and BIAL’s interest in the jointly owned Development Intellectual Property and Joint Patents to use, market, distribute, import, commercialize, offer for sale and sell the Licensed Products under the Trademark within the Field and

Territory. The “sole” license means that, save that BIAL retains the right to co-promote as set forth in Section 2.10 below and subject to Section 2.1(g)(ii), NBIX has the exclusive (even as to BIAL) license under the BIAL Patents and BIAL Know-How and BIAL’s interest in the jointly owned Development Intellectual Property and Joint Patents to use, market, distribute, import, commercialize, offer for sale and sell the Licensed Products under the Trademark within the Field and Territory.

(a) BIAL reserves to itself all rights not expressly granted to NBIX under this Agreement, including all rights under the BIAL Know-How and BIAL’s interest in Development Intellectual Property and in Joint Patents for all uses outside of the Territory.

(b) NBIX agrees not to directly or indirectly export, develop, manufacture, use, quality control, package, register, market (except as expressly set forth in Exhibit 2.1(g)(i)), distribute, commercialize, offer for sale or sell BIA 9-1067 in any form or formulation and/or any Licensed Products and/or use the Trademarks outside the Territory. NBIX shall promptly notify BIAL if it has reason to believe that any Licensed Product has been or will be exported from the Territory. Other than in accordance with this Agreement and the Supply Agreement, BIAL agrees not to directly or indirectly license any Third Party licensees or distributors to export, develop, manufacture, use, quality control, package, register, market, distribute, commercialize, offer for sale or sell BIA 9-1067 in any form or formulation and/or any Licensed Products and/or use the Trademarks in the Territory. BIAL shall promptly notify NBIX if it has reason to believe that any Licensed Product (other than Licensed Product supplied to NBIX) has been or will be exported into the Territory. Upon either Party notification to the other pursuant to this Section 2.1(b), the Parties shall in good faith discuss any possible actions to be undertaken by any or both Parties, provided that neither Party shall be under an obligation to agree on any such actions.

(c) NBIX shall not have any right or license under the BIAL Patents, BIAL Know-How, BIAL’s interest in any Development Intellectual Property and in Joint Patents, Trademarks or Manufacturing Know-How to manufacture or have manufactured Licensed Products, except as separately agreed by the Parties in writing.

(d) NBIX shall not have any right to develop or have developed Subsequent Products unless separately agreed by the Parties in writing.

(e) Subject to Sections 2.3 and 2.4, the primary and secondary packaging of the Licensed Product shall bear the Trademark and BIAL’s trade dress and logo and, to the extent permitted by applicable laws and regulations in the Territory, shall contain with legible letters of reasonable size the words “under license from [BIAL Logo]” unless BIAL determines in its sole discretion that such reference shall be “under license from BIAL”.

(f) Subject to Section 2.4, the promotional materials and documents that are used by NBIX in connection with the development, marketing, distribution, importation, commercialization, offer for

sale and sale of the Licensed Products shall, to the extent allowed under the laws and regulations in the Territory, contain with legible letters of reasonable size the words “under license from [BIAL Logo]” or, as determined by BIAL in its sole discretion, “under license from BIAL”.

(g) The Parties agree that (i) NBIX shall have certain rights to engage in marketing-related activities with respect to Licensed Products in cooperation with BIAL outside the Territory, for the purpose of promotion of Licensed Products by NBIX and its Affiliates in the Field in the Territory, and (ii) BIAL shall have certain rights to engage in marketing-related activities with respect to Licensed Products in cooperation with NBIX in the Territory, for the purpose of promotion of Licensed Products by BIAL and its Affiliates and licensees outside the Territory and to prepare a Co-Promotion Plan in accordance with Section 2.10(b), in each case, strictly in accordance with **Exhibit 2.1(g)**. For clarification, nothing herein or in Exhibit 2.1(g) shall give NBIX any license or other right to develop, use, sell, offer for sale, and import Licensed Products outside the Territory.

(h) For greater certainty, NBIX shall not have any right, license or authorization, during or after the Term, to practice or otherwise use (directly or via any Affiliates or Third Parties) any BIAL Know-How, BIAL Patents, Joint Patents, BIAL Development Intellectual Property or Trademark outside of the Territory until the end of the term of the confidentiality obligation hereunder and further provided that NBIX can obtain such BIAL Know-How and BIAL Development Intellectual Property from a Third Party publicly available source.

2.2 Non-Exclusive Development License: BIAL grants to NBIX during the Term a non-exclusive and non-sublicensable license under the BIAL Patents, BIAL Know-How and BIAL’s interest in jointly owned Development Intellectual Property and Joint Patents to develop Licensed Products within the Field and Territory (the “**Development License**”).

(a) The development of Licensed Products under the Development License includes all activities necessary or useful for regulatory and commercialization purposes within the Field and Territory. All development of Licensed Products under the Development License shall in all cases be subject to the prior approval of the JSC in accordance with Article 5 and all development of Subsequent Products shall be subject to the prior written approval of BIAL in accordance with Section 2.9.

(b) BIAL retains the right, in accordance with this Section 2.2(b), to, directly or via its Affiliates or Third Party contractors, carry out any development activities with respect to Licensed Products and/or the BIA 9-1067 API in the Territory. BIAL shall provide not less than [...***...] days advance notification to NBIX before seeking to commence any Clinical Trial of any Licensed Product in the Territory and shall consult with NBIX as to the scope (*i.e.* intended number of patients to be recruited), Clinical Trial design, and location of such Clinical Trial and shall consider NBIX’s comments and suggestions in good faith. BIAL shall not conduct any Clinical Trial with respect to any Licensed Product in the Territory in the event that NBIX objects to such Clinical Trial and it is able to

reasonably demonstrate in writing that conducting such Clinical Trial could adversely affect NBIX's development and/or commercialization of any Licensed Product in the Territory.

2.3 Trademark License: BIAL grants NBIX during the Term a sole, non-sublicensable, royalty-free license to use the Trademark solely in connection with the promotion, marketing, distribution and sale of the Licensed Products in the Field in the Territory. The "sole" license means that, save that BIAL retains the right to co-promote as set forth in Section 2.10 and subject to Section 2.1(g), NBIX has the exclusive rights even as to BIAL.

(a) BIAL or its Affiliate shall own all right, title and interest in the Trademark and the goodwill associated therewith. BIAL shall be solely responsible for registering and maintaining such Trademark and shall not abandon such Trademark or license others to use such Trademark in the Territory without the prior written consent of NBIX. If reasonably requested by BIAL, NBIX shall assist and cooperate with BIAL in the selection, registration and maintenance of the Trademark in the Territory, at BIAL's expense.

(b) Any marketing, promotion, sale or distribution of Licensed Products by or on behalf of NBIX under the license set forth in Section 2.1, shall take place exclusively under the Trademark.

(c) The Trademark shall be the same selected by BIAL and approved by the EMA (*i.e.* Ongentys®); provided that (i) in the event that such Trademark is not accepted by the relevant Agency in the Territory or (ii) NBIX can demonstrate to BIAL in writing via properly documented market research that such Trademark is not appropriate for the Licensed Products in the Territory, the Parties shall discuss and mutually select other trademark or trademarks from those listed Exhibit 2.3.

(d) In the event that (i) such other Trademark or Trademarks listed Exhibit 2.3 is/are not accepted by the Agency or (ii) NBIX can demonstrate to BIAL in writing via properly documented market research that such Trademark or Trademarks is/are not appropriate for the Licensed Products in the Territory, the Parties shall discuss and mutually agree upon trademarks ("**Alternative Trademarks**") other than the Trademarks. In the event that any of the Alternative Trademarks are not already registered or applied for by BIAL, then NBIX shall, with the prior written consent of BIAL, apply for such trademarks (if not already registered or applied for by NBIX), and NBIX shall propose one or more of the Alternative Trademarks to the FDA for approval and in the event that the FDA approves an Alternative Trademark, NBIX shall within [...***...] days after such FDA approval, assign the approved Alternative Trademark or Alternative Trademark application and all right, title and interest in and to, including the goodwill associated thereto, such Alternative Trademark to BIAL or its Affiliate at no cost to BIAL and thereafter such Alternative Trademark shall be deemed a Trademark such that it shall be automatically added to Exhibit 2.3, pursuant to this Section 2.3(c), and all other Trademarks or Trademark applications listed in Exhibit 2.3 will be considered automatically excluded from Exhibit 2.3 and from the Trademark license granted hereunder.

(e) NBIX shall not file or obtain any trademark application or registration, or Internet domain name registration, comprised of, containing or confusingly similar with, any Trademarks, Alternative Trademarks, trademarks used for the Licensed Products outside the Territory, or the INN Opicapone, or any variations thereof, without BIAL's express written permission.

(f) BIAL reserves to itself all rights in and to the Trademarks outside of the Territory; provided, however, NBIX shall have the right to use the Trademark as expressly provided in Section 2.1(g).

2.4 BIAL Logo License:

(a) BIAL grants NBIX a non-exclusive license during the Term to use the BIAL Logo on all packaging materials, promotional materials and documents that are used by NBIX either directly on its own and/or through its contractors in connection with the marketing, distribution, importation, commercialization, offer for sale and sale of the Licensed Products. NBIX shall use the BIAL Logo on all such materials on which it also uses the NBIX logo to the extent permitted by the relevant Agency.

(b) If BIAL modifies or otherwise changes the BIAL Logo then:

(i) BIAL shall pay for all official fees associated with varying or amending any Approvals in respect of such change of the BIAL Logo;

(ii) NBIX shall have the right to continue to use its stocks of packaging materials, promotional materials and documents with the previous BIAL Logo that existed at the time of such change or are on order at that date until such stocks are exhausted, unless BIAL pays NBIX for the costs of replacement materials bearing the new BIAL Logo.

2.5 Contracting:

NBIX shall have the right to contract with Third Parties in the Territory to perform its development and commercialization (i.e. marketing services, such as market research, development of marketing materials, or pricing research, but not services such as Detailing) responsibilities under this Agreement in accordance with the terms of this Agreement; provided: (i) that NBIX markets, imports, distributes, commercializes, offers for sale and sells the Licensed Products at all times in its own name, (ii) that NBIX enters into a written agreement with such Third Parties, which imposes obligations on such Third Parties substantially similar to those imposed on NBIX under this Agreement (as appropriate to the particular arrangements with the Third Party), (iii) that, unless otherwise requested by BIAL pursuant to Section 15.5(i) (A) or agreed between the Parties or required by applicable law, an institutional review board or a drug safety monitoring board, or a clinical trial site, despite the use of Commercially Reasonable Efforts by NBIX, all contracts relating to Licensed Products shall terminate automatically on early termination of this Agreement, (iv) that any such contracts contain confidentiality provisions consistent with this Agreement, (v) that NBIX obtains an assignment from such Third Parties

of any Development Intellectual Property made by such Third Parties under such agreement and **(vi)** that NBIX remains, at all times, solely responsible and liable to BIAL for all of such Third Parties' activities and for any failure by such Third Parties to comply with the terms of this Agreement.

2.6 **Delivery of BIAL Know-How:**

(a) Kick-Off Meeting: Promptly following the Effective Date but in no event later than [...***...] Business Days following the Effective Date, the Parties shall hold a face to face meeting at BIAL's head-office, at a mutually agreed appropriate time ("**Kick-Off Meeting**"), in order to discuss and agree the transfer of the existing BIAL Know-How necessary for the development, promotion, marketing and sale of the Licensed Products in the Territory, including the transfer to NBIX in accordance with Section 2.6(b). The Alliance Managers shall be responsible for co-ordinating and setting up the meeting. The agenda for the meeting shall be mutually agreed by both Parties.

(b) Technology Transfer: Promptly following the Effective Date, BIAL shall commence the transfer to NBIX of all BIAL Know-How pursuant to the technology transfer plan set forth in Exhibit 2.6(b) (the "**Transfer Plan**"). BIAL shall complete the transfer described in the Transfer Plan within [...***...] days after the Kick-Off Meeting. If such transfer is not completed by the end of such [...***...] day period, then all development and commercialization timelines set forth in this Agreement will be extended by the number of days by which the completion of the technology transfer is delayed. Each Party shall bear its own expenses in conducting such technology transfer.

(c) IND Ownership of BIA 9-1067 IND: Within [...***...] Business Days after the Effective Date, BIAL shall submit to the FDA the application requesting the transfer of the BIA 9-1067 IND to NBIX. BIAL shall transfer all right, title and interest in the BIA 9-1067 IND to NBIX, subject to the reservation set forth in Section 2.6(c)(ii), for the Term of this Agreement. NBIX shall promptly notify the FDA in writing that the BIA 9-1067 IND has been transferred to NBIX and that NBIX accepts all rights and responsibilities thereunder.

(i) Subject to the exclusive licenses granted to NBIX herein, BIAL retains all right, title and interest in all BIAL Know-How submitted in support of the BIA 9-1067 IND, including but not limited to, all safety and effectiveness data, provided that NBIX has the right to rely upon and utilize such BIAL Know-How during the Term to support any future regulatory applications or submissions to the FDA, Health Canada, or any other relevant regulatory bodies in the Territory related to the Licensed Products and to the extent consistent with the terms of this Agreement.

(ii) BIAL reserves the right to use and refer to the BIA 9-1067 IND and BIAL Know-How submitted in support of the BIA 9-1067 IND, including but not limited to, all safety and effectiveness data for **(A)** any purpose outside the Territory, including without limitation for any development and regulatory activities, and **(B)** in accordance with the provisions of Section

2.2(b) and Article 6, for the sole purpose of conducting permitted development activities within the Territory.

(iii) Upon the expiration or termination of this Agreement, all right, title, and interest in the BIA 9-1067 IND shall be assigned back to BIAL in accordance with Section 15.5(c).

(d) **BIAL Know-How and BIAL Development Intellectual Property during the Term:** BIAL shall, as soon as reasonably practicable, and in any event on a Calendar Year basis or as reasonably requested by NBIX, provide NBIX, in the form agreed upon by the Parties, with any BIAL Know-How (including without limitation, BIAL Development Intellectual Property) that comes under BIAL's Control after the Effective Date and during the Term.

(e) All BIAL Know-How (including without limitation BIAL Development Intellectual Property) disclosed to NBIX under Sections 2.6(a), 2.6(b) and 2.6(c) above, is subject to the terms and conditions of this Agreement, including without limitation, the confidentiality provisions of Article 13 and Section 9.4(a).

2.7 NBIX License to BIAL under NBIX Patents, NBIX Development Intellectual Property, Joint Patents and NBIX Know-How :

(a) NBIX shall, as soon as reasonably practicable, and in any event on a Calendar Year basis or as reasonably requested by BIAL, provide BIAL, in the form agreed upon by the Parties, with any NBIX Know-How and any NBIX Development Intellectual Property created during the Term.

(b) NBIX grants to BIAL a royalty-free, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses to BIAL's Affiliates and Third Party licensees through multiple tiers of sublicensees, in any country outside the Territory, under NBIX Patents, NBIX's interest in Joint Patents, NBIX's Development Intellectual Property and NBIX Know-How (including Data) to develop, use, manufacture, package, make, have made, import, register, distribute, market, offer for sale, commercialize and sell products that contain or comprise BIA 9-1067, alone or in combination with other active pharmaceutical ingredient(s), in any form or formulation, and/or use processes to manufacture such products, in each case outside the Territory ("**NBIX License**"); provided however that, under the NBIX License, BIAL shall also have a royalty-free, irrevocable, perpetual, non-exclusive license, with the right to grant sublicenses to BIAL's Affiliates and Third Party licensees through multiple tiers of sublicensees, in any country outside the Territory, under NBIX Patents, NBIX's interest in Joint Patents, NBIX's Development Intellectual Property and NBIX Know-How (including Data) to manufacture, have manufactured, package, have packaged, make, have made, import and/or have imported products that contain or comprise BIA 9-1067, alone or in combination with other active pharmaceutical ingredient(s), in any form or formulation, and/or use processes to manufacture such products in the Territory. For the avoidance of doubt, notwithstanding that the NBIX License under this Section 2.7(b) is non-exclusive, NBIX shall not, without the prior written consent of BIAL (which, for

the avoidance of doubt, BIAL may withhold at its discretion), have any license, right or any authorization to practice or otherwise use (directly or via any Affiliates or Third Parties) NBIX Patents, NBIX's interest in Joint Patents, NBIX Development Intellectual Property and NBIX Know-How (including Data) for any purpose whatsoever outside the Territory during the Term and thereafter for the period that BIAL Controls outside the Territory any Blocking BIAL IP.

(c) After the Term and thereafter the period that BIAL Controls outside the Territory any Blocking BIAL IP, the NBIX License under Section 2.7(b) shall continue as a royalty-free, irrevocable and non-exclusive license, provided, however, that in the event that BIAL is interested to negotiate an exclusive license under NBIX Patents, NBIX's interest in Joint Patents, NBIX Development Intellectual Property and NBIX Know-How (including Data), then the Parties shall negotiate in good faith the terms of a license, including consideration payable by BIAL for such exclusivity.

(d) NBIX shall use Commercially Reasonable Efforts to ensure that NBIX retains all right, title and interest in and to any of NBIX Know-How, NBIX Patents and NBIX Development Intellectual Property. If NBIX is unable to retain all right, title and interest in and to any NBIX Know-How, NBIX Patents and NBIX Development Intellectual Property, NBIX shall use Commercially Reasonable Efforts to obtain an exclusive, worldwide license under such NBIX Know-How, NBIX Patents and NBIX Development Intellectual Property, to import, develop, manufacture, quality control, package, use, market, distribute, commercialize, offer for sale and sell products that contain or comprise BIA 9-1067, alone or in combination with other active pharmaceutical ingredient(s), in any form or formulation, and/or use processes to manufacture such products, in each case outside the Territory, with the right to grant BIAL a sublicense consistent with the terms in Sections 2.7(b) and 2.7(c).

2.8 Non-Compete Undertaking:

(a) During the Term of this Agreement, NBIX and its Affiliates shall not directly or indirectly, use, develop, market, distribute, import, commercialize, promote, offer for sale or sell any Competing Product within the Field and Territory.

(b) In the event that a Third Party becomes an Affiliate of NBIX after the Effective Date through merger, acquisition, consolidation or other similar transaction (other than a Change of Control of NBIX), and such Third Party, as of the closing date of such transaction, is conducting any activities with respect to a Competing Product that would cause NBIX to breach Section 2.8(a), then NBIX and its new Affiliate or Affiliates shall have [...] from the closing date of such transaction to complete the Divestiture of such Competing Product. The conduct of activities with respect to such Competing Product by NBIX and any applicable Affiliate during such [...] period shall not deemed a breach of this Section 2.8, provided that such new Affiliate conduct such activities with respect to such Competing Product during such [...] period independent from the activities under this Agreement and does not use any BIAL Confidential Information, BIAL Patents, Development Intellectual Property or any BIAL Know-How in the conduct of such activities.

“**Divestiture**”, as used in this Section 2.8(b), means the sale or transfer of rights to the Competing Product to a Third Party without retaining any decision-making related to or Control of such Competing Product.

2.9 **Subsequent Product(s):**

(a) If NBIX is interested in developing any Subsequent Product in the Territory by conducting Nonclinical Studies, Phase I or Phase II Clinical Studies (such research or development to be referred to as “**Subsequent Product Development**”), then, subject to NBIX (i) demonstrating to BIAL with written evidence that [...***...], and (ii) providing BIAL with [...***...], then the Parties may agree in their absolute discretion that such Subsequent Product may be developed. In such event, the Parties shall discuss whether any amendments to the SDEA, the Supply Agreement and the Quality Agreement are necessary.

(b) If, after reaching an agreement on the matters identified in Section 2.9(a) and completing Subsequent Product Development, NBIX is interested in developing and commercializing in the Territory any Subsequent Product by conducting Phase III Clinical Trial(s), then subject to NBIX (i) demonstrating to BIAL with written evidence that [...***...], and (ii) providing BIAL with [...***...], then the Parties may agree in their absolute discretion that such Subsequent Product may be developed. In such event:

(A) the Parties shall negotiate in good faith to determine whether NBIX or BIAL will supply such Subsequent Product and either (A) a supply price and minimum supply price for the supply, from BIAL or its Affiliate or designee to NBIX, of the Subsequent Product and/or IMP to be used for Development Studies; or (B) the amount to be paid to BIAL in respect of each Unit of Subsequent Product and/or the IMP to be used for Development Studies manufactured by or on behalf of NBIX and the mechanism for such payment; and

(B) the Parties shall enter into appropriate amendments to this Agreement, the SDEA, the Supply Agreement and the Quality Agreement.

(c) In the event that the Parties fail to reach an agreement with respect to the matters identified in Sections 2.9(a) and 2.9(b) and other terms and conditions thereof within the period of [...***...]

[...***...] after NBIX's notification to BIAL pursuant to Section 2.9(a), then NBIX shall not have any rights (including, without limitation, the right to develop, manufacture, register or commercialize) with respect to such Subsequent Product, and for clarity BIAL shall have no such rights in the Territory during the Term either.

2.10 **Co-Promotion:**

(a) **Option.** Starting the earlier of (i) [...***...] to a period of [...***...] thereafter after or (ii) during the period [...***...], BIAL shall have the right to, directly or via an Affiliate or contractor (subject to the terms of 2.10(c) below), and in common and coordinated with NBIX, to initiate co-promotion of the Licensed Products in the US (the “**Co-Promotion Option**”). For purposes of this Section 2.10, “co-promote” or “co-promotion” means the Detailing of such Licensed Product by BIAL or its Affiliates or contractors under the then-current Approval and the Trademark, and shall not mean the sale or distribution of such Licensed Product by BIAL or its Affiliates or contractors other than in accordance with this Agreement. For the avoidance of doubt, NBIX shall continue to book all sales in the Territory.

(b) **Notice.** BIAL may exercise the Co-Promotion Option by providing NBIX with [...***...] advance written notice and a plan (the “**Co-Promotion Plan**”) with respect to its intended promotional efforts, including but not limited to, the number of representatives and their geographical alignment, estimated number of Details (which shall not in any event exceed [...***...]) of the Detailing effort then being made by NBIX), compensation structure and sales force hiring plans and a reasonable sales projection. Following delivery of such notice and Co-Promotion Plan, the Parties shall negotiate a Co-Promotion Agreement (as defined below) reasonably and in good faith and with such diligence as is required to execute and deliver the Co-Promotion Agreement by [...***...]. If the Parties cannot agree the terms of the Co-Promotion Agreement within such [...***...] period then the terms shall be determined in accordance with the Final Position Arbitration Procedure set out in **Exhibit 2.10**.

(c) **Terms of Co-Promotion Agreement.** The terms and conditions of a co-promotion arrangement shall be set forth in a co-promotion agreement (the “**Co-Promotion Agreement**”) to be entered into between the Parties as set forth in this Section 2.10(c).

(i) Subject to the provisions of Sections 2.10(d) to 2.10(i), the Parties shall negotiate and agree (A) the minimum number of Details (not to exceed [...***...]) and the prioritization of such Details to be provided by BIAL based on BIAL's, its Affiliates' or contract sales force capabilities, and (B) the minimum number of Details and the prioritization of such Details to be provided by

NBIX taking into account the then-current commercial requirements for the Licensed Products (“ **Minimum Detail Effort** ”) .

(ii) BIAL shall have the right to use a contract sales force (“**CSO**”) at the time it initiates its Co-Promotion Option, provided that BIAL provides NBIX, with a detailed written plan to convert the relevant CSO employees to BIAL employees within [...***...].

(iii) Except as specifically provided in the Co-Promotion Agreement, BIAL shall have exclusive responsibility for all costs and expenses of its CSO and/or its employees (collectively, “**BIAL Representatives**”), including all training (other than internal NBIX training costs), compensation, salaries, benefits and expenses, which shall include but not be limited to, sales infrastructure and support costs (such costs referred to as “ **BIAL Representatives Costs** ”).

(iv) For so long as Licensed Product(s) are the only product(s) being promoted by BIAL Representatives, the BIAL Representatives Costs shall be paid [...***...]. In the event the BIAL Representatives are promoting products other than the Licensed Products, the foregoing reimbursement mechanism shall be adjusted commensurately using the following guidelines:

- (A) If BIAL Representatives are promoting [...***...], then the product in the first Detail position shall be responsible for [...***...]) of the BIAL Representatives Costs and the product in the second Detail position shall be responsible for [...***...]) of the BIAL Representatives Costs; and
- (B) If BIAL Representatives are promoting [...***...], then the product in the first Detail position shall be responsible for [...***...]) of the BIAL Representatives Costs, the product in the second Detail position shall be responsible for [...***...]) of the BIAL Representatives Costs, and the product in the third Detail Position shall be responsible for [...***...]) of the BIAL Representatives Costs.

(v) The Co-Promotion Plan shall be reviewed and agreed on an annual basis as part of the Annual Commercialization Plan and the Parties shall agree the Minimum Detail Effort that each Party shall make to target prescribers during each Calendar Year. The Parties shall also agree the maximum number of Details that BIAL may perform in any given Calendar Year. Either Party shall have the right to terminate the Co-Promotion Agreement if [...***...], or, in the event BIAL uses a CSO, if BIAL has not

converted the CSO to BIAL employees after [...***...] of initiating the Detailing the Licensed Products under the Co-Promotion Agreement.

(vi) The Co-Promotion Agreement shall include such provisions as are usual and customary in co-promotion agreements in the Territory, including provisions related to sales force training and qualifications, incentive compensation, sales reporting system and data access, sales territory alignment, compliance with applicable laws, Detail allocation and Minimum Detail Effort requirements.

(vii) The Parties shall establish a co-promotion steering committee (the “**Co-Promotion Steering Committee**”) with equal management representation from both Parties who shall be directly involved in the co-promotion. The Co-Promotion Steering Committee shall jointly oversee the strategy and tactics for the marketing and sale of the Licensed Products on an annual basis and provide an Annual Commercialization Plan to the JSC for review and approval. The Co-Promotion Steering Committee shall report to the JSC and any disputes shall be resolved at the JSC; provided however, that if the JSC is unable to resolve the dispute, then NBIX shall have final decision-making authority to the extent it does not cause BIAL to incur additional costs or liabilities.

(d) Upon entry into the Co-Promotion Agreement and subject to performing the agreed Minimum Detail Effort and implementing the agreed Annual Commercialization Plan and associated promotional budget, the obligations under Sections 8.3(f), 8.3(g) and 8.3(h) shall not apply.

2.11. Change of Control Notice: Within [...***...] after a Change of Control of NBIX, NBIX shall forthwith give notice in writing (a “ **Change of Control Notice** ”) to BIAL. A Change of Control Notice shall inform BIAL of the Change of Control and provide details of the person or entity which has obtained control of NBIX. A failure to provide such a Change of Control Notice shall be considered to be an incurable material breach of this Agreement allowing BIAL to terminate this Agreement in accordance with Section 15.2(a).

ARTICLE 3

PAYMENTS

3.1 **License Fees and Milestone Payments:** NBIX shall make the following payments to BIAL:

(a) **License Fee:** Within [...***...] Business Days after the Effective Date, NBIX shall pay to BIAL Thirty Million United States Dollars (US\$30,000,000), as a licensing fee. This license fee is not refundable under any circumstances and is not creditable against any payments due by NBIX under this Agreement or any other agreements between the Parties.

(b) Milestone Payments: NBIX shall make the following one-time milestone payments (the “**Milestone Payments**”) to BIAL upon the first occurrence of each of the milestone events specified below (each, a “**Milestone Event**”):

	Milestone Event	Milestone Payment (in US Dollars)
(i)	Upon confirmation from the FDA that [...***...] is not required to be completed prior to [...***...] for the [...***...] in the [...***...]:	\$[...***...]
(ii)	Upon acceptance by the FDA of the [...***...] for the [...***...] in the [...***...]:	
	(a) In the event that [...***...] is not required to be completed prior to [...***...] for the [...***...] in the [...***...]:	\$[...***...]
Or		
	(B) In the event that [...***...] is required to be completed prior to [...***...] for the [...***...] in the [...***...]:	\$[...***...]
(iii)	Grant of [...***...] by the FDA for the [...***...] in the [...***...]:	US\$[...***...]
(iv)	Upon the first occurrence of Net Sales in the Territory equal to or greater than [...***...] US Dollars (US\$[...***...]) in any Calendar Year:	US\$[...***...]
(v)	Upon the first occurrence of Net Sales in the Territory equal to or greater than [...***...] US Dollars (US\$[...***...]) in any Calendar Year:	US\$[...***...]
(vi)	Upon the first occurrence of Net Sales in the Territory equal to or greater than [...***...]	US\$[...***...]

[...***...] US Dollars (US\$[...***...]) in any Calendar Year:

(c) NBIX shall report in writing the occurrence of each of Milestone Events (i), (ii) and (iii) to BIAL within [...***...] of the date on which the Milestone Event has occurred, and shall pay the corresponding Milestone Payment within [...***...] after the occurrence of the applicable Milestone Event. NBIX shall report in writing the occurrence of each of Milestone Events (iv), (v) and (vi), and shall pay the corresponding Milestone Payment, within [...***...] the Milestone Event occurs. If two or more of the milestones set forth in Sections 3.1(b)(iv), (v) or (vi) occur in the same Calendar Quarter, then all applicable milestones shall be payable following such Calendar Quarter. The Milestone Payments are not refundable under any circumstances and are not creditable against any payments due by NBIX under this Agreement or any other agreements between the Parties.

3.2 Tax Matters:

(a) The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of payments made by NBIX to BIAL under Section 3.1, namely in accordance with the treaty between Portugal and the US to avoid double taxation.

(b) BIAL will pay and otherwise be responsible for all value added taxes and transfer taxes and/or taxes of equivalent effect in connection with any payment made to BIAL pursuant to this Agreement or the Supply Agreement, for all applicable sales, goods and services. For the avoidance of doubt, customs and import duties and levies and/or taxes of equivalent effect arising out or in connection with the supply of the Licensed Products or IMP by or on behalf of BIAL to NBIX shall be borne and paid in full by NBIX.

(c) Except as set forth in Section 3.2(b) above, any income or other tax that one Party hereunder is required to withhold and pay on behalf of the other Party hereunder with respect to amounts payable under this Agreement shall be deducted from said amounts prior to payment to the other Party; provided, however, that in regard to any tax so deducted, the Party making the withholding shall give or cause to be given to the other Party all assistance reasonably necessary to enable that other Party to claim exemption therefrom or credit therefor, and in each case shall promptly furnish the Party on whose behalf amounts were withheld, proper evidence of the taxes paid on its behalf and execute and provide such Party with any documents reasonably necessary in connection therewith. Each Party shall comply with reasonable requests of the other Party to take any proper actions that may minimize any withholding obligation. BIAL shall provide to NBIX a properly completed and executed Form W8-BEN prior to any payment made to BIAL and annually thereafter.

3.3 Interest: If NBIX fails to make payment within any of the above stated timeframe, BIAL is entitled, without prejudice to any other right or remedy available to BIAL, to charge NBIX interest (both before and after judgment) on the unpaid amount for every day that the amount remains unpaid at a rate of [...***...]) annually until the payment is made; provided, however, that in no event shall such rate exceed the maximum legal annual interest rate.

3.4 Any and all sums payable under this Agreement and any costs and expenses incurred by NBIX in connection with this Agreement are not refundable under any circumstances.

ARTICLE 4 **SUPPLY AND MANUFACTURE**

4.1 General:

(a) During the Term, BIAL or its Affiliate shall supply or have supplied to NBIX, and NBIX shall purchase from BIAL or its Affiliate or its or their designee at the Supply Price stipulated in Paragraph 1.1(a) of Exhibit 4 all of NBIX's requirements of Initial Product and IMP.

(b) Promptly after the Effective Date and within a period of [...***...] thereof (or as otherwise agreed in writing by the Parties), BIAL and its Affiliate and NBIX shall negotiate in good faith and enter into a supply agreement (the "**Supply Agreement**") for the clinical supply of IMP and commercial supply of Licensed Products to NBIX. The Supply Agreement shall include the terms set out in Exhibit 4 and other customary terms for an agreement of such nature.

ARTICLE 5 **COLLABORATION MANAGEMENT**

5.1 Collaboration Management: The Parties will manage the collaboration in good faith to **(i)** conduct the Transfer Plan as efficiently and effectively as possible in order for NBIX to submit an NDA for an Initial Product by the earliest date possible, for **(ii)** NBIX to develop the Initial Product for all indications in the Field for which it can be demonstrated there is a scientific and commercial justification (subject, in any event, to the provisions of Article 6) and **(iii)** to, subject to Section 7.2, support labelling designed to ensure the broadest commercial success for the Initial Product.

5.2 Joint Steering Committee Formation: The Parties shall within the period of [...***...] after the Effective Date form a Joint Steering Committee (the "**JSC**"), with overall coordination and strategic oversight over the Parties' activities hereunder and to provide a forum for regular exchange of information (to the extent required under this Agreement) relating to the Licensed Products.

5.3 Make-up of the JSC:

(a) The JSC shall consist of [...] members, namely, [...] members from each of BIAL or its Affiliates and NBIX, each of whom shall be an Executive Officer of such Party. Each of its JSC members shall have the knowledge, experience and seniority to take decisions within the JSC's purview.

(b) BIAL and NBIX may each replace any or all of its representatives on the JSC at any time upon written notice to the JSC members and Alliance Manager of the other Party, provided however that each Party shall use its reasonable endeavours to reduce replacements as much as reasonably possible.

(c) BIAL and NBIX each may, in its sole discretion, invite to attend in a non-voting capacity meetings or portions of such meetings JSC non-member representatives of such Party (including, without limitation, its employees or non-employee professional advisors), with a maximum of [...] non-member representatives per meeting unless otherwise agreed by the Parties, who have a reasonable purpose for attending such JSC meeting or portion of such JSC meeting. The inviting Party shall ensure that each such representative is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

(d) The Parties acknowledge and agree that the development and commercialization of Licensed Products in and outside the Territory will benefit from the Parties' regular communications and interactions. From time to time, the JSC may establish subcommittees with appropriate technical, regulatory or commercial personnel as it deems appropriate, to oversee specific matters, activities and obligations of the Parties under this Agreement, the SDEA, the Supply Agreement and the Quality Agreement as set forth herein in order to facilitate the effective coordination between the Parties and to make progress with respect to such matters, activities and obligations. Such subcommittees are not empowered with decision making responsibility, except as expressly delegated by the JSC and recorded in writing between the Parties, and shall keep the JSC regularly updated of all progress. The Parties acknowledge and understand that the JSC and subcommittees shall have only the powers expressly assigned to it in this Article 5 and elsewhere in this Agreement, and shall not have any power to amend, modify or waive compliance with this Agreement.

(e) It is understood between the Parties that in no event shall the activities to be performed by, or under oversight of, the JSC (or any subcommittee) be intended or allowed to violate any applicable law (including, without limitation, any competition or antitrust law).

5.4 JSC Responsibilities: Responsibilities of the JSC shall be the following:

(i) Discussing and reviewing the development and regulatory strategies and activities for the Licensed Products in and outside the Territory and, to the extent reasonably possible, coordinating strategies in and outside the Territory;

(ii) Discussing and reviewing the commercialization strategies and activities of the Licensed Products in and outside the Territory and, to the extent reasonably possible, coordinating strategies in and outside the Territory;

(iii) Discussing and reviewing the matters relating to supply that are not specifically addressed within the Supply Agreement of the Licensed Products by BIAL to NBIX for use hereunder;

(iv) Discussing, reviewing and approving the Development and Regulatory Plan and amendments thereto prior to adoption or implementation thereof;

(v) Discussing, reviewing and approving the Annual Commercialization Plan, and updates or amendments thereto prior to adoption or implementation thereof;

(vi) Reporting on the status of ongoing Development Studies and other development activities with respect to Licensed Products in the Field in and, to the extent BIAL has the right to disclose them, outside the Territory;

(vii) Reporting on the status of ongoing commercial activities with respect to Licensed Products in the Field in and, to the extent BIAL has the right to disclose them, outside the Territory;

(viii) Reviewing and agreeing the Agreed Sales Forecast;

(ix) Resolving disputes in respect of proposed publications in accordance with Section 9.3; and

(x) Performing such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon in writing by the Parties from time to time.

5.5 **Meetings:**

(a) The JSC may meet, convene or be polled in person or by video or telephone conference (where all Parties can hear and be heard). In addition, the JSC may be polled through electronic mail or correspondence.

(b) The JSC shall meet on such dates, and at such places and times or in such manner, as the members of the JSC shall agree from time to time. The first JSC meeting shall be held in person immediately following the Kick-Off Meeting and, unless otherwise agreed upon by the Parties, the subsequent JSC meetings shall be held [...***...] where one such meeting shall always be held in person.

(c) Meetings of the JSC that are held in person shall alternate between the offices of BIAL's facility in Portugal and NBIX's facility in San Diego, California, USA, or at such other place as the Parties may agree, with each Party bearing its own costs associated with attendance at such meetings.

(d) The chairperson of the JSC shall alternate at each meeting between one of BIAL's JSC members designated by BIAL and one of NBIX's JSC members designated by NBIX.

(e) Acting on behalf of the chairperson, the Alliance Managers shall establish the timing (at a mutually agreed upon time with the other Party) and agenda for all JSC meetings and shall send notice of such meetings to all JSC members, including the agenda at least [...***...] prior to the meeting; provided, however, that either Party may request an *ad-hoc* JSC meeting (which may be held by teleconference or videoconference) by providing at least [...***...] advance notice to the other Party, if the Party requesting such *ad-hoc* meeting reasonably believes that a significant matter must be addressed prior to the next scheduled (in person) JSC meeting, and the *ad-hoc* meeting will be held as requested.

(f) The Alliance Managers shall be responsible for circulating all relevant materials to enable discussion and decision making at a JSC meeting at least [...***...] prior to such meeting and shall jointly preside at the meeting to ensure the preparation of the meeting minutes. For the avoidance of doubt, the Alliance Managers shall not vote on any decisions of the JSC.

(g) The minutes shall be circulated to both Parties' JSC members promptly following the JSC meeting for review, comment and written approval; provided, however, that both Parties acknowledge that the Alliance Manager of the Party to which the chairperson belongs shall prepare a first draft of the minutes within [...***...] after each meeting.

5.6 Decision-making: The JSC may make decisions with respect to any subject matter within the JSC's functions as described above. Except as expressly provided in this Agreement, all decisions which are to be made by the JSC shall be made by unanimous vote or written consent, with each Party having one vote in all decisions. The JSC shall use best efforts to resolve any disputes over the matters within its roles and functions or otherwise referred to it, and each Party's JSC representatives shall consider in good faith the views of the other Party's JSC representatives in making decisions.

5.7 Right to Decide:

(a) If, with respect to a decision that is to be made by the JSC pursuant to Section 5.6, the JSC cannot reach consensus within [...***...] after it has met to discuss and reach consensus on such matter, the dispute in question shall be referred to the head of the relevant department ("Department Heads") of each of the Parties.

(b) If the Department Heads of the Parties cannot resolve the matter within [...***...], then the matter shall be referred to the President/Chief Executive Officer ("**President/CEO**") of BIAL and the President/CEO of NBIX for resolution. The President/CEOs shall use best efforts to resolve the matter referred to them.

(c) If the Presidents/CEOs cannot resolve the matter within [...***...], then (subject to Section 5.7(d)):

(i) if the dispute relates to [...***...], the President/CEO of NBIX shall have the right to decide the matter, provided that NBIX shall not have the right to decide any matter:

(A) [...***...],

or

(B) [...***...]; and

(ii) if the dispute relates to [...***...], the President/CEO of BIAL shall have the right to decide the matter, provided that BIAL shall not have the right to decide [...***...];

and

(iii) If the dispute relates to [...***...], then neither Party shall have the right to decide the matter [...***...].

(d) For clarity, if the Parties cannot agree the Agreed Sales Forecast or revised Net Sales Estimation then [...***...].

5.8 **Alliance Managers:**

(a) Each Party shall, within the period of [...***...] after the Effective Date, appoint an individual having the appropriate experience, including a general understanding of pharmaceutical development and commercialization matters, to act as the alliance manager for such Party (the “ **Alliance Manager** ”).

(b) The Alliance Managers are not permitted to be a member of the JSC but shall attend meetings of the JSC to perform the functions of the Alliance Manager pursuant to Sections 5.5(e), 5.5(f) and 5.5(g). The Alliance Managers shall be the primary contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder, including facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties.

(c) Each Party may replace its Alliance Manager with an alternative representative at any time with prior written notice to the other Party, but each Party shall use its reasonable endeavours to reduce replacements of its Alliance Manager as much as reasonably possible.

(d) The Alliance Managers shall not, in any manner, take over the role of the JSC and shall not have any rights, powers or discretion except as expressly granted to the Alliance Managers hereunder. In no event will the Alliance Managers have any power to modify or amend this Agreement or to waive any Party's rights under it.

ARTICLE 6
DEVELOPMENT OF THE LICENSED PRODUCTS
IN THE FIELD AND TERRITORY

6.1 Responsibility:

All development activities under the Development License including any Development Studies shall be managed and funded fully and exclusively by NBIX.

6.2 Development Activity:

(a) NBIX shall use Commercially Reasonable Efforts to conduct and complete, at its own expense, each and all of the activities in respect of the development of the Initial Product (and Subsequent Products, if any) in accordance with the then current development and regulatory plan for the Initial Product (and Subsequent Products, if any) within the Field and Territory, including obtaining all possible Exclusivity Rights for the Licensed Products (the "**Development and Regulatory Plan**").

(b) NBIX shall use Commercially Reasonable Efforts to complete any Development Studies and all other activities in the Development and Regulatory Plan in accordance with the timelines set out therein.

(c) NBIX shall at all times, when carrying out any Development Studies, or any other development activities with respect to the Licensed Products, comply with all applicable laws and regulations, including, without limitation, as applicable, the GCPs and GLPs.

(d) NBIX shall not carry out any research or development in respect of any Subsequent Product except in accordance with Section 2.9.

6.3 Development and Regulatory Plans:

(a) The initial development and regulatory plan with an estimated development and regulatory schedule until the US NDA filing for the Initial Product for the Initial Indication within the Field and Territory agreed by the Parties as of the Effective Date (the “ **First Development and Regulatory Plan** ”) is attached hereto as **Exhibit 6.3(a)** .

(b) The First Development and Regulatory Plan is (i) of the essence of this Agreement for BIAL and NBIX and (ii) subject to update in accordance with Section 6.3(c).

(c) NBIX shall submit to the JSC, for JSC’s review and approval (further subject to Section 6.3(f) and to BIAL’s rights under Section 6.3(h)), a revised Development and Regulatory Plan providing updates on a necessary basis but at least once per Calendar Year by [...***...].

(d) Each Development and Regulatory Plan shall (to the extent appropriate to the stage of development reached by the relevant Licensed Product at the date of submission of such plan and/or the time on the market from first commercial sale of the relevant Licensed Product) include a detailed description of the following matters together with a detailed description of the overall budget and the resources to be expended:

(i) proposed Development Studies including their design, purpose, estimated timing of initiation and estimated timings for completion;

(ii) any major regulatory events such as timings for submission of updates to the BIA 9-1067 IND, consultation meetings with the FDA, US NDA filing and anticipated Approval;

(iii) proposals for any Subsequent Products or Subsequent Indications within the Field and Territory;

(iv) publication plans;

(v) market and key opinion leader development plans, including plans to support continuing medical education;

(vi) field based medical science liaison activity plans and strategies; and

(vii) any other development or regulatory information reasonably requested by BIAL.

(e) It is understood that the format in which the information within a Development and Regulatory Plan shall be provided by NBIX to BIAL shall be determined in good faith by NBIX but shall contain, as applicable, a detailed description of the items in Section 6.3(d) and an update thereof.

(f) Subject to (a) NBIX's obligations to consider in good faith all BIAL's comments to each draft Development and Regulatory Plan, and (b) BIAL's right set forth in Section 6.3(h), NBIX shall have the right to make modifications to the then-current Development and Regulatory Plan only to the extent necessary to reflect substantial changes:

(i) [...***...];

(ii) [...***...];

(iii) [...***...];

(iv) [...***...].

(g) The JSC shall review and approve each Development and Regulatory Plan within [...***...] of receipt thereof.

(h) BIAL (rather than the JSC) shall have the right to object to the relevant part of each Development and Regulatory Plan and/or to each Development Study (" **Right to Object** ") within the period of [...***...] mentioned in each of Sections 6.3(g), 6.3(i) and 6.3(j), as applicable, if and only to the extent that:

(i) the relevant part of such Development and Regulatory Plan does not comply with NBIX's obligations under Sections 6.3(f); or

(ii) BIAL reasonably believes in good faith and provides an explanation of such reasonable belief to NBIX that the relevant part of such Development and Regulatory Plan and/or Development Study [...***...].

(i) NBIX shall submit any proposed amendments to the Development and Regulatory Plan for the JSC's review and comment within the period of [...***...] after receipt thereof and subject to all other provisions under this Section 6.3.

(j) If not submitted as part of the Development and Regulatory Plan, NBIX shall submit any proposed Development Study for the Initial Product (and Subsequent Product, if any) in the Territory,

including the final draft protocol thereof, for review and comment by the JSC within the period of [...***...] after receipt thereof.

(k) NBIX shall regularly, through the JSC, keep BIAL fully informed of the status of any Development Study.

6.4 **BIAL Studies:** BIAL shall use Commercially Reasonable Efforts to carry out the BIAL Studies set out in **Exhibit 6.4** .

ARTICLE 7 **REGULATORY**

7.1 General:

(a) NBIX shall be responsible for the filing of and shall own any and all INDs (including the BIA 9-1067 IND), US NDA and other regulatory filings for the Licensed Products within the Field and Territory during the Term.

(b) NBIX shall, in coordination and agreement with BIAL, file all appropriate Orange Book listings in the US and equivalent listings in Canada, if applicable, to provide the maximum protection for Licensed Products that is available under such regulatory procedures.

(c) In addition to the provisions of Article 6 with respect to the Development and Regulatory Plan, the Parties shall discuss NBIX's regulatory strategy for the Licensed Products at the JSC meetings and, if applicable, subteam meetings and NBIX shall in good faith take into consideration BIAL's comments in relation thereto. The Parties acknowledge and agree that [...***...], and each Party, while exercising its rights and fulfilling its responsibilities in Section 7.2, will [...***...] (for the avoidance of doubt, the foregoing shall not be interpreted or construed as limiting BIAL's Right to Object under Section 7.2(b)).

(d) NBIX shall use Commercially Reasonable Efforts to obtain an Approval and all applicable Exclusivity Rights for the Licensed Products within the Field in the Territory.

(e) For so long as BIAL is supplying Licensed Product for the Territory, BIAL shall be responsible for the timely filing and maintenance of the DMF pursuant to Section 7.4 and providing NBIX will all other (i.e., not contained in the closed part of the DMF) chemistry, manufacturing and controls ("CMC ") information necessary for Regulatory Filings in the Territory.

7.2 Regulatory Filings and Interactions with an Agency:

(a) NBIX shall inform BIAL, through the Development and Regulatory Plan, regular JSC meetings and subcommittee meetings if applicable, of any regulatory filings or material interactions with an Agency. Within [...***...], the heads of regulatory for each Party shall begin discussions on a draft label to be submitted to an Agency. In addition, NBIX shall, prior to submission or responding to an Agency, provide BIAL, for review and written approval for a period of [...***...], with a draft of any label related documents and materials, including a summary of product characteristics, patient information leaflet and primary and secondary packaging (**“Label Related Documents & Materials”**). Notwithstanding the terms of the previous sentence, in the event that the Parties agree that NBIX should respond to the relevant Agency within a period shorter than [...***...], the Parties shall also agree a time period for BIAL’s review of the draft Label Related Documents & Materials. In the event that the Parties agree that NBIX should respond to the relevant Agency within a period shorter than [...***...] but are unable to agree the time period for BIAL’s review, NBIX shall, as a minimum, provide BIAL with a draft of the Label Related Documents & Materials to be submitted to the Agency for review by BIAL [...***...], and BIAL shall have [...***...] to review such materials.

(b) BIAL shall have the right to withhold its approval to the draft Label Related Documents & Materials (**“Right to Object”**) prior to the first submission thereof to an Agency in the Territory if the Label Related Documents & Materials or part thereof would, in BIAL’s reasonable opinion, [...***...]; provided, however, in exercising its Right to Object, BIAL shall not object to [...***...]. After the first submission of the Label Related Documents & Materials approved by BIAL, BIAL shall only have the Right to Object if the Label Related Documents & Materials or part thereof would, in BIAL’s reasonable opinion, have the potential to materially adversely affect [...***...]. Notwithstanding the foregoing, BIAL’s Right to Object may not be exercised by BIAL in respect of any portion of the Label Related Documents & Materials that [...***...]

[...***...] despite NBIX having used Commercially Reasonable Efforts to clear or overcome it.

(c) NBIX shall inform BIAL of any proposed filings, including annual updates, in respect of the BIA 9-1067 IND (the “ **IND Filings** ”) and provide BIAL, for review within the period of [...***...], with a draft of any such IND Filings. BIAL shall have the right to comment on such IND Filings and NBIX shall take all comments of BIAL into account before such IND Filings are filed with an Agency. Notwithstanding the terms of the previous sentence, in the event that the Parties agree that NBIX should submit an IND Filing other than an annual update to the FDA within a period shorter than [...***...], the Parties shall also agree a time period for BIAL’s review of the draft. In the event that the Parties agree that NBIX should respond to the relevant Agency within a period shorter than [...***...] but are unable to agree the time period for BIAL’s review, NBIX shall, as a minimum, provide BIAL with a draft of such IND Filing by BIAL at the same time as such IND Filing is first circulated for review within NBIX, and BIAL shall have the same amount of time as NBIX personnel to review and comment on such IND Filing. NBIX shall provide BIAL with a copy of each IND Filing in respect of the BIA 9-1067 IND in the form that it has been filed with the relevant Agency.

(d) NBIX shall provide BIAL with a copy of each document filed with an Agency in connection with the Licensed Products. In addition, BIAL shall have the right to participate in any NBIX internal meetings related to Agency Interactions or regulatory filings for a Licensed Product in the Territory.

(e) BIAL shall have the right to participate in or attend any in-person or material telephonic meetings with the FDA or other Agencies in the Territory (“ **Agency Interactions** ”) to the extent that Agency permits the participation or attendance of BIAL. Prior to any such Agency Interactions, NBIX shall provide BIAL with a draft (or electronic access thereto) of any communication, agenda and/or notice (“ **Interaction Agenda** ”) of any planned interaction [...***...] and shall consider in good faith any comments provided by BIAL within the period of [...***...]. Notwithstanding the terms of the previous sentence, in the event that such Interaction Agenda is not available [...***...], NBIX shall provide BIAL with a draft of such Interaction Agenda for review by BIAL [...***...], and BIAL shall have [...***...] to review such Interaction Agenda.

(f) NBIX understands and acknowledges that BIAL, as the Marketing Authorization holder of Licensed Products containing the BIA 9-1067 API outside the Territory and/or as licensor and/or supplier of such Licensed Products within and outside the Territory, may be interested in, from time to time, submitting or having submitted certain variations, supplements, amendments, changes or updates to any IND (including the BIA 9-1067 IND), NDAs, Approvals or any other regulatory filings to an Agency in the Territory, in order to keep such regulatory filings up to date with other regulatory filings outside the Territory (“ **Data Update Filings** ”) and/or to register other manufacturers (including packagers) and/or routes or processes of manufacture (including packaging) of BIA 9-1067 API or Licensed Products (“ **Supply Related Filings** ”). BIAL acknowledges and understands that NBIX, as the holder of the BIA 9-1067 IND and the eventual Marketing Authorization holder for Licensed Products in the Territory, is responsible for assuring that any such regulatory submissions meet regulatory standards. Accordingly, subject to Section 7.4, NBIX shall, within the period of [...***...], review and provide comments regarding the documentation to BIAL, which BIAL shall reasonably consider in good faith. In the event NBIX and BIAL are unable to agree on the documentation, the issue will be submitted to the JSC for discussion and final decision to determine if any such comments by NBIX are necessary to assure such regulatory filings meet regulatory standards. NBIX shall be under the obligation to adopt the JSC’s comments, recommendations, and proposed changes if any to such regulatory filings. Should the Parties be unable to reach a joint decision at the JSC within [...***...] of the matter being referred to the JSC, then such matter shall be finally decided [...***...]. If NBIX does not provide any comments, or after NBIX has received the revised documentation from BIAL following BIAL’s receipt of NBIX’s comments, or after BIAL has confirmed, following BIAL’s receipt of NBIX’s comments, that it has no modifications to the documentation, then within [...***...], NBIX shall file at the appropriate Agency in the Territory any and all such variations, amendments, changes or updates to any IND (including the BIA 9-1067 IND), NDAs, Approvals or any other regulatory filings as requested in accordance with the terms of this Section 7.2(f) by BIAL.

7.3 **NDA:**

(a) Subject to Sections 7.3(d) and (e), NBIX shall use Commercially Reasonable Efforts to file an NDA in the US for the Initial Product for:

(i) the Initial Indication, by the later of (A) [...***...] or (B) [...***...] after the receipt of meeting minutes from the pre-NDA meeting with the FDA confirming that there is sufficient or adequate information to file an NDA submission in the US;

And

(ii) each Subsequent Product and/or Subsequent Indication, by the date set forth in the then current and approved Development and Regulatory Plan.

(b) Subject to Sections 7.3(d) and 7.3(e), in the event that the FDA does not require any further Phase III Clinical Trial for the submission of an application for an Approval of the Initial Product for the Initial Indication, then if NBIX has not submitted an NDA in the US by [...***...] (despite NBIX having used its Commercially Reasonable Efforts to do so), then BIAL shall have the right to terminate the Agreement under Section 15.2(c).

(c) Subject to Section 7.3(d), in the event that the FDA requires a further Phase III Clinical Trial for the submission of an application for an Approval of the Initial Product for the Initial Indication, then if NBIX has not submitted an NDA in the Territory by [...***...] (despite NBIX having used its Commercially Reasonable Efforts to do so), then BIAL shall have the right to terminate the Agreement under Section 15.2(c).

(d) If **(i)** BIAL is in material breach of, or is materially delayed in performing, any of its obligations under this Agreement, including timely completion of the Transfer Plan under Section 2.6(b) and timely DMF submission under Section 7.4, or if **(ii)** NBIX's development of the Initial Product is delayed by reason of an unexpected significant safety issue not within the control of NBIX, and by reason of that material breach, material delay or significant safety issue, the filing of the NDA in the US is delayed, then in each case the deadlines in Sections 7.3(b) and 7.3(c) shall be extended by [...***...].

(e) If:

(i) the FDA does not require any further Phase III Clinical Trial for submission of an application for an Approval of the Initial Product for the Initial Indication but does requires Clinical Trials which are not contemplated in the First Development and Regulatory Plan,

and

(ii) by reason of carrying out such Clinical Trials the filing of the NDA in the US is delayed,

then the deadline in Section 7.3(b) shall be extended by [...***...]. For clarity, the delays set forth in this Section 7.3(e) and 7.3(d) are cumulative, if applicable.

(f) Without prejudice to the foregoing provisions of this Section 7.3, NBIX shall use Commercially Reasonable Efforts to, within [...***...] from the Effective Date, request an FDA

meeting seeking guidance from the FDA on the appropriateness of the data package for a potential NDA filing and whether the FDA will require an additional Phase III Clinical Trial to be completed prior to submission of the NDA for the first Licensed Product in the Initial Indication.

7.4 Drug Master File: BIAL, itself or through its Affiliate, shall be responsible for filing and maintaining, directly or through a Third Party appointed by BIAL, the Drug Master File relating to the manufacture of the BIA 9-1067 API (“**DMF**”). BIAL shall file and maintain such DMF in its own name and/or in the name of its relevant suppliers and shall permit NBIX to cross-reference such DMF in its regulatory filings for Licensed Products in the Territory. BIAL, itself or through a Third Party appointed by BIAL, shall be responsible for providing to NBIX all information requested by NBIX related to the manufacture of Licensed Products by dates set forth in the applicable Regulatory and Development Plan.

7.5 Pharmacovigilance

(a) Promptly following the Effective Date, but in no event later than [...****...] thereafter, BIAL or its Affiliate and NBIX shall develop and agree upon safety data exchange procedures in a separate and detailed Safety Data Exchange Agreement (“**SDEA**”). The SDEA shall, *inter alia*, describe the collection, investigation, analysis, reporting and exchange of information concerning adverse events and product safety relating to the Licensed Products, sufficient to permit each Party to comply with its legal or regulatory obligations, including to the extent applicable, those obligations contained in ICH guidelines.

(b) NBIX shall be responsible for pharmacovigilance activities in the Territory, including maintenance of a local safety database of the Licensed Products for the Territory, and shall provide BIAL with the data in such safety database.

(c) BIAL or its Affiliates shall be responsible for pharmacovigilance activities outside the Territory, including the maintenance of worldwide database for the Initial Product and, subject to Section 7.5(d), Subsequent Products, which will include the data in the local safety database of the Licensed Product for the Territory provided by NBIX.

(d) In the event that any Combination Product is agreed to be developed and/or commercialized by NBIX, the Parties shall also discuss and agree appropriate pharmacovigilance provisions with respect to such Combination Product.

7.6 Audits:

(a) During the Term, NBIX shall allow (and cause its contractors to allow) BIAL or a Third Party appointed by BIAL to access, examine or audit, in accordance with the Quality Agreement and the SDEA, (i) the conduct and results of any Development Studies and (ii) all the safety and pharmacovigilance activities related to the development or commercialization of the Licensed Products

in the Territory, including in each case (i) and (ii) the facilities and equipment at or with which the activities are or were conducted, and personnel, procedures, programming, and any documents, data and records related to such activities, with reasonably advanced written notice (except in the event of For Cause Audits pursuant to Section 7.6(b)) during regular business hours to determine whether such activities are being or have been conducted in accordance with this Agreement, the SDEA, the Supply Agreement and the Quality Agreement and with all applicable laws and regulations, including without limitation, and as applicable, Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices, and Good Pharmacovigilance Practices. NBIX shall also cooperate (and cause its contractors to cooperate) with BIAL by providing, in a timely manner, all the information and resources necessary for the preparation, conduct and report of the audit. After the audit and upon receipt of the audit findings in the form of a report, NBIX agrees to (and cause its contractors to) define and implement corrective and/or preventive actions in a timely manner.

(b) In the event that an audit pursuant to Section 7.6(a) reveals material non-compliance issues with NBIX's obligations under this Agreement, the SDEA, the Supply Agreement and the Quality Agreement, BIAL or its Affiliates shall have the right to subsequently audit NBIX and/or its contractors by providing reasonable advance written notice but in any event such advance written notice may be made within [...***...] of completion of the audit conducted pursuant to Section 7.6(a) (“ **For Cause Audit** ”).

(c) During the Term, BIAL shall allow (and use Commercially Reasonable Efforts to cause its contractors to allow) NBIX or a Third Party appointed by NBIX to access, examine or audit, in accordance with the Quality Agreement, the Supply Agreement, and the SDEA, **(i)** the conduct and results of any Development Studies, **(ii)** all the safety and pharmacovigilance activities related to the development or commercialization of the Licensed Products in the Territory, and **(iii)** the manufacture of Licensed Product, including in each case (i), (ii) and (iii) the facilities and equipment at or with which the activities are or were conducted, and personnel, procedures, programming, and any documents, data and records related to such activities, with reasonably advanced written notice (except in the event of For Cause Audits pursuant to Section 7.6(d)) during regular business hours to determine whether such activities are being or have been conducted in accordance with this Agreement, the SDEA, the Supply Agreement and the Quality Agreement and with all applicable laws and regulations, including without limitation, and as applicable, Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices, and Good Pharmacovigilance Practices. BIAL shall also cooperate (and use reasonable efforts to cause its contractors to cooperate) with NBIX by providing, in a timely manner, all the information and resources necessary for the preparation, conduct and report of the audit. After the audit and upon receipt of the audit findings in the form of a report, BIAL agrees to (and use reasonable efforts to cause its contractors to) define and implement corrective and/or preventive actions in a timely manner.

(d) In the event that an audit pursuant to Section 7.6(c) reveals material non-compliance issues with BIAL's obligations under this Agreement, the SDEA, the Supply Agreement and the Quality Agreement, NBIX or its Affiliates shall have the right to subsequently audit BIAL and/or its contractors

by providing reasonable advance written notice but in any event such advance written notice may be made within [...***...] of completion of the audit conducted pursuant to Section 7.6(c) (“ **For Cause Audit** ”).

7.7 Medical inquiries:

(a) NBIX shall be responsible for handling all medical questions or inquiries for the Field in the Territory with regard to the Licensed Products (including setting up a call center or other centralized response center in connection therewith), but shall consider in good faith input from BIAL or its Affiliate in connection therewith.

(b) NBIX shall promptly forward any and all medical questions or inquiries which it receives in relation to the Licensed Product in the Field outside the Territory to BIAL in accordance with all applicable laws.

(c) BIAL or its Affiliate shall be responsible for handling all medical questions or inquiries for the Field with regard to the Licensed Products outside the Territory, but shall consider in good faith input from NBIX or its Affiliate in connection therewith.

(d) BIAL or its Affiliate shall promptly forward any and all medical questions or inquiries which it receives in relation to the Licensed Product in the Field in the Territory to NBIX in accordance with all applicable laws.

(e) The Parties shall timely cooperate and establish the procedures reasonably necessary (such as periodic meetings via teleconference or videoconference) to ensure the consistency and correctness of the medical information provided by the Parties.

7.8 Recalls and Withdrawals:

(a) **Notification and Determination:** In the event that any Agency threatens or initiates any action to recall or withdraw a Licensed Product from the market in or outside the Territory, the Party receiving notice thereof shall promptly notify the other Party of such communication, but in no event later than [...***...] after receipt thereof. NBIX, as the Approval holder for the Licensed Products in the Territory, shall determine whether to initiate any recall or withdrawal of such Licensed Product in the Territory, including the scope of such recall or withdrawal (*e.g.* , a full or partial recall, or a temporary or permanent recall); provided, however that to the extent practicable and appropriate based on the reasons for the recall or withdrawal, before NBIX initiates a recall or withdrawal, the Parties shall promptly discuss in good faith the reasons therefor, provided that such discussions shall not delay any action that any Party reasonably believes has to be taken in relation to any recall. In the event of any such recall or withdrawal, NBIX shall implement any necessary action to conduct such recall or withdrawal. As the manufacturer of Licensed Products, BIAL shall use a batch tracing system which will allow NBIX to identify, on a prompt basis, customers within the Territory or patients enrolled in

Development Studies in the Territory who have been supplied with Licensed Product of any particular batch(es), and to recall such batches from such customers or patients, as the case may be. For clarity, all matters relating to a withdrawal or recall of a Licensed Product outside the Territory will be determined, coordinated and controlled by BIAL.

(b) **Cost Allocation:** All out-of-pocket and internal costs and expenses incurred by the Parties for implementing the recall or withdrawal or market notification of a Licensed Product (“ **Recall Costs** ”) in the Territory shall initially be borne by each Party and subsequently be allocated between BIAL and NBIX as follows:

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

(c) **Assistance for the Licensed Product:** Each Party shall promptly inform the other Party of any notification of any action by, or other information which it receives (directly or indirectly) from, any Regulatory Authority (together with copies of correspondence related thereto), which (i) raises any material concerns regarding the safety, efficacy or quality of a Licensed Product, (ii) indicates or suggests a potential material liability for either Party to Third Parties arising in connection with a Licensed Product or (iii) which indicates a reasonable potential for a recall or market withdrawal of a Licensed Product.

7.9. **Re-Manufacturing Costs:**

All out-of-pocket and internal costs and expenses incurred by BIAL in connection with the replacement, re-manufacturing, re-packaging or re-labeling of Licensed Products, including without limitation, where applicable, costs of the BIA 9-1067 API and other materials (collectively, “ **Re-Manufacturing Costs** ”) shall be allocated between the Parties as follows:

[...***...]

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

ARTICLE 8
COMMERCIALIZATION OF THE LICENSED PRODUCTS
IN THE FIELD AND TERRITORY

8.1 General:

(a) NBIX shall be solely responsible for commercializing the Licensed Products within the Field and Territory and for the day-to-day commercial activities in the Territory at its sole expense and in accordance with all applicable laws and regulations.

(b) Notwithstanding anything in this Agreement to the contrary, [...***...]:

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

8.2 Annual Commercialization Plan:

(a) NBIX shall prepare a draft annual commercialization plan (“**Annual Commercialization Plan**”) for review, comment and approval by the JSC. The first draft Annual Commercialization Plan shall be provided to the JSC by [...***...].

(b) NBIX shall submit to the JSC, for the JSC’s review, comment and approval, a new Annual Commercialization Plan updated on a necessary basis but at least once a year by [...***...] of each Calendar Year.

(c) Each Annual Commercialization Plan shall, to the extent relevant when considering either the time to the first commercial sale of the Licensed Products or the time from the first commercial sale of the Licensed Products, provide an estimated plan for implementing each of the following activities, together with a reasonable description of the overall budget and the resources to be expended, which budget and resources must reflect an appropriate resource commitment for the applicable Commercial Year, and NBIX's reasonable justification for each of the expenditures set forth in such budget:

(i) Plans for conducting market research on the Licensed Products and their findings;

(ii) Market analysis including customer and competitor assessments, revised and updated as and when new compounds enter the market;

(iii) Plans for positioning, branding and key messages for the Licensed Products and any changes from previous Calendar Years, including promotional materials, campaigns and messaging by audience;

(iv) Plans and strategies for presenting the Licensed Products at national or international congresses or major meetings in the Territory;

(v) Market access plans for the Licensed Products including strategies and distribution plans with respect to managed care organizations, hospital systems, group purchasing organizations, physicians networks, pharmacies and any other private or government healthcare providers or reimbursement entities;

(vi) Sales force activity plans for the Licensed Products by sales territory, customer segmentation by prescribing decile, the minimum number of Details to be executed, sales training activities and promotional materials;

(vii) Sales forecast for the Licensed Products for the following [...***...]; and

(viii) Relevant commercial or marketing information that is reasonably requested by the JSC.

(d) It is understood that the format in which the information within an Annual Commercialization Plan shall be provided by NBIX to the JSC shall be determined in good faith by NBIX .

(e) The JSC shall review and approve each Annual Commercialization Plan within [...***...] of receipt thereof. NBIX shall be under the obligation to consider and adopt the JSC's comments, recommendations and proposed changes made to the Annual Commercialization Plan.

(f) NBIX shall submit any proposed amendments to the Annual Commercialization Plan for JSC review, comment and approval within the period of [...***...] after receipt thereof. NBIX shall be under the obligation to consider and adopt the JSC's comments, recommendations and proposed changes made to such proposed amendments to the Annual Commercialization Plan.

(g) The Parties agree, in order to manage the commercial collaboration, to set up a commercial subteam, operating under the JSC. NBIX shall at each such subteam meeting, provide a detailed update to BIAL summarizing, on an item by item basis, the implementation of the Annual Commercialization Plan and the results thereof, including, without limitation, commercial performance of the Licensed Products.

8.3 NBIX's Commercialization Obligations:

(a) NBIX shall use Commercially Reasonable Efforts to market and sell each Licensed Product in the Field in the US, and, subject to the terms of the rest of this Section 8.3, shall invest such resources for such marketing and sale that are consistent with its exercise of Commercially Reasonable Efforts.

(b) NBIX shall at all times market and promote the Licensed Products in accordance with the Approvals and applicable laws.

(c) In accordance with the Annual Commercialization Plan, NBIX shall use Commercially Reasonable Efforts:

(i) to launch each Licensed Product for each indication within the Field within [...***...] after the grant of an Approval by each relevant Agency (and other Agency or other governmental or legal requirements necessary for launch) for such indications;

(ii) to ensure a competitive share of voice, including without limitation the agreed number and type of field based personnel, as set out in the then current Annual Commercialization Plan in order to maximize the commercial value of the Licensed Product for approved indications in the Territory during the Term; and

(iii) to employ or otherwise engage, prior to the anticipated first commercial sale of the Initial Product in the US, and maintain during at least the first [...***...], at least the following resources to be utilized by NBIX in commercializing the Initial Product:

- a. a field sales force of at least [...***...] Detailing the License Products to movement disorder neurologists and other select neurologists who prescribe L-dopa to drive initial trial and adoption;

- b.** a national accounts/payor group of at least [...] presenting Licensed Products to key commercial, Medicare Part D, and Medicaid health plan payers and decision-makers to secure formulary coverage and/or to remove step therapy requirements or unreasonably high patient co-pays;
- c.** a medical science liaison force of at least [...] engaging with payors and key opinion leaders/thought leaders in Parkinson’s disease to develop advocacy and support for the Licensed Products. MSLs will also interface with patient advocacy organizations like the National Parkinson’s Foundation and the Michael J. Fox foundation to build awareness and educate their constituencies;
- d.** a medical affairs and publications group of at least [...] will support scientific communications, including presentation of key data at medical congresses such as the International Parkinson’s and Movement Disorder Society annual meetings, the American Academy of Neurology, and other relevant scientific meetings. In addition, this group will respond to inbound questions from prescribers on off-label topics;
- e.** a brand team of at least [...] will support Licensed Products by creating a branded campaign for health care professionals (sales materials, journal ads, website, etc.), building a speakers bureau to enable peer-to-peer education, branded booth and promotional activities at scientific meetings, and , if appropriate, direct-to-patient education and advertising to drive product requests.

(d) The Parties shall discuss and agree the first Sales forecast in Units of Initial Product for the [...] (each a “ **Commercial Year** ”) following the first commercial sale of the Initial Product in the US (the “ **Agreed Sales Forecast** ”) at the JSC meeting following the receipt of meeting minutes from the pre-NDA meeting with the FDA confirming that there is sufficient or adequate information to file an NDA submission in the US. Thereafter the Agreed Sales Forecast shall be agreed on an annual basis for the following [...] by the JSC following submission of the Annual Commercialization Plan.

(e) The Parties agree that, based on the assumptions set forth in **Exhibit 8.3(e)** (the “ **Assumptions** ”), the Agreed Sales Forecasts are expected to be consistent with achieving Net Sales of [...] in the [...] (the “ **Net Sales Estimation** ”). The Parties acknowledge and agree that such Assumptions are the basis for determining the first Agreed Sales Forecast but to the extent that [...], then the Parties shall consider their impact on the Net Sales Estimation and, if any, the Parties shall discuss and agree a revised Net Sales Estimation and the Agreed Sales Forecasts that are consistent with achieving such a revised Net Sales Estimation.

If the Parties cannot agree the Agreed Sales Forecast or the revised Net Sales Estimation, then the matter shall be referred to the President/CEO of each Party for resolution, and if such President/CEOs are not able to resolve the matter, it shall be [...***...].

(f) Subject to Section 8.3(i), starting in the [...***...] until and including the [...***...], NBIX shall sell at least [...***...] for such Commercial Year (“**Minimum Sales**”).

(g) Subject to Section 8.3(i), in the event that NBIX fails to achieve the Minimum Sales in [...***...] Commercial Year (i.e., [...***...]), as NBIX’s sole liability and BIAL’s sole remedy for such failure, NBIX shall pay BIAL an amount corresponding to [...***...] (the “**Difference**”). The Difference for the purposes of this Section 8.3(g) and Section 8.3(h) shall be calculated as [...***...].

(h) Subject to Section 8.3(i), in the event that NBIX fails to achieve the Minimum Sales in any [...***...] Commercial Years, including any Commercial Years in which NBIX has paid the Difference to BIAL, as NBIX’s sole liability and BIAL’s sole remedy for such failure (but shall not be NBIX’s sole liability and BIAL’s sole remedy to the extent that such failure was caused by a material breach of any of NBIX’s other obligations under this Agreement), BIAL shall have the right at its discretion to **(i)** request NBIX to pay the Difference for such second Commercial Year or **(ii)** terminate the Agreement pursuant to Section 15.2(c).

(i) NBIX shall not be in breach of its Minimum Sales obligations to the extent that the failure to achieve Minimum Sales is a result of one or more of the following circumstances (as NBIX shall be under the obligation to demonstrate):

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

8.4 Promotional Materials and Documents:

(a) In addition to the provisions of Section 2.1(e), all promotional materials and documents used by NBIX shall be prepared by reference to the Global Brand Identity for the Licensed Products as defined by BIAL, to the extent allowed under the laws and regulations in the Territory.

(b) NBIX shall provide BIAL with final copies of key promotional materials for the Licensed Product to be used by NBIX in the Territory. Notwithstanding the foregoing, all liability in connection with such promotional materials and their compliance with the Approvals, applicable laws and regulations shall lie solely with NBIX, except as may be provided otherwise in the Co-Promotion Agreement.

(c) NBIX shall provide BIAL with drafts of core promotional materials for the Licensed Product to be used by NBIX in the Territory for BIAL's review and comment within the period of [...***...] upon receipt thereof. NBIX shall be under the obligation to take into good faith consideration all BIAL's reasonable comments. Notwithstanding the foregoing, all liability in connection with such promotional claims and their compliance with the Approvals, applicable laws and regulations shall lie solely with NBIX.

8.5 Sales Information:

(a) NBIX shall, through the JSC, and at all times upon BIAL's written reasonable request, keep BIAL informed of the status of the commercialization of the Licensed Products in the Territory.

(b) Notwithstanding the above, NBIX shall provide BIAL, by the [...***...] after the end of each calendar month, with a summary of Net Sales, Net Sales Volume and Net Selling Price for the preceding calendar month for the Licensed Products in the Territory. All such information shall be NBIX's Confidential Information.

ARTICLE 9

COOPERATION, DATA SHARING AND PUBLICATIONS

9.1 Cooperation:

(a) Each Party shall keep the other Party reasonably informed through the JSC and any relevant subcommittees as to its and its Affiliates' development, regulatory, manufacturing (to the extent required in the Supply Agreement), and commercialization efforts, as applicable, with respect to the Licensed Products in the Field, in the case of BIAL outside the Territory, and in the case of NBIX, inside the Territory.

(b) BIAL shall have the right to inform its licensees outside the Territory of NBIX's development, regulatory and commercialization efforts and activities with respect to the Licensed

Products in the Field in the Territory solely for the purpose of the development, manufacture, registration and commercialization of the Licensed Products in their respective territory outside the Territory. BIAL shall, to the extent Controlled by BIAL, keep NBIX informed of BIAL's licensees' development, regulatory and commercialization efforts and activities with respect to the Licensed Products in the Field in their respective territories solely for the purpose of NBIX's development, registration and commercialization of the Licensed Products in the Territory. BIAL acknowledges and agrees that, as of the Effective Date, it has the right to keep NBIX informed of its Existing Licensees' development, regulatory and commercialization efforts and activities with respect to the Licensed Products in the Field in their respective territories. [...***...].

(c) Each Party shall cooperate as reasonably requested by the other Party in an effort to ensure that the development of the Licensed Products within the Field is coordinated worldwide; *provided however* that this shall not be interpreted or construed as limiting BIAL's and NBIX's rights and obligations, or expanding BIAL's or NBIX's obligations, in each case under this Agreement.

9.2 Data Sharing:

(a) NBIX and BIAL, respectively, shall provide to each other access to or a copy of their respective Data, free of charge and in a timely fashion and as promptly as possible upon request of each of BIAL or NBIX. Each Party shall have the right to use and reference such Data for the purpose of, as applicable, developing, manufacturing, registering and/or commercializing the Licensed Products (i) with respect to NBIX in the Field and in the Territory during the Term and after expiration (but not after termination) of this Agreement and (ii) with respect to BIAL outside the Territory during and after the Term.

(b) BIAL shall have the right to sublicense its right to use and cross-reference NBIX's Data to BIAL's Affiliates outside the Territory and to BIAL's or BIAL's Affiliates' licensees outside the Territory to use and cross-reference Data of NBIX in seeking Marketing Authorizations for Licensed Products in their respective territories outside the Territory

(c) BIAL and its Affiliates existing licensees to the Licensed Products as of the Effective Date are set forth on Exhibit 9.2(c) (the "Existing Licensees"). BIAL shall, to the extent Controlled by BIAL, grant the right to NBIX to use and cross-reference the Existing Licensees' Data inside the Territory. [...***...]. BIAL shall use reasonable efforts to obtain from its and its Affiliates' future licensees outside the Territory the right and license to provide to NBIX, without any further payment

obligations, access to, and the right to use and reference, the Data (including all data required by an Agency) owned or controlled by such licensees.

(d) For clarity, none of NBIX, BIAL, BIAL's Affiliates or BIAL's or its Affiliates' licensees shall be obligated to successfully obtain Data and the provisions of this Section 9.2 shall only apply to the extent such Data are actually obtained.

9.3 **Publications:**

(a) Each Party recognizes that the publication of papers regarding results of research and clinical studies and other information regarding the Licensed Products, including oral presentations and abstracts, could contribute to not only the profits of the Parties but also the development of science and technology in the world, provided, however, that such publications are subject to reasonable control to protect the other Party's Confidential Information. Accordingly:

(i) BIAL shall have the right to review and comment on any material, manuscript or abstract proposed for disclosure or publication by NBIX, such as by written, visual or other form of presentation, manuscript or abstract, relating to the Licensed Products, and

(ii) NBIX shall have the right to review and comment on any material, manuscript or abstract proposed for disclosure or publication by BIAL, such as by written, visual or other form of presentation, manuscript or abstract, relating to the Licensed Products.

(b) Before any such material, abstract or manuscript is submitted for publication or presentation, the Party proposing publication (" **Publishing Party** ") shall deliver its complete copy, in English language, to the other Party at least [...***...] prior to submitting the material, abstract or manuscript to a Publishing Party or initiating any other disclosure. Such other Party shall make reasonable efforts to expedite review of such materials, abstract or manuscripts, and shall return such items as soon as practicable to Publishing Party with appropriate comments, if any, but in no event later than [...***...] from the date of delivery to the non-publishing Party. Publishing Party shall comply with the other Party's request to delete references to the other Party's Confidential Information in any such material, abstract or manuscript and agrees to delay any submission for publication or other public disclosure for a period of at least additional [...***...] for the purpose of allowing the preparation and filing of appropriate patent applications.

(c) Neither Party may publish a paper in the event that the other Party objects based on sound scientific reasons and provides written justification for such objection. If such justification is acceptable to the Publishing Party, then the Publishing Party shall edit the proposed publication in accordance with the other Party's comments. In the event that there still exists a dispute between the Parties in respect of a proposed publication, the dispute shall be submitted to the JSC and shall be decided in accordance with the mechanism set forth in Section 5.4(ix) and Section 5.7(c)(iii).

(d) For clarity, nothing in this Section 9.3 shall affect either Party's obligations under applicable laws, regulations and guidelines to disclose any data relating to the development of Licensed Products.

9.4 Use of BIAL Know-How, NBIX Know-How, Data, publications and other regulatory documents:

(a) NBIX:

(i) NBIX shall only use and disclose BIAL Know-How, Data, publications and regulatory documents Controlled by BIAL and provided pursuant to Sections 2.6 and 9.2 to its Affiliates and Third Party contractors as required or useful to develop, file, obtain and maintain Approval of and commercialize Licensed Products in the Field in the Territory pursuant to the licenses granted to NBIX under this Agreement.

(ii) NBIX may use and disclose such BIAL Know-How, Data, publications and regulatory documents Controlled by BIAL to NBIX Affiliates and Third Party contractors in connection with development activities, marketing activities, medical education activities, professional services activities and public relations activities; or for purposes of obtaining consultation services in the normal course of business (such as business consultants, advertising agencies, law firms, accounting firms, etc.) in each case solely to the extent necessary or useful for development, filing, obtaining and maintaining Approvals and commercialization of Licensed Products in the Field in Territory. Any disclosure of such Data, publications and regulatory documents shall be subject to Article 13 and NBIX shall be responsible for the conduct of such NBIX's Affiliates and NBIX's Third Party contractors in respect of such Data.

(iii) NBIX may not use (or permit any Affiliate or Third Party to use) any such BIAL Know-How, Data, publications and regulatory documents outside the Territory, or outside the Field, or for any products other than the Licensed Products.

(b) BIAL:

(i) BIAL shall only use and disclose NBIX Know-How, Data, regulatory filings, publications and regulatory documents Controlled by NBIX and provided pursuant to Sections 9.2 and 9.3 to BIAL's Affiliates, and to BIAL's or BIAL's Affiliates' licensees outside the Territory, as required or useful to develop, file for, obtain and maintain Marketing Authorization for, and commercialize Licensed Products in the Field outside the Territory pursuant to the licenses granted by NBIX to BIAL under this Agreement.

(ii) BIAL may use and disclose such Data, regulatory filings, publications and regulatory documents to Affiliates and Third Party contractors in connection with development activities, marketing activities, medical education activities, professional services activities and

public relations activities; or for purposes of obtaining consultation services in the normal course of business (such as business consultants, advertising agencies, law firms, accounting firms, etc.) in each case solely to the extent necessary for development, filing, obtaining and maintaining Marketing Authorization and commercialization of Licensed Products in the Field outside the Territory. Any disclosure of such Data shall be subject to Article 13 and BIAL shall be responsible for the conduct of such BIAL's Affiliates and BIAL's or BIAL's Affiliates' licensees in respect of such Data.

(iii) BIAL may not use (or permit any Affiliate or Third Party to use) any such Data, regulatory filings, publications and regulatory documents inside the Territory, or outside the Field or for any products other than the Licensed Products or products comprising BIA 9-1067.

9.5 Maintenance of Records:

Each Party shall, in accordance with its same practice for its own products or compounds, maintain records for the minimum period by law applicable to such records, in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes, which shall fully and properly reflect works done and results achieved by or on behalf of each Party in the performance of development activities pursuant to this Agreement.

9.6 No Insider Trading:

BIAL acknowledges that NBIX is a publicly traded company and that under this Agreement BIAL will learn of material, non-public information regarding NBIX. BIAL understands that federal and state securities laws prohibit employees of BIAL from purchasing or selling NBIX securities while in possession of any such information and from disclosing such information to others.

ARTICLE 10 DEVELOPMENT INTELLECTUAL PROPERTY

10.1 Ownership of Development Intellectual Property: All Development Intellectual Property conceived solely by the employees of a Party shall be owned by that Party. Development Intellectual Property conceived by employees of both Parties shall be jointly owned by the Parties, each having an equal and undivided interest in such Development Intellectual Property.

(a) Any Development Intellectual Property that BIAL Controls or is jointly owned by the Parties shall, with respect to the Territory, be encompassed by the licenses set forth in Section 2.1 without additional consideration other than the payments set forth in Article 3.

(b) The Parties agree that, to the extent it is required by the laws of any country, the Parties shall execute necessary documentation to reflect or record any licenses under jointly owned Developmental Intellectual Property granted to the other Party in accordance with this Agreement.

10.2 Prosecution of BIAL Patents covering Development Intellectual Property, Joint Patents and NBIX Patents :

(a) Each Party shall have the right, at its own expense, to file, prosecute, maintain, defend and enforce the Patents covering Development Intellectual Property which are owned or Controlled solely by that Party, subject to the remainder of this Section 10.2. Upon filing of such Patents of BIAL, it shall become a BIAL Patent as set forth in the definition of BIAL Patents. Upon filing of such Patents of NBIX, it shall become a NBIX Patent as set forth in the definition of NBIX Patents.

(b) BIAL shall have the right to file, prosecute and maintain inside and outside the Territory any Joint Patents; provided however that BIAL shall provide NBIX with a copy of such Patents to be filed by BIAL and a copy of communications between its agents and any patent office regarding such Joint Patents, within a reasonable deadline prior to submitting such Joint Patents and communications to the patent office. Provided that NBIX responds within the specified deadline, BIAL shall consider or cause its agents to consider, in good faith, any reasonable comments NBIX may have regarding such Joint Patents or communication, provided that the final prosecution decisions shall rest solely with BIAL. NBIX shall be responsible for any expenses that it may incur in providing its comments.

(c) NBIX shall provide BIAL with a copy of any NBIX Patents to be filed by NBIX and a copy of communications between its agents and any patent office regarding such NBIX Patents, within a reasonable deadline prior to submitting such NBIX Patents and communications to the patent office. Provided that BIAL responds within the specified deadline, NBIX shall consider or cause its agents to consider, in good faith, any comments BIAL may have regarding that NBIX Patents or communications, provided that final prosecution decisions shall rest with NBIX. BIAL shall be responsible for any expenses that it may incur in providing its comments. NBIX shall pay all official taxes, annuities, renewal and maintenance fees required to keep in force all issued NBIX Patents covering Development Intellectual Property solely owned or Controlled by NBIX.

(d) BIAL has the right to file a Patent covering Development Intellectual Property Controlled by NBIX in any country in which NBIX decides not to file. NBIX shall notify BIAL of the decision not to file a Patent in a particular country within [...***...] of making that decision, but not later than [...***...] prior to the time when any statutory bar might foreclose filing of a Patent in that country. Upon receipt of such notification, BIAL shall have the option to assume full responsibility, at its own discretion and expense, to file a Patent in any such country under the name of NBIX. Following the filing of such Patent under the name of NBIX, NBIX shall cooperate and assist BIAL, at BIAL's expense, in executing a written assignment of the NBIX Patent to BIAL and provide at BIAL's expense any other conveyance instruments, documents or assistance as may be reasonably necessary or desirable to assign ownership to BIAL or to support the prosecution of such Patent, at BIAL's sole expense. In the event that such Patent becomes the subject of an opposition or related proceeding, or if any Patent(s) to issue becomes involved in any adversary proceeding (e.g. litigation, invalidity or revocation

proceedings), BIAL shall provide NBIX notice of such proceeding and BIAL shall provide NBIX reasonable opportunity to comment to BIAL.

(e) NBIX shall advise BIAL if it no longer desires to continue prosecution or pay maintenance fees on any NBIX Patent either in the Territory or outside the Territory. Such notification shall be in writing and be provided not less than [...***...] before the expiration of a response period or the payment due date for a maintenance fee. Upon receipt of such notification, BIAL shall have the option, exercisable upon written notification to NBIX, to assume the prosecution and/or maintenance of the NBIX Patent, in which event NBIX shall reasonably cooperate with and assist BIAL, at BIAL's expense, in executing a written assignment of the NBIX Patent to BIAL and provide at BIAL's expense any other conveyance instruments, documents or assistance as may be reasonably necessary or desirable to assign ownership to BIAL or to support the prosecution and maintenance of such Patent, at BIAL's sole expense. For clarity, in the event that a NBIX Patent is assigned to BIAL pursuant to this Section 10.2(e), it shall be deemed to be a BIAL Patent under this Agreement, provided that if BIAL subsequently determines not to continue prosecution or pay maintenance fees, Section 10.2(f) shall not apply to such previously assigned Patent.

(f) BIAL shall provide NBIX with a copy of any BIAL Patents to be filed by BIAL in the Territory covering Development Intellectual Property solely owned or Controlled by BIAL and a copy of communications between its agents and any patent office regarding such BIAL Patents in the Territory, within a reasonable deadline prior to submitting such BIAL Patents and communications to the patent office. Provided that NBIX responds within the specified deadline, BIAL shall consider or cause its agents to consider, in good faith, any comments NBIX may have regarding such BIAL Patents or communication, provided that final prosecution decisions shall rest with BIAL. NBIX shall be responsible for any expenses that it may incur in providing its comments. BIAL shall pay all official taxes, annuities, renewal and maintenance fees required to keep in force all issued BIAL Patents in the Territory covering Development Intellectual Property solely owned or Controlled by BIAL. If BIAL desires to discontinue the maintenance or prosecution, or payment of a maintenance fee, with respect to any Patent in the Territory included in the BIAL Patents under this Section 10.2(f), it shall notify NBIX in writing not less than [...***...] before the deadline of a response period or the payment due date for a maintenance or other applicable fee. In the absence of any notification by NBIX within such [...***...] period, BIAL may discontinue the maintenance or prosecution of such BIAL Patent in the Territory. Upon receipt of such notification by NBIX, NBIX shall have the option to assume, at its discretion and expense, the prosecution and maintenance of the affected Patent(s) in the Territory, in which event BIAL shall reasonably cooperate with and assist NBIX, at NBIX's expense, in executing a written assignment of such BIAL Patent to NBIX and provide at NBIX's expense any other conveyance instruments, documents, or assistance as may be reasonably necessary or desirable to assign ownership of the Patents or to support of the prosecution of the application. Any expenses incurred by NBIX for the prosecution and maintenance of the affected Patent(s) are not refundable under any circumstances. For clarity, in the event that a BIAL Patent is assigned to NBIX pursuant to this Section 10.2(f), it shall

be deemed to be a NBIX Patent under this Agreement, provided that if NBIX subsequently determines not to continue prosecution or pay maintenance fees, Section 10.2(e) shall not apply to such previously assigned Patent.

(g) Subject to BIAL's right set out below to assign Joint Patents in the Territory to NBIX if BIAL no longer wishes to prosecute or maintain them, BIAL shall file, prosecute and maintain Joint Patents in the Territory, covering Development Intellectual Property jointly-owned by the Parties. All costs including legal fees, official taxes, annuities, renewal, and maintenance fees required to prosecute all such applications and keep in force all issued Joint Patents that are jointly owned by the Parties, shall be shared equally by the Parties with respect to Joint Patents in the Territory and borne by BIAL with respect to Joint Patents outside the Territory. If BIAL desires to discontinue its participation in the prosecution of any Joint Patents or maintenance fee of an issued Joint Patent in the Territory, it shall notify NBIX in writing not less than [...***...] before the expiration of a response period or the payment due date for a maintenance fee. Upon receipt of such notification, NBIX shall have the option to assume full responsibility, at its discretion and expense, for the prosecution and maintenance of the affected Joint Patent(s) in the Territory, in which event BIAL shall reasonably cooperate with and assist NBIX, at NBIX's expense, in executing a written assignment of the Joint Patent to NBIX and provide at NBIX's expense any other conveyance instruments, documents, or assistance as may be necessary or desirable to establish ownership of the Joint Patent or to support the prosecution of the Joint Patents.

(h) Neither Party may grant a license under a Joint Patent filed in or outside the Territory without the express written consent of the other Party; provided, however, that BIAL may license BIAL's and NBIX's interest in a Joint Patent outside the Territory without the express written consent of NBIX and without accounting to NBIX; provided that any such license shall be subject to BIAL's rights under the NBIX License post termination and expiry of this Agreement.

ARTICLE 11

PATENT PROSECUTION AND MAINTENANCE

11.1 Prosecution and Maintenance of BIAL Patents Controlled Solely by BIAL: BIAL shall, at BIAL's expense, file, maintain and prosecute or cause to be filed, maintained, prosecuted or continue to maintain and prosecute to issuance in the Territory the BIAL Patents (excluding the BIAL Patents addressed in Article 10). BIAL shall timely pay all official taxes, annuities, renewal and maintenance fees required to keep in force all issued Patents included in such BIAL Patents in the Territory. If BIAL desires to discontinue the maintenance or prosecution, or payment of a maintenance fee, on any Patent included in the BIAL Patents, it shall notify NBIX in writing not less than [...***...] before the deadline of a response period or the payment due date for a maintenance fee. In the absence of any notification by NBIX within such [...***...] period, BIAL may discontinue the maintenance or prosecution of such BIAL Patent. Upon receipt of such notification by NBIX, NBIX shall have the option to assume, at its discretion and expense, the prosecution and maintenance of the affected Patent(s) in the Territory, in which event BIAL shall reasonably cooperate with and assist

NBIX, at NBIX's expense, in executing a written assignment of such BIAL Patent in the Territory to NBIX and provide at NBIX's expense any other conveyance instruments, documents, or assistance as may be reasonably necessary or desirable to assign ownership of the Patents or to support of the prosecution of the application. Any expenses incurred by NBIX for the prosecution and maintenance of the affected Patent(s) are not refundable under any circumstances. For clarity, in the event that a BIAL Patent is assigned to NBIX pursuant to this Section 11.1, it shall be deemed to be a NBIX Patent under this Agreement.

11.2 Abandonment of Opposition Contest: Notwithstanding the foregoing Section 11.1, in the event that BIAL is not willing to defend an opposition, *inter partes* review, post grant review, re-examination, nullity action, or other similar action (“ **Opposition Contest** ”), BIAL shall provide NBIX with advance written notice of any decision by BIAL not to defend such Opposition Contest in the Territory relating to a BIAL Patent. NBIX shall have a reasonable time period from receipt of such notice to elect to continue prosecuting and defending such Patent. In the event NBIX elects not to do so within [...***...] after receipt of BIAL's notification, BIAL may discontinue prosecuting and defending such BIAL Patent. NBIX shall bear the cost of such an Opposition Contest that NBIX elects to continue, and any expenses or fees paid by NBIX in defending such an Opposition Contest shall not be refundable under any circumstances BIAL shall, at NBIX's request and expense, provide NBIX with reasonable assistance including providing available documents and making witnesses available reasonably requested or required by NBIX to continue prosecuting and defending such patent or patent applications, including cooperation of any consultants of BIAL, at NBIX's expense. BIAL, at its own expense, shall have the right to participate in such Opposition Contest, or designate its own counsel to so participate, throughout each step of the Opposition Contest; provided that all decisions and conduct of activities in such Opposition Contest shall be the exclusive right of NBIX, further provided that NBIX shall take in good faith consideration any and all comments provided by BIAL.

11.3 Notices of Issued Patent: BIAL shall notify NBIX promptly but at least within [...***...] of the issuance of each US and Canadian Patent included among the BIAL Patents along with the date of issuance and the Patent number for each such Patent.

11.4 Patent Term Extension:

(a) In the event that applicable law in the Territory provides for the extension of the term of any BIAL Patent, BIAL shall have the exclusive right, but not the obligation, following a good faith consultation with NBIX, to seek BIAL Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law) in the Territory in relation to any such BIAL Patent. NBIX agrees to cooperate with BIAL including without limitation to provide necessary information and assistance as BIAL may reasonably request in obtaining such extension.

(b) In the event that applicable law outside the Territory provides for the extension of the term of any NBIX Patent, NBIX shall have the exclusive right, but not obligation, to seek NBIX Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law), provided however that NBIX may only reference a Marketing Authorization of BIAL with the prior written consent of BIAL, which BIAL may withhold or refuse in its absolute discretion. If BIAL gives such consent, BIAL agrees to cooperate with NBIX including without limitation to provide necessary information and assistance as NBIX may reasonably request in obtaining such extension. NBIX may not, directly or indirectly, exercise this right such that it has the effect of preventing BIAL from obtaining an extension of a BIAL Patent. For clarity, unless specifically authorized by BIAL, NBIX has no right to a Marketing Authorization for any product containing BIA 9-1067 outside the Territory.

(c) In the event that applicable law in the Territory provides for the extension of the term of any NBIX Patent, NBIX shall have the exclusive right, but not the obligation, to seek NBIX Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law). NBIX may not, directly or indirectly, exercise this right such that it has the effect of preventing BIAL from obtaining an extension of a BIAL Patent.

(d) With respect to the Joint Patents, BIAL shall have the exclusive right, but not the obligation, to seek Joint Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law) outside the Territory in relation to any such Joint Patent and NBIX shall have the exclusive right, but not obligation, to seek Joint Patent term extensions (including any patent term extension certificates, supplemental protection certificates and the like available under applicable law) in the Territory in relation to such any Joint Patent. NBIX may not, directly or indirectly, exercise this right such that it has the effect of preventing BIAL from obtaining an extension of a BIAL Patent. The Parties understand and agree that an application of Joint Patent term extensions shall be made in the name of the Parties, and if a Party has the exclusive right to seek such Joint Patent term extension determined to do so, the other Party agrees to cooperate with such Party including without limitation to provide necessary information and assistance as such Party may reasonably request in obtaining such extension.

(e) Should the law require the Party not having the exclusive right as set forth herein (“**Non-extension Party**”) to apply for such an extension directly, the Party having the exclusive right as set forth herein (“**Extension Party**”) shall cooperate with the Non-extension Party in obtaining such an extension and shall execute such documents and take such additional actions as the Non-extension Party may reasonably request in connection therewith. Should applicable law in the Territory require that any such authorization be held in the name of the Non-extension Party, such authorization shall be held by the Non-extension Party solely for the benefit of and in trust for the Extension Party and, upon termination or expiration of the Term of this Agreement, the Non-extension Party agrees to assign such authorization to Extension Party, its Affiliate or nominee and to provide any other conveyance, instruments, documents or assistance as may be necessary or desirable to establish ownership of such

authorization in Extension Party. Notwithstanding anything to the contrary contained herein, the Parties shall use reasonable efforts to agree upon a joint strategy relating to patent term extensions with respect to BIAL Patents, Joint Patents and NBIX Patents, but, in the absence of mutual agreement with respect to any extension issue, Extension Party shall have the final decision making authority, except as otherwise set forth in this Agreement.

11.5 Patent Certifications:

(a) Each Party will immediately give written notice to the other of any certification of which it becomes aware that has been filed pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), or § 355(j)(2)(A)(vii)(IV) (or any amendment or successor statute thereto or Canadian equivalent statute) claiming that the BIAL Patents, Joint Patents or NBIX Patents covering the Licensed Product are invalid, unenforceable, and/or that infringement will not arise from the manufacture, use, offer for sale or sale, of such Third Party product by a Third Party. BIAL shall have the first right, but shall not be obligated, to bring suit against the Third Party that filed the certification. If BIAL decides not to bring infringement proceedings against the Third Party making such a certification with respect to any BIAL Patent or Joint Patent and a Licensed Product, BIAL will give notice to NBIX of its decision not to bring suit within [...***...] after receipt of notice of such certification (or, if the time period permitted by law is less than [...***...], within half of the time period permitted by law for NBIX to commence such action). NBIX shall then have the right, but shall not be obligated, to bring suit against the Third Party that filed the certification. Any suit by either Party may be in the name of either or both Parties, as may be required by law. For this purpose, the Party not bringing suit will execute such legal papers necessary for the prosecution of such suit and will provide assistance at the other Party's expense as may be reasonably requested by the Party bringing suit, including joining such action as a party. In any event, the Party bringing the suit shall **(i)** seek approval of the law firm selected to litigate such action from the other Party (such approval not to be unreasonably withheld or delayed) and **(ii)** provide regular updates from its counsel on the status of such action to the other Party. In addition, the Party not bringing suit has the right to be present, but not to actively participate, for all depositions, settlement negotiations, and other significant meetings or hearings.

(b) If BIAL commences infringement proceedings against the Third Party, BIAL will be solely responsible for the expenses and costs of prosecuting that lawsuit, even if BIAL names NBIX as a co-plaintiff or otherwise brings NBIX into the lawsuit. BIAL will seek the advice of and consult with NBIX regarding the strategy and prosecution of the lawsuit. In no event will BIAL dismiss or otherwise resolve such lawsuit without the participation of and express written consent of NBIX, which shall not be unreasonably withheld, conditioned or delayed.

(c) If NBIX commences infringement proceedings against the Third Party, NBIX will be solely responsible for the expenses and costs of prosecuting that lawsuit, even if NBIX names BIAL as a co-plaintiff or otherwise brings BIAL into the lawsuit. NBIX will seek the advice of and consult with BIAL regarding the strategy and prosecution of the lawsuit. In no event will NBIX dismiss or

otherwise resolve such lawsuit without the participation of and express written consent of BIAL, which shall not be unreasonably withheld, conditioned or delayed.

ARTICLE 12 **INFRINGEMENT**

12.1 Infringement of the BIAL Patents:

(a) If either Party identifies a Third Party infringement of an issued BIAL Patent or Joint Patent in the Territory (other than via a certification notice mentioned under Section 11.5) it shall promptly (within [...***...]) notify the other Party of the alleged infringement. NBIX will have [...***...], from the date that NBIX either receives a notice of alleged infringement from BIAL or provides such a notice to BIAL, to: [...***...]. NBIX shall have the initial right, at its own expense, to enforce BIAL Patents and Joint Patents in the Territory. If NBIX initiates a suit against the infringer, BIAL shall cooperate with NBIX, at NBIX's expense, including joining in the action as a party to the extent necessary to permit NBIX to pursue the action. NBIX shall assume all costs of any action it pursues against the Third Party and shall reimburse BIAL for its costs (including reasonable attorneys' fees and expenses) of assisting in the action as requested by NBIX.

(b) If NBIX does not complete one of the three actions described in Section 12.1(a) within [...***...] after the notice, BIAL may initiate the action against the infringer and NBIX shall cooperate fully with BIAL, at BIAL's expense, including joining the action to the extent necessary to permit BIAL to pursue the action. BIAL shall assume all costs of asserting a claim of infringement against the Third Party, and shall reimburse NBIX for its costs (including reasonable attorneys' fees and expenses) of assisting in the action.

(c) Any damages or other monetary awards recovered in any action brought by one of the Parties against an infringer of a BIAL Patent or Joint Patent in the Territory shall be applied to the reimbursement of the Parties for their respective out-of-pocket expenses (including reasonable attorneys' fees and expenses) incurred in prosecuting such infringement action on a pro rata basis based upon their respective out-of-pocket expenses until all such expenses have been recovered, and any remaining balance, if any, will be divided [...***...] to NBIX and [...***...] to BIAL. The Party who initiated a lawsuit as specified in this Section may only settle any law suit or agree the terms of any sublicense that in each case would in any manner alter, diminish, or be in derogation of the other Party's rights under this Agreement, with the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed.

(d) Any action under Section 11.5 shall be subject to the terms of Section 11.5 and not Sections 12.1(a) and (b).

12.2 Alleged Infringement of Third Party Patents:

(a) If either Party becomes aware that the development, making, packaging, labelling, handling, storage, importation, transportation, use, distribution, promotion, offer for sale, marketing or sale of a Licensed Product within the Territory infringes or is alleged to infringe a patent of a Third Party (each, an “**Alleged Infringement**”), it shall promptly, but in any event no later than [...] after becoming aware, notify the other Party.

(b) The Parties shall thereafter attempt to agree upon a course of action which may include, without limitation: [...***...]. In the event that the Parties do not agree upon a course of action pursuant to the preceding sentence within [...] after learning of such Alleged Infringement, NBIX [...***...]; provided however, that with respect to an Alleged Manufacturing Infringement, [...***...]. If NBIX declines to assume control of the defense of any Alleged Infringement in the Territory, then NBIX shall provide an explanation to BIAL regarding its decision to decline to assume control, and then BIAL shall have the right, but not the obligation, to assume such defense, at BIAL's expense. Upon request of the Party controlling the defense of any such action, the other Party shall, at the controlling Party's expense, join in any such litigation and will have the obligation to reasonably cooperate with the controlling Party (including giving testimony and producing documents lawfully requested, and using its reasonable efforts to make available to the other such employees who may be helpful with respect to such suit, investigation, claim or other proceeding). The controlling Party shall only have the right to settle any Alleged Infringement and agree the terms of such settlement (which may include a license), with the other Party's consent, which shall not be unreasonably withheld.

(c) In the event that (i) the development, making, packaging, labelling, handling, storage, importation, transportation, use, distribution, promotion, offer for sale, marketing or sale of a Licensed Product is deemed by a court of competent jurisdiction to infringe a claim of a patent(s) owned or controlled by a Third Party in the Territory, or (ii) NBIX or its Affiliate obtains a license under such patent(s) in settlement of such claims with the consent of BIAL (such consent shall not be unreasonably

withheld or delayed), or **(iii)** NBIX determines that it is commercially necessary to pay royalties or other fees to a Third Party to obtain a license to practice any Third Party's rights in order for NBIX to carry out the activities envisaged by this Agreement in the Territory as well as to avoid the infringement of a claim of a patent(s) owned or controlled by a Third Party in the Territory ("**Third Party License**"), during the Term, then [...***...].

(d) In the event there is an Alleged Manufacturing Infringement, **(i)** if BIAL determines it is commercially necessary to modify the process(es) for making or packaging the relevant Licensed Product to avoid the Alleged Manufacturing Infringement, all costs related to such modification (hereinafter "**Process Modification Costs**"), and/or **(ii)** if the Parties determine that it is commercially necessary to pay royalties or other fees to obtain Third Party License to avoid the Alleged Manufacturing Infringement in the Territory, then all such costs, license fees and royalties for such Third Party License, and **(iii)** all Losses (as defined in Section 16.1 hereof) resulting from such Alleged Manufacturing Infringement in the Territory (such costs, fees, and Losses described in clauses (i), (ii), and (iii) of this sentence shall be referred to as "**Alleged Manufacturing Infringement Costs**"), then, notwithstanding any other provision of this Agreement, any and all Alleged Manufacturing Infringement Costs shall [...***...]; provided however that, in the event there is also an alleged manufacturing infringement outside the Territory which requires the incurrence of Process Modification Costs, then the Process Modification Costs [...***...]:

[...***...]:

NBIX Portion = [...***...]

NBIX Portion = [...***...]

NBIX Portion = [...***...]

NBIX Portion = [...***...]

In addition, if BIAL determines the appropriate action to take in response to an Alleged Manufacturing Infringement is to modify the process(es) for making or packaging a Licensed Product to avoid the Alleged Manufacturing Infringement, then such activities will be undertaken as a collaborative effort between the Parties and overseen by the JSC.

ARTICLE 13 **CONFIDENTIALITY**

13.1 Confidential Information:

(a) As used in this Agreement, the term “**Confidential Information**” means, with respect to a Party, all data, know-how and other information, whether written or oral, technical or non-technical, that is disclosed by or on behalf of such Party (including by or on behalf of or through a parent, subsidiary, Affiliate, contractor or licensee) to the other Party (including by or on behalf of or through a parent, subsidiary, Affiliate, contractor or licensee) in the performance of this Agreement, the SDEA, the Supply Agreement and the Quality Agreement. Confidential Information may include BIAL Know-How, NBIX Know-How, commercial information, Development and Regulatory Plans, Development Studies protocols, financial statements, reports, pricing, trade secrets, secret processes, formulas, customer data (including customer lists), business information, business methods, business plans, and pricing, cost, supplier and manufacturing information, All Confidential Information shall remain the property of the disclosing Party. In addition, all information disclosed by BIAL under that certain Confidentiality Agreement between the Parties dated June 10, 2015 (the “**Confidentiality Agreement**”), shall be deemed BIAL’s Confidential Information, and any use or disclosure thereof by NBIX that is permitted under this Agreement shall not be deemed a breach of the Confidentiality Agreement.

(b) The term “Confidential Information” does not include any such items for which the receiving Party can show by competent written proof or other reasonable support that such item:

(i) was known to and existed in documentary or other physical form in the possession of the receiving Party at the time of disclosure;

(ii) subsequent to the receipt hereunder, is made available to the receiving Party on a non-confidential basis by a Third Party which is legally entitled to make such information available;

(iii) was or becomes publicly known through no fault of the receiving Party; or

(iv) is independently developed by employees or agents of the receiving Party without access to Confidential Information disclosed hereunder.

13.2 Obligations of Confidentiality: Subject to the provisions in Section 13.1(b), during the Term and for as long as the Confidential Information relating thereto is not made public by the disclosing Party, each Party agrees:

(a) to preserve the confidentiality of all Confidential Information received from the other Party, and not to disclose any such Confidential Information to a Third Party without first obtaining the written consent of the disclosing Party, except as may be otherwise provided herein;

(b) to take all necessary steps to ensure that Confidential Information received from the other Party is securely maintained and to inform those who are authorized to receive such Confidential Information of their obligations under this Agreement; and

(c) to use any and all Confidential Information received from the other Party solely in connection with, or as permitted by, this Agreement (including exercising its rights and performing its obligations hereunder) and for no other use.

13.3 Right to Disclose:

(a) Nothing herein shall be construed as preventing either Party from disclosing any Confidential Information received from the other Party to its officers, directors and employees, Affiliates, distributors, licensees, sublicensees, consultants, professional advisors, agents and contractors (the “**Representatives** ”), in each case where such person or entity has a reasonable need to know such Confidential Information, provided that the Representatives have undertaken similar written obligations of confidentiality and non-use with respect to the Confidential Information.

(b) Nothing contained in this Article restricts the Parties or their respective Affiliates from disclosing the other Party’s Confidential Information as reasonably required for: (i) seeking any Marketing Authorization or other authorization required under or for the purposes of this Agreement, (ii) regulatory, tax or customs reasons, (iii) audit purposes, (iv) the development, manufacture, use, sale, external testing or marketing trials of products in a manner consistent with the terms of this Agreement, the SDEA, the Supply Agreement and the Quality Agreement, or (v) the filing or prosecuting Patents as contemplated by this Agreement, without violating the above secrecy provision (it being understood that publication of such Patents within [...***...] of filing will not violate such secrecy provisions), or (vi) by court order or other government order or request. With respect to disclosing Confidential Information pursuant to a court order or other government order or request, prompt notice of such order or request shall be provided to the disclosing Party and, to the extent legally possible, the disclosure shall not occur until the disclosing Party either approves the disclosure or has had the

opportunity to seek a protective order or other appropriate remedy to curtail such disclosure. In the event that the disclosing Party is unsuccessful in preventing the disclosure of Confidential Information to the court or government, the other Party shall take reasonable efforts to protect the confidentiality of the Confidential Information and will disclose only that portion of Confidential Information which it is legally required to disclose.

13.4 Disclosure of Financial and Other Terms:

(a) Except as required by applicable laws, treaties or agreements (including securities laws and regulations), the Parties agree that the terms of this Agreement, the SDEA, the Supply Agreement and the Quality Agreement will be considered Confidential Information of both Parties.

(b) Notwithstanding the foregoing, (i) either Party may disclose such terms as are required to be disclosed in its publicly-filed financial statements or other public statements, in order to comply with applicable laws, regulations or stock exchange rules, provided that, to the extent legally possible, such Party shall provide the other Party with a copy, in English language, of the proposed text of such statements or disclosure sufficiently in advance of the scheduled release or publication thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text, and (ii) either Party has the right to disclose this Agreement (but, for the avoidance of doubt, not any other Confidential Information of the other Party) under a confidentiality obligation no less protective than that set forth in this Agreement (but which may be of shorter duration, but at least [...***...]), to any potential acquirer, merger partner, providers of financing, or potential providers of financing and their advisors.

(c) Neither Party shall make any other statement to the public regarding the execution and/or any other aspect of the subject matter of this Agreement except as provided in Section 13.5 and except: (i) where disclosure is required under applicable laws and (ii) either Party may use the text of a statement previously approved in writing by the other Party.

13.5 Publicity/Use of Names.

(a) Except as otherwise provided in this Agreement, neither Party nor any of its Affiliates or Third Party licensee shall use the name, trademark, trade name or logo of the other Party or any of its Affiliates or Third Party licensee, or the names of their respective employees, in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by law.

(b) Each Party may issue a press release announcing the entry into this Agreement in a form approved by the Parties in writing as of the Effective Date. Neither Party nor any of its Affiliates shall originate any other publicity, news release or other public announcement including, without limitation, online announcement or disclosure, written or oral, relating to the terms or conditions contained in this Agreement, or the existence of and information about any performance, including, without limitation,

any Development Studies, conducted by any Party and/or any of its Affiliates under this Agreement without the prior written approval, and agreement upon the nature and text of such announcement or disclosure, of the other Party, which approval and agreement shall not be unreasonably withheld or delayed. For clarity, BIAL shall have the right to provide its or its Affiliates' licensees outside the Territory with a copy of each draft copy of announcement of NBIX for their review and comment.

(c) Notwithstanding the foregoing, either Party may make such disclosures without the prior consent of the other Party if such disclosure is required by law; *provided, however*, that any disclosure required by law shall be subject to the last sentence of Section 13.3(b) *mutatis mutandis* .

(d) The Party desiring to make any public announcement or other disclosure, as provided above, shall inform the other Party of the proposed announcement or disclosure in reasonably sufficient time, and in any event at least [...***...], to the extent practicable with respect to legally required disclosures, prior to public release, and shall provide the other Party with a written copy thereof, in English language, in order to allow such other Party to comment upon such announcement or disclosure.

(e) The Parties acknowledge that no further approval is required for disclosure of information for which consent has previously been obtained and information of a similar nature to that which has been previously disclosed publicly with respect to the subject matters contained in this Agreement and/or the existence of and information about any performance conducted under this Agreement or related to Licensed Product in any country in and outside the Territory.

(f) The Parties agree that generally they shall make press releases simultaneously; *provided, however*, that in the event that one Party informs the other Party that it does not desire to make a press release, such Party shall not be obligated to make such press release and the other Party may make a unilateral press release on its own behalf subject to the provisions of this Section 13.5.

(g) All press releases of NBIX related to Licensed Products or where the Licensed Products are mentioned shall include a phrase to the effect that all rights to Licensed Products and BIA 9-1067 are licensed from BIAL in the same manner as set forth in Section 2.1(f).

13.6 Consequences of Breach: The Parties understand that monetary damages may be inadequate or insufficient to protect any breach of any of the provisions of this Article 13 by either Party or its officers, directors and employees, its Affiliates, distributors, licensees, sublicensees and contractors, or any other person or entity acting in concert with it or on its behalf. Accordingly, the non-breaching Party will be able to seek all remedies available at law or in equity, including the right to request injunctive relief, specific performance of the provisions of this Article 13 and/or to claim damages in a court of competent jurisdiction.

ARTICLE 14
REPRESENTATIONS AND WARRANTIES

14.1 Representations and Warranties by BIAL: BIAL hereby represents and warrants to NBIX as of the Effective Date, that:

(a) Exhibit 2.1 attached hereto (i) contains a true and complete list of the BIAL Patents in the Territory as of the Effective Date and (ii) includes all Patents owned or in-licensed by BIAL in the Territory that claim or cover BIA 9-1067 or any Licensed Product.

(b) Exhibit 2.3 attached hereto contains the [...***...] trademarks selected by BIAL for the Territory as of the Effective Date;

(c) BIAL is the sole owner of the entire right, title and interest in and to the BIAL Patents and the Trademarks as at the Effective Date, free and clear from any mortgages, pledges, liens, security interests, conditional and instalment sale agreements, encumbrances, charges or claims of any kind. BIAL has the full power, authority and legal right to enter into this Agreement, to perform its obligations hereunder and to license them to NBIX on the terms of this Agreement and, together with its Affiliates, to perform BIAL's obligations hereunder, and to the Knowledge of BIAL no person or governmental authority, has any claim of ownership with respect to BIAL Patents listed on Exhibit 2.1 and/or Trademarks listed on Exhibit 2.3 as of the Effective Date;

(d) to the Knowledge of BIAL but having made no investigations, no Third Party is infringing or is threatening to infringe or make unauthorized use of any of the BIAL Patents or the BIAL Know How or Trademarks in the Territory;

(e) there are no pending or, to the Knowledge of BIAL, threatened actions, suits, claims, interference proceedings or governmental investigations in any court, arbitration, patent office, administrative or other tribunal in the Territory by or against BIAL or its Affiliates involving BIA 9-1067, the BIAL Patents, the BIAL Know How or Trademarks. In particular, there is no pending or, to the Knowledge of BIAL threatened product liability action nor intellectual property right litigation inside or outside the Territory (other than the trademark oppositions and cancellation action which BIAL has informed NBIX of), including, but not limited to, a challenge to the validity or ownership of BIA 9-1067, the BIAL Patents or the BIAL Know How or Trademarks, relating to BIA 9-1067;

(f) there are no pending or, to the Knowledge of BIAL, threatened claims or actions claiming that the development, manufacture, sale, offering for sale, importation or use of the Licensed Products in the Territory would infringe the intellectual property rights of any Third Party;

(g) to the Knowledge of BIAL, the development, manufacture, sale, offering for sale, importation and use of the Initial Product for the Initial Indication in the Territory will not infringe or misappropriate the valid and issued patent rights of any Third Party;

(h) to the Knowledge of BIAL, the claims of the issued BIAL Patents are valid and enforceable.

(i) it has not previously granted rights under the BIAL Patents, BIAL Know-How and/or Trademarks, or any portion thereof, that conflict with the rights and licenses granted to NBIX under this Agreement for the Territory;

(j) all necessary consents, approvals and authorizations of all Regulatory Authorities, other governmental authorities and other persons or entities required to be obtained by BIAL in order to enter into this Agreement have been obtained;

(k) To the Knowledge of BIAL, BIAL it has materially complied with GCP, GMP and GLP in connection with the development of BIA 9-1067 and other applicable laws, rules and regulations; and

(l) BIAL has not intentionally withheld or concealed from NBIX (i) any material written information requested by NBIX and in BIAL's possession or Control as of the Effective Date relating to the Initial Product (other than with respect to the Manufacturing Know-How) or (ii) any material information requested by NBIX and in BIAL's possession or Control relating to the BIAL Patents.

14.2 Representations and Warranties by NBIX: NBIX hereby represents and warrants to BIAL as of the Effective Date that:

(a) all necessary consents, approvals and authorizations of each Agency, other governmental authorities and other persons or entities required to be obtained by NBIX in order to enter into this Agreement have been obtained; and

(b) the First Development and Regulatory Plan represents all NBIX's plans for its activities in respect of the development of the Licensed Products, which are developed based on the information provided by BIAL prior to the Effective Date, and it has not intentionally withheld or concealed from BIAL any material information relating to NBIX's intended activities in respect of BIA 9-1067 and/or the Licensed Products; and

(c) there are no Competing Products under development or being commercialized in the Field in the Territory that are Controlled by or on behalf of NBIX or its Affiliates; and

(d) there are no compounds or drug products under development by NBIX or its Affiliates which would be covered by any of the BIAL Patents; and

(e) there are no NBIX Patents or NBIX Know-How.

14.3 Mutual Representations and Warranties: Each Party hereby represents and warrants to the other Party as of the Effective Date, that:

(a) Such Party is a corporation duly organized, validly existing and in good standing under the laws of its place of incorporation.

(b) The execution and delivery of this Agreement by such Party has been duly authorized by all necessary corporate actions on the part of such Party. Such Party has full power, authority and legal right to execute and deliver this Agreement and to perform its obligations hereunder. This Agreement has been duly executed and delivered by such Party, is a legal and valid obligation binding upon such Party and enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable insolvency and other laws affecting creditors' rights generally or by the availability of equitable remedies.

(c) The execution, delivery and performance of this Agreement does not and will not violate (i) the organizational documents or by-laws of such Party, or (ii) any provision of any agreement or other instrument or document to which such Party is a party or by which any of its assets or properties is bound or affected.

14.4 Negation of Implications: Except as expressly stated herein, nothing in this Agreement will be construed as:

(a) An obligation on the part of either Party to bring or prosecute actions or suits against Third Parties for infringement of any of the Patents or other intellectual property rights of the Parties;

(b) Conferring on either Party a right to use in advertising, publicity, or otherwise any trademark, service mark, or trade name of the other Party; or

(c) Granting by implication, estoppel, or otherwise, any licenses or rights under patents or other intellectual property of a Party other than those rights expressly granted herein.

14.5 Non Reliance; Disclaimer:

(a) The warranties and representations of each Party set forth in this Agreement are intended for the sole and exclusive benefit of the other Party hereto, and may not be relied upon by any Third Party.

(b) NBIX waives any right it may have to rescind this Agreement for any misrepresentation by BIAL.

(c) EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE LICENSED PRODUCTS OR ANY PATENTS, KNOW-HOW, TRADEMARKS OR OTHER INTELLECTUAL PROPERTY DISCLOSED, DEVELOPED, OR LICENSED UNDER THIS AGREEMENT. EXCEPT TO THE EXTENT

EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE LICENSED PRODUCTS OR ANY PATENTS, KNOW-HOW, TRADEMARKS OR OTHER INTELLECTUAL PROPERTY DISCLOSED, DEVELOPED, OR LICENSED UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION ANY WARRANTY OR REPRESENTATION OF NON-INFRINGEMENT, MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 15

TERM AND EXPIRATION AND TERMINATION OF THIS AGREEMENT

15.1 Term:

(a) This Agreement commences as of the Effective Date and shall remain in force, on a Licensed Product by Licensed Product and country by country basis, unless otherwise terminated in accordance with any of the provisions of this Article 15, until the last day of the first Calendar Quarter during which a Generic Product in respect of such Licensed Product is sold in such country [...***...] in such country in such Calendar Quarter (the “**Term**”).

(b) Upon the expiration of this Agreement in respect of a Licensed Product in a country in the Territory, the licenses granted to NBIX in Section 2.1 and 2.2 shall (save with respect to the Trademark) become fully-paid, perpetual and irrevocable in respect of such Licensed Product (but not, for the avoidance of doubt, in respect of any other Licensed Product) in such country (but not, for the avoidance of doubt, in respect of the other country within the Territory) and shall include the right to manufacture and have manufactured such Licensed Product.

(c) Upon NBIX’s written request [...***...] prior to the estimated expiration of the Term in respect of a Licensed Product, the Parties shall negotiate in good faith the terms under which BIAL may continue to supply such Licensed Product to NBIX after the Term and shall use reasonable efforts to conclude such negotiation and enter into a supply agreement containing such terms prior to expiration of the Term, provided that if the Parties fail to enter into such agreement prior to the end of the Term, the Supply Agreement shall continue to govern the supply of such Licensed Product for [...***...] post expiration of this Agreement.

(d) After the Term and if BIAL is not supplying a certain Licensed Product, NBIX shall pay BIAL a royalty of [...***...] percent ([...***...]%) of Net Sales of such Licensed Product sold by NBIX and/or its Affiliates under or in relation to the Trademark. Such royalties shall be paid by NBIX to BIAL within [...***...] following the end of each Calendar Quarter together with a statement showing the aggregate gross sales in value and in Units, the type and value of deductions made in calculation of Net

Sales, the aggregate Net Sales in such Calendar Quarter and the amount of royalties due to BIAL in respect of that Calendar Quarter. BIAL shall have the right to audit all of the foregoing pursuant to, *mutatis mutandis*, Paragraphs 1.7(a) and (b) of **Exhibit 4**.

15.2 Termination for Cause: Prior to expiration of the Term as set forth in Section 15.1, either Party may terminate this Agreement, without prejudice to any other remedies available to it at law or in equity, upon the occurrence of any of the following events (each, a “**Termination Event**”):

(a) either Party may terminate this Agreement upon written notice to the other Party, if the other Party materially breaches or defaults in the performance of any of its obligations hereunder (except an alleged breach by NBIX of any obligation requiring it to use Commercially Reasonable Efforts) and such breach is uncurable or it fails to cure such breach or default within [...***...] (or [...***...], solely with respect to a payment breach) following receipt of written notice from the non-breaching Party specifying the breach or default in reasonable detail; provided, however, that the Parties shall meet in person and discuss in good faith the alleged breach or default and potential cures (if applicable) for such alleged breach or default within the [...***...] or [...***...] day timeframe (as applicable) prior to such termination becoming effective.

(b) If it is determined in accordance with Sections 17.1(d) and 17.1(e) that NBIX has breached any of its obligations to use Commercially Reasonable Efforts and if NBIX fails to take the action to remedy the breach or default described by the arbitrator in its decision within the period set out in the arbitrator’s decision, BIAL may terminate this Agreement by giving, at any time within three months after the end of that period, not less than thirty (30) days’ notice;

(c) by BIAL pursuant to Section 7.3(b) or 7.3(c) upon [...***...] days written notice to NBIX; or by BIAL pursuant to Section 8.3(h) upon [...***...] days written notice to NBIX;

(d) by either Party if the other Party voluntarily files or a resolution is passed for its administration, winding up, or dissolution, or should a trustee administrative or other receiver, manager, administrator, liquidator or similar officer be appointed for all or any of its retained business assets or operations or it enters into or proposes any composition or arrangement with its creditors generally or anything similar to the foregoing occurs in any applicable jurisdiction;

(e) Within thirty (30) Business Days of receipt of a Change of Control Notice, BIAL may elect, by giving [...***...] notice in writing to NBIX, to terminate this Agreement if NBIX has undergone a Change of Control involving any of the following circumstances (i) to (iii):

(i) the Third Party involved in the Change of Control, whether by absorption of, absorption by, acquisition of, acquisition by, consolidation or merger with, NBIX or otherwise (the “**Change of Control Entity**”) is developing, importing, using, promoting, distributing, commercializing, offering for sale or selling a Competing Product in and/or outside the Territory and such Change of Control Entity:

- (A) does not provide notice to BIAL within [...***...] of the Change of Control of its intention to divest itself of such Competing Product;
- (B) having provided such notice to BIAL, does not use Commercially Reasonable Efforts to divest itself of such Competing Product within [...***...] of such Change of Control ; and
- (C) having provided such notice to BIAL, does not actually divest itself of such Competing Product within the earlier of (1) [...***...] of such Change of Control or (2) such timeframe ordered by the Federal Trade Commission of the US; or
 - (ii) the Change of Control Entity is or has been within [...***...] engaged in litigation (in court, arbitral tribunal or otherwise) against BIAL, or written correspondence exists threatening litigation or allegations of infringement of any Patent, trademarks or other intellectual property right of BIAL or its Affiliates, whether or not relating to the Licensed Products and in and/or outside the Territory; or
 - (iii) the Change of Control Entity (together with the NBIX entity or assets it has acquired) does not have the capabilities (including, without limitation, the financial capability) and resources (including, without limitation, know-how and personnel) at least comparable to NBIX's capabilities and resources to meet the obligations under this Agreement.
- (f) In the event that NBIX undergoes a Change of Control prior to the first Approval and such Change of Control does not involve any of the circumstances under Section 15.2(e), BIAL may also elect to terminate this Agreement within [...***...] of receipt of the Change of Control Notice, by giving [...***...] notice in writing to NBIX (such notice hereinafter referred to as the “ **Section 15.2(f) Notice** ”); provided however that, [...***...]), then the Agreement shall not be terminated but shall continue in full force and effect as modified by the foregoing written confirmation.

15.3 Termination For Convenience: NBIX may terminate this Agreement in its entirety for any or no reason, upon:

- (a) [...***...] prior written notice to BIAL if such notice is given prior to the first NDA Approval of the Initial Product in the US, in which case:

(i) if such termination notice is provided (A) prior to or after first learning from the FDA that no Phase III Study is required or (B) after learning that a single Phase III Clinical Study [...] is required for NDA submission, NBIX shall pay to BIAL [...] US Dollars (US\$[...]) within [...] of the date of such notice.

(ii) Should the fee in Section 15.3(a)(i) not be payable, NBIX shall be under the obligation to complete all ongoing development activities prior to the conclusion of the termination notice period or such other period reasonably necessary to complete such activities.

(b) [...] prior written notice to BIAL if such notice is given after the first NDA Approval of the Initial Product in the US.

15.4 Waiver of Termination Event: The right of either Party to terminate this Agreement as provided in Sections 15.2 or 15.3 shall not be affected in any way by such Party's waiver or failure to take action upon the occurrence of a previous Termination Event.

15.5 Rights and obligations upon Termination of the Agreement: If this Agreement is terminated:

(a) All licenses granted by BIAL under this Agreement shall terminate save that during the wind-down periods referenced in this Section 15.5 (if applicable), the license granted to NBIX with respect to Licensed Products in the Field in the Territory shall be non-exclusive and limited to the activities expressly contemplated by this Section 15.5, and, without limiting the foregoing, BIAL shall have the right to engage one or more other distributors and/or licensees of the Licensed Products in the Field in the Territory;

(b) If this Agreement is terminated by BIAL in accordance with Section 15.2(a), 15.2(b) or 15.2(c), NBIX and its Affiliates shall not use, develop, import, promote, distribute, market, commercialize, offer for sale or sell within the Field and Territory, any Competing Product for the period of one (1) year after the date of termination;

(c) NBIX shall promptly assign to BIAL, or to its Affiliate or nominee, all right, title and interest in and to any INDs for Licensed Products and/or BIA-9-1067 (including the BIA-9-1067 IND) in the Territory and NBIX shall notify the FDA and other applicable Agencies in writing that ownership of such INDs has been assigned to BIAL or its Affiliate or nominee;

(d) NBIX shall promptly assign to BIAL or its Affiliate or nominee, any Approval(s), and any pending or approved NDAs for any Licensed Products in the Territory;

(e) Any Patent term extensions of a NBIX Patent covering or relating to BIA 9-1067 shall be assigned to BIAL, its Affiliate or nominee;

(f) The NBIX License shall convert to an exclusive, fully paid-up, royalty-free, irrevocable, perpetual and worldwide (including the Territory) license;

(g) NBIX shall promptly assign and deliver to BIAL or its Affiliate documents, material, data, reports, Regulatory Authority or development correspondence, rights and information, Controlled by NBIX, directly relating to or concerning BIA 9-1067 or the relevant Licensed Products; and

(h) At the written request of BIAL, NBIX shall assign to BIAL or to its Affiliate or nominee any Licensed Product-specific Third Party agreements, to the furthest extent possible, provided that such assignment is permitted under the Licensed Product-specific agreement or is accepted by the Third Party. In the event such assignment is not requested by BIAL or is not accepted by such Third Party, then the rights of such Third Party with respect to Licensed Products shall terminate upon termination of this Agreement. NBIX shall use Commercially Reasonable Efforts to ensure that such Third Parties (if its contract is not assigned to BIAL pursuant to this Section 15.5(h)) shall transition any remaining Licensed Products back to BIAL in the manner set forth in this Section 15.5, and to include provisions requiring compliance with these provisions in the agreements with Third Parties.

(i) At BIAL's discretion and upon BIAL's written request which shall be delivered prior to the effective date of the termination, during a period starting on the date of notice of termination and not exceeding six (6) months following the effective date of termination:

(A) the Parties shall work together in good faith to adopt a plan to wind-down any development activities with respect to the Licensed Products in the Territory in an orderly and reasonable fashion or, at BIAL's election, promptly transition such development activities to BIAL or its designee, at NBIX's expense (except in the event of termination by NBIX for a BIAL breach pursuant to Section 15.2 hereof, in which case it shall be at BIAL's expense), with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials of Licensed Products and take any actions the Parties deem reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable laws. NBIX shall perform or cause to be performed its outstanding non-cancellable obligations with respect to the development of any Licensed Products that existed or accrued prior to the notice date of termination; and

(B) NBIX shall continue, to the extent that NBIX continues to have an inventory of Licensed Products, to fulfil orders received from customers for Licensed Products in the Territory prior to the effective date of termination. For the Licensed Products sold by NBIX or its Affiliates after the effective date of termination, NBIX shall continue to make payments to BIAL in accordance with the terms and conditions of this Agreement. Notwithstanding the foregoing, NBIX and its Affiliates shall cease such activities upon sixty (60) days' written notice given by BIAL at any time after the effective date of a termination requesting that such activities cease. Within [...***...] after BIAL has given notice to NBIX requesting the cessation of

activities pursuant to the provision of this Section 15.5(i)(B), NBIX shall notify BIAL of an estimate of the quantity of Licensed Products and shelf life remaining in NBIX's inventory and BIAL shall have the right, but not the obligation, to purchase any such quantities of Licensed Products from NBIX at a price mutually agreed by the Parties. To the extent BIAL does not purchase such quantities, NBIX may sell such quantities during the period of [...***...] after the receipt by NBIX of a notice specifying that BIAL does not intend to purchase such quantities within the shelf life remaining for such Licensed Products.

15.6 Survival: The following terms and provisions will survive the termination or expiry of the Agreement: Articles 1, 13 (for the period as specified therein) and 16 (in respect of claims resulting from activities occurring or failing to occur prior to termination or expiry); and Sections 2.1(a), 2.1(b), 2.1(c) and 2.1(h); 2.5 (in respect of liabilities accruing prior to termination or expiry); 2.6(c)(iii); 2.7(b) and 2.7(c); 3.1(b), 3.1(c), 3.2, 3.3 and 3.4 (all in respect of payments that have become due prior to termination or expiry); 7.5 (b) and 7.5(c); 7.7(b); 7.8 (in respect of recall events occurring prior to termination or expiry); 9.2(a) and 9.2(b); 9.4(b); 9.5; 9.6; 10.1(first paragraph); 10.2(g); 10.2(h); ; 15.1(b), 15.1(c) and 15.1(d); 15.5; 15.6; 15.7; 17.1; 17.2; 17.4; 17.6; 17.7; 17.8; 17.9; 17.10; 17.11; 17.13 and 17.14.

15.7 Accrued Rights and Obligations: Expiration or any early termination of this Agreement will not relieve the Parties of any obligation or liability accruing prior to such termination or expiration, including, without limitation, the payment obligations set forth in Article 3.

ARTICLE 16 **INDEMNIFICATION**

16.1 Indemnity by BIAL: In addition to any other remedy available to NBIX, except as otherwise provided in Section 16.2, BIAL shall indemnify, defend and hold harmless NBIX and its Affiliates and their respective agents, employees, directors and officers (collectively, the “**NBIX Indemnitees**”) from and against any liabilities, assessments, fines, losses, expenses, costs, interest and penalties (including reasonable legal and other professional adviser's fees and disbursements) (collectively, “**Losses**”) resulting from any Third Party claims, suits and demands, whether or not such Losses were foreseeable at the Effective Date (each, a “**Claim**”), to the extent that such Losses arise from:

(a) alleged or actual bodily injury or property damage resulting from BIAL's failure to supply the Licensed Products in accordance with the Product Specifications;

(b) the gross negligence or intentional misconduct of any of BIAL, its Affiliates or its or their agents, directors, officers or employees in performing its or their obligations under the Agreement;

(c) any material breach by BIAL of its obligations and warranties under this Agreement, the Supply Agreement, or the Co-Promotion Agreement;

(d) BIAL's failure to comply with applicable laws and regulations; or, in the case of any allegation arising pursuant to BIAL's promotional efforts under the Co-Promotion Agreement, any allegation that BIAL failed to comply with applicable laws and regulations; and

(e) the activities of the BIAL Representatives in the Territory after BIAL exercises its Co-Promotion Option pursuant to Section 2.10, except to the extent such activities specifically fall within the scope of the then current Co-Promotion Plan or have otherwise been agreed between the Parties or approved by NBIX (for the avoidance of doubt, this shall not be interpreted or construed as limiting NBIX indemnification obligations under Section 16.2).

except, in each case (a)-(e), to the extent that such Losses arise from the negligence or intentional misconduct of any NBIX Indemnitee or NBIX's breach of this Agreement, the Supply Agreement or the Co-Promotion Agreement.

16.2 Indemnity by NBIX: In addition to any other remedy available to BIAL, except as otherwise provided in Section 16.1, NBIX shall indemnify, defend and hold harmless BIAL, its Affiliates and their respective agents, employees, directors and officers (collectively, the " **BIAL Indemnitees** ") from and against any Losses resulting from any Third Party Claims, to the extent that such Losses arise from:

(a) alleged or actual bodily injury or property damage resulting from the labelling, handling, storage, transportation, use, distribution, promotion, marketing, offer for sale or sale of the Licensed Products by or on behalf of NBIX;

(b) the use, effects or safety of any Licensed Products in the Territory;

(c) any claim of infringement or misappropriation of any patent, patent application, trade secret, copyright, trademark, trademark application, or other proprietary right arising out of the manufacturing, development, labelling, handling, storage, importation, transportation, use, commercialization, distribution, promotion, marketing, offer for sale or sale of the Licensed Products in the Territory by or on behalf of NBIX;

(d) the gross negligence or intentional misconduct of NBIX, its Affiliates or its or their agents, directors, officers or employees in performing its or their obligations under this Agreement, the Supply Agreement or the Co-Promotion Agreement;

(e) any material breach by NBIX of its obligations and warranties under this Agreement, and

(f) NBIX's failure in the Territory to comply with applicable laws and regulations, including the terms of the applicable Approvals;

except, in each case (a)-(f), to the extent that such Losses arise from the negligence or intentional misconduct of any BIAL Indemnitee or BIAL's breach of this Agreement, the Co-Promotion Agreement or the Supply Agreement.

16.3 Conditions of Indemnification: All indemnification claims in respect of any indemnitee seeking indemnity under Section 16.1 or 16.2, as applicable (collectively, the “**Indemnitees**” and each an “**Indemnitee**”) will be made solely by the corresponding Party (the “**Indemnified Party**”). The Indemnified Party will give the indemnifying Party (the “**Indemnifying Party**”) prompt written notice (an “**Indemnification Claim Notice**”) of any Losses and any legal proceeding initiated by a Third Party against the Indemnified Party as to which the Indemnified Party intends to make a request for indemnification under Section 16.1 or 16.2, as applicable, but in no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice which materially prejudices the defense of such proceeding. Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). Together with the Indemnification Claim Notice, the Indemnified Party will furnish promptly to the Indemnifying Party copies of all notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim. If an Indemnified Party seeks indemnification under this Article 16, the Indemnifying Party **(i)** may assume control and direction of any such claim at its expense, **(ii)** may use legal counsel of its choice, **(iii)** shall keep the Indemnified Party informed of the progress of the claim, **(iv)** shall consult with the Indemnified Party on the nature of any defense, and **(v)** shall not settle any such claim without the approval of the Indemnified Party, such approval not to be unreasonably withheld or delayed, unless such settlement is for money damages only. The Indemnified Party and its Indemnitees shall cooperate fully with the Indemnifying Party and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification.

16.4 Limitation of Liability:

(a) Nothing in this Agreement excludes or limits each Party's liability for: **(i)** death or personal injury caused by that Party's negligence; **(ii)** fraud or fraudulent misrepresentation; or **(iii)** any liability which cannot legally be excluded or limited.

(b) Subject to Sections 16.1, 16.2, and 16.4(a), and except for damages available for breach of Article 13, neither Party shall be liable, whether in contract, tort (including negligence or breach of statutory duty), misrepresentation or otherwise in connection with this Agreement for any indirect, special or consequential loss or damage, howsoever arising. In addition to the foregoing, neither Party shall be liable, whether in contract, tort (including negligence or breach of statutory duty), misrepresentation or otherwise in connection with this Agreement for any: **(i)** loss of profit; **(ii)** loss of revenue; **(iii)** loss of business; or **(iv)** loss of anticipated savings; in each case whether direct or indirect.

ARTICLE 17
MISCELLANEOUS

17.1 Dispute Resolution:

(a) It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. Any dispute, controversy or claim arising out of, relating to, or in connection with this Agreement, including any question regarding its existence, validity or termination (“ **Dispute** ”) will be submitted in the first instance to the CEO of BIAL, or such person’s designee of equivalent or superior position, and the CEO of NBIX, or such person’s designee of equivalent or superior position.

(b) Except to the extent that final decision-making authority is specifically provided in any provision in this Agreement, if the CEO of BIAL and the CEO of NBIX cannot resolve the Dispute within [...***...] after such Dispute is posed to each Party’s CEO, then the Parties shall attempt in good faith to resolve such dispute through mediation with a mutually agreed mediator. If the mediation of such dispute does not commence within [...***...] (or such other period of time mutually agreed upon by the Parties) of the receipt of a written request for such mediation by the other Party, or if the dispute is not resolved within [...***...] (or such other period of time mutually agreed upon by the Parties) of commencing such mediation, or if the Parties are unable to agree upon a mediator, then except with respect to Excluded Claims, either Party may proceed to arbitration under Sections 17.1(c) to (g) (inclusive).

(c) Subject to Section 17.1(k), any Dispute shall be referred to and finally resolved by arbitration under the Rules of the LCIA, which rules are deemed to be incorporated by reference into this Section. Any arbitration commenced pursuant to this Section 17.1(c) shall be administered by the LCIA. The appointing authority shall be the LCIA. The standard LCIA Administrative Procedures and Schedule of Costs shall apply. The place of arbitration shall be London, UK. The language to be used in the arbitral proceedings shall be English.

(d) If such Dispute relates to (i) an amount less than [...***...] Euro (€[...***...]) in controversy, including claims and counterclaims, or (ii) if only injunctive relief is requested, or (iii) any of NBIX’s diligence obligations to use Commercially Reasonable Efforts, there will be one (1) arbitrator, who shall be selected jointly by NBIX and BIAL in accordance with the LCIA Rules, within [...***...] of receipt by respondent of a copy of the demand for arbitration. If NBIX and BIAL are not able to select such one (1) arbitrator, then LCIA shall finally select one (1) arbitrator whom it believes to be neutral and impartial for the Parties. Such arbitrator will have [...***...] from the date of appointment to render a decision.

(e) If the dispute relates to any of NBIX’s obligations to use Commercially Reasonable Efforts, the arbitrator’s decision in accordance with Section 17.1(d) shall include reasons as to whether

or not NBIX has complied with its diligence obligations to use Commercially Reasonable Efforts and, subject to Section 17.1(f), if such decision is that NBIX has not complied, such decision will set out a detailed plan as to how the position can be remedied in a reasonable period of time that shall not be more than [...***...].

(f) If an arbitrator acting in accordance with Sections 17.1(d) and 17.1(e) has previously decided that NBIX has breached a certain obligation to use Commercially Reasonable Efforts and NBIX has cured such breach, but subsequently, under the procedure set out in Section 17.1(d), an arbitrator decides that NBIX has breached the same obligation (i.e. the obligation to use Commercially Reasonable Efforts under the same Section of the Agreement) , then NBIX shall not have the right to cure such breach and BIAL may terminate the Agreement by giving [...***...] prior written notice following the decision.

(g) In the case of any Dispute other than that specified in Section 17.1(d) above, there will be three (3) neutral and impartial arbitrators, one appointed by NBIX and one appointed by BIAL, in both cases within [...***...] of receipt by respondent of a copy of the demand for arbitration, and the third arbitrator, who shall serve as chair of the arbitral tribunal, will be appointed by agreement of the Party-appointed arbitrators within [...***...] of the appointment of the second arbitrator. The arbitration shall be conducted as expeditiously as practicable, and the Parties and the arbitrators shall use their best efforts to hold the hearing on the merits no later than [...***...] after the appointment of the arbitration tribunal and the arbitrators shall use their best efforts to issue a final award within [...***...] after the close of the hearing.

(h) Any arbitrator appointed in accordance with Sections 17.1(d) and (e) shall have significant experience with the arbitration of similar large, complex, commercial disputes between pharmaceutical companies. All arbitration proceedings shall be conducted in the English language. The Parties agree that only documents directly relevant to the issues in Dispute must be produced in any such arbitration.

(i) In addition to damages, the arbitration tribunal may award any remedy provided for under applicable law and the terms of this Agreement, including, without limitation, specific performance or other forms of injunctive relief. The arbitration tribunal is not empowered to award damages in excess of compensatory damages, and each Party hereby irrevocably waives any right to recover punitive, exemplary and multiplied (including without limitation treble) damages with respect to any Dispute. The arbitration award must be in writing and will state, in English and in reasonable detail, the findings of fact and conclusions of law on which it is based. The arbitration award shall be final and binding on the Parties and shall not be appealable except for error in arbitration procedure, or as otherwise provided for by applicable treaty or law and may be entered and enforced in any court having competent jurisdiction.

(j) Each Party shall bear its own costs and expenses and attorneys' fees in the arbitration, except that the arbitrators may order the non-prevailing Party to bear all or an appropriate part (reflective of the relative success on the issues) of the costs and expenses and reasonable attorneys' fees incurred by the prevailing Party based on the relative merits of each Party's positions on the issues in the Dispute. The Party that substantially prevails in the arbitration proceeding shall be reimbursed any payments it has made in respect of the arbitrators' fees and expenses and any administrative fees of arbitration.

(k) As used in this Section, the term "Excluded Claim" means a dispute, controversy or claim that concerns (a) the validity, enforceability or infringement of a patent, trademark or registered copyright or (B) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory. Excluded Claims shall be brought in the courts in the applicable country in the Territory where the patent, trademark or copyright is registered or the antitrust, anti-monopoly or competition law or regulation has allegedly been breached. If the subject matter of the Excluded Claim is relevant to the subject matter of a pending dispute that is subject to arbitration then the Excluded Claim must also be brought only within the arbitration and not in the courts in order to avoid multiple proceedings and forum shopping.

17.2 **Interim Measures:** Notwithstanding Section 17.1, either Party may, without inconsistency with this Agreement, apply to a court to seek pre-arbitral provisional injunctive relief to maintain the status quo or prevent irreparable harm, pre-arbitral attachment, or any other relief or order in aid of arbitration proceedings and the enforcement of any award. Without prejudice to such provisional remedies as may be available under the jurisdiction of a court, the arbitration tribunal will have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any temporary or preliminary relief issued by such court, and to award damages for the failure of any Party to respect the arbitrator(s)' orders to that effect.

17.3 **Force Majeure:** If any circumstance beyond the reasonable control of either Party occurs which delays or renders impossible the performance of that Party's obligations under this Agreement on the dates herein provided (a " Force Majeure "), such obligation shall be postponed for such time as the event of Force Majeure exists, provided such Party notifies the other Party in writing as soon as practicable. The Party so affected shall give to the other Party a good faith estimate of the continuing effect of the Force Majeure condition and the anticipated duration of the affected Party's non-performance. Notwithstanding the foregoing, if the period of any previous actual non-performance of a Party because of Force Majeure conditions plus the anticipated future period of non-performance because of such conditions shall exceed an aggregate of [...***...], then then the Parties shall promptly meet and discuss in good faith appropriate measures to minimise the impact of the Force Majeure for both Parties, including without limitation a possible amendment to this Agreement or the termination thereof. Events of Force Majeure shall include, without limitation, war, revolution, invasion, insurrection, riots, mob violence, sabotage or other civil disorders, acts of God, earthquake, tsunami, limitations imposed by exchange control regulations or

foreign investment regulations or similar regulations, laws, regulations or rules of any government or governmental agency, any inordinate delays in the regulatory review or governmental approval process that are within the sole control of such government or governmental agency. A Party shall be considered affected by an event of Force Majeure to the extent that any of its suppliers or contractors is affected by such an event.

17.4 Assignment:

(a) Neither Party may, except as set forth in Sections 15.2(e) and 17.4(b), assign, transfer or otherwise dispose of this Agreement or any rights or obligation hereunder to any Affiliate or Third Party without the prior written consent of the other Party.

(b) BIAL may assign or transfer this Agreement, in whole or in part, or any right or obligation hereunder without NBIX's consent (i) to any of its Affiliates or (ii) to a Third Party successor in connection with its merger, acquisition or transfer or sale of all or substantially all of its assets related to Licensed Products in the Territory or the business relating thereto.

(c) Any attempted or purported assignment or transfer of rights or obligations other than provided herein shall be void.

17.5 Performance by Affiliates and subcontractors: Either Party may exercise any of its respective rights and perform any of its respective obligations hereunder through any of its Affiliates or contractors (in the case of NBIX, pursuant to Section 2.5). However, either Party shall remain responsible for the full and complete performance of and compliance with all of its obligations and duties under this Agreement and for all activities of its Affiliates and contractors to the same extent as if such activities had been undertaken by such Party itself.

17.6 No Third Party Beneficiaries:

(a) Subject to Section 17.6(b), this Agreement does not confer any right upon any person or entity other than NBIX and BIAL and their respective successors and permitted assigns to enforce any provision of this Agreement (whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise).

(b) The Affiliates of the Parties and the agents of the Parties and their Affiliates' directors, officers, employees and agents may enforce the provisions of Article 16 subject to and in accordance with Section 16.3 and the provisions of the Contracts (Rights of Third Parties) Act 1999.

(c) The rights of the Parties to terminate, rescind or agree any variation, waiver or settlement under this Agreement are not subject to the consent of any person that is not a party to this Agreement.

17.7 Waiver: The rights and remedies of either Party in respect of this Agreement shall not

be diminished, waived or extinguished by the granting of any indulgence, forbearance or extension of time granted by that Party to the other Party nor by any failure of, or delay in ascertaining or exercising any such rights or remedies. Any waiver of any breach of this Agreement shall be in writing. The waiver by either Party of any breach of this Agreement shall not prevent the subsequent enforcement of that provision and shall not be deemed to be a waiver of any subsequent breach of that or any other provision.

17.8 Governing Law: This Agreement and any dispute or claim arising out of or in connection with it (whether contractual or non-contractual in nature such as claims in tort, from breach of statute or regulation or otherwise) shall be governed by and construed in accordance with the laws of England and Wales, without reference to its conflicts of law principles.

17.9 Unenforceable Provisions: Any provision hereof that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof or affecting the validity or enforceability of such provision in any other jurisdiction. The Parties will replace such ineffective provision for such jurisdiction with a valid and enforceable provision which most closely approaches the idea, intent, and purpose of this Agreement, and in particular, the provision to be replaced.

17.10 Relationship Between the Parties: The Parties' relationship, as established by this Agreement, is solely that of independent contractors. Neither Party may pledge the credit of the other Party nor represent itself as being the other Party nor an agent, partner, employee or representative of the other Party and neither Party may hold itself out as such nor as having any power or authority to incur any obligation of any nature, express or implied, on behalf of the other. Nothing in this Agreement, and no action taken by the Parties pursuant to this Agreement, creates, or is deemed to create, a partnership or joint venture or relationship of employer and employee or principal and agent between the Parties.

17.11 Entire Agreement:

(a) This Agreement, including the exhibits attached hereto, and the agreements referred to herein contain the entire agreement between the Parties in relation to its subject matter and supersedes any prior arrangement, understanding written or oral agreements between the Parties in relation to such subject matter.

(b) The Parties acknowledge that this Agreement has not been entered into wholly or partly in reliance on, nor has either Party been given, any warranty, statement, promise or representation by the other or on its behalf other than as expressly set out in this Agreement.

(c) Each Party agrees that the only rights and remedies available to it arising out of or in connection with any warranties, statements, promises or representations will be for breach of contract

and irrevocably and unconditionally waives any right it may have to any claim, rights or remedies including any right to rescind this Agreement which it might otherwise have had in relation to them.

(d) All warranties, conditions, terms and representations not set out in this Agreement whether implied by statute or otherwise are excluded to the extent permitted by law.

17.12 Amendments: The Parties may from time to time during the continuance of this Agreement modify, vary or alter any of the provisions of this Agreement, but only by written agreement of the Parties.

17.13 Notices: All communications, reports, payments and notices required by this Agreement will be addressed to the Parties at their respective addresses set forth below or to such other address as requested by a Party by notice in writing to the other Party.

(a) If to BIAL:

BIAL – Portela & Ca, S.A.
Attention: Chief Executive Officer
À Avenida da Siderurgia Nacional
4745-457 S. Mamede do Coronado
Portugal
Fax: +351 229 866 199

with a copy to:

BIAL – Portela & Ca, S.A.
Attention: Legal Director
À Avenida da Siderurgia Nacional
4745-457 S. Mamede do Coronado
Portugal
Fax: +351 229 866 190

(b) If to NBIX:

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

Fax: +1-858-777-3488

with a copy to:

Neurocrine Biosciences, Inc.
Attention: Chief Legal Officer
12780 El Camino Real
San Diego, CA 92130
USA
Fax: +1-858-777-3488

(c) All such notices, reports, payments, and communications will be made by First Class mail, postage prepaid or by reputable overnight courier providing evidence of receipt, or by facsimile (and promptly confirm by mail or overnight courier), and will be considered made as of the date of confirmed receipt.

17.14 Language: This Agreement is entered into in the English language. All amendments or correspondence concerning or relating to this Agreement, the Supply Agreement, the Quality Agreement, the Co-Promotion Agreement (if any), or the SDEA, and all notices given and all documentation to be delivered by either Party to the other under this Agreement shall be in writing in the English language.

17.15 Counterparts: This Agreement may be executed simultaneously in any number of counterparts, but all such counterparts taken together will constitute one and the same agreement. This Agreement will be treated in all manner and respects and for all purposes as an original agreement or instrument and will be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

< Signature page follows >

IN WITNESS WHEREOF, and intending to be legally bound, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

BIAL – PORTELA & CA, S.A.

By: /s/ António Portela
Name: António Portela
Position: Chief Executive Officer

Date: 2/9/2017

By: /s/ Isabel Morgado
Name: Isabel Morgado
Position: Member of the Board of Directors

Date: 2/9/2017

NEUROCRINE BIOSCIENCES, INC

By: /s/ Kevin Gorman
Name: Kevin Gorman
Position: Chief Executive Officer

Date:

EXHIBIT 2.1

BIAL Patents

[...***...]

EXHIBIT 2.1(g)

Cooperation Terms

1. Trade Meetings: If, in respect of a Licensed Product, **(i)** BIAL or one of its Affiliates or licensees outside the Territory wishes to attend any professional or trade meeting, including scientific congresses, inside the Territory or **(ii)** NBIX or one of its Affiliates wishes to attend any professional or trade meeting, including scientific congresses, outside the Territory, then each such Party shall provide reasonable advance notice to the other Party. The Parties shall endeavour to cooperate in respect of their attendance in organized events and organizing non-core events relating to the Licensed Product during such meeting; provided, however, that in the event such events occur in the territory of other BIAL's licensees, [...***...]. In no event shall any such activities of BIAL or its Affiliates or licensees be directed at sales of Licensed Products by or on behalf of BIAL or its Affiliates in the Territory, and in no event shall any such activities of NBIX or its Affiliates be directed at sales of Licensed Products by or on behalf of NBIX or its Affiliates anywhere in the world except in the Territory. Each Party shall bear its own costs of participation at any such meeting.

2. Key Opinion Leaders:

(a) The Parties acknowledge that, from time to time, NBIX or its Affiliates may be interested in engaging Outside Territory KOLs for the purposes of providing consultancy services to NBIX in connection with the Licensed Products within the Territory. To the extent that such services or interactions with such KOLs are not intended as or otherwise constitute a promotional, marketing or development activity outside the Territory, NBIX shall have the right to conduct such activities outside the Territory; provided, however, that NBIX shall previously inform BIAL of such any activities and coordinate such activities with BIAL. For the avoidance of doubt, confidential advisory boards and confidential consultancy meetings with KOLs do not constitute promotional, marketing or development activity.

(b) The Parties acknowledge that, from time to time, BIAL or its Affiliates or licensees may be interested in engaging Territory KOLs for the purposes of providing consultancy services to BIAL in connection with Licensed Products outside the Territory. To the extent that such services or interactions with KOLs are not intended as or otherwise constitute a promotional or marketing activity in the Territory, BIAL shall have the right to conduct such activities inside the Territory; provided, however, that BIAL shall previously inform NBIX of such any activities and coordinate such activities with NBIX. For the avoidance of doubt, confidential advisory boards and confidential consultancy meetings with KOLs do not constitute promotional or marketing activity.

3. **Co-Promotion Plan:** In accordance with Section 2.10(b), BIAL shall have the right to conduct commercialization activities in the Territory in order to prepare a Co-promotion Plan and NBIX shall assist in the provision of data and information as reasonably requested by BIAL and if not previously provided as part of the Annual Commercialization Plan.

EXHIBIT 2.3

Trademarks

[...***...]

EXHIBIT 2.4

BIAL Logo

[...***...]

EXHIBIT 2.6(b)

Transfer Plan

[...***...]

EXHIBIT 2.10(b)

Final Position Arbitration Procedure

Final position arbitration shall be commenced and conducted as follows:

1. Arbitrator: The determination of terms and conditions of the proposed Co-Promotion Agreement that remain unresolved after good faith negotiations shall be referred to and decided and settled by a single independent arbitrator selected by the LCIA with input from both NBIX and BIAL. Such arbitrator must have at least [...] years of experience in negotiating and structuring co-promotion and/or co-commercialization arrangements in the pharmaceutical field for specialty products. Selection of the arbitrator shall be made within [...] after the date of the first notice of demand and within [...] after any resignation, disability or other removal of such arbitrator.

2. Costs of Arbitration: The cost of arbitration proceedings, including the arbitrator's compensation and expenses, hearing room charges and court reporter transcript charges shall be borne by the Parties equally or otherwise as the arbitrator may determine.

3. Location of Proceedings: All arbitration proceedings shall be held in London, England, unless the Parties agree otherwise, at a location selected by the Parties.

4. Conduct of Arbitration:

(a) Pre-hearing Conference. Within [...] after appointment, the arbitrator shall hold a pre-hearing conference to establish the framework of substantive provisions to be included in a Co-Promotion Agreement proposal by the Parties, schedules for exchange of exhibits and witness lists, for arbitration briefs, for the hearing, and to decide procedural matters and all other questions that may be presented.

(b) Not less than [...] before the date of the hearing, each Party shall deliver to the arbitrator its final position with respect to the Co-Promotion Agreement or a specific term or terms thereof in dispute, which shall include in all instances a draft of a Co-Promotion Agreement containing all provisions sought by the submitting Party and which the submitting Party is willing to execute upon the conclusion of the arbitration if the submitting Party prevails in such arbitration, such final position (including the draft Co-Promotion Agreement) delivered by BIAL being referred to as “ **BIAL's Final Position** ” and such final position (including the draft Co-Promotion Agreement) delivered by NBIX being referred to as “ **NBIX's Final Position** ”). If either Party fails to timely deliver its

final position or its final draft Co-Promotion Agreement, that Party shall be deemed to have accepted the final position and draft Co-Promotion Agreement of the other Party. The arbitrator shall select mutually agreed upon provisions from such draft Co-Promotion Agreements, in their entirety, and may not determine an alternative or compromise to those provisions. With respect to other provisions where the Parties have not reached agreement, the arbitrator may select, on a provision by provision basis, either position proposed by a Party but in any event not an entirely alternative or compromise position. In making his/her determination, the arbitrator shall take into account usual industry practice and a position that is fair to both Parties taking into consideration the capabilities and resources then existing for the respective Parties. No less than [...] before the date of the hearing, the arbitrator shall deliver to each Party the draft Co-Promotion Agreements as determined by the arbitrator.

(c)Hearing Procedures:

- (i)** The hearing shall be conducted to preserve its privacy and to allow reasonable procedural due process. Rules of evidence need not be strictly followed, and the hearing shall be streamlined.
- (ii)** The hearing should be held on consecutive business days without interruption to the maximum extent practicable.
- (iii)** No pre-hearing discovery shall be permitted or taken in the resolution of any matter subject to the provisions hereof.
- (iv)** Expert reports may be utilized.
- (v)** Charts, graphs, and summaries shall be utilized to present voluminous data, provided that the underlying data was made available to the opposing Party [...] prior to the hearing.
- (vi)** The arbitrator shall establish all other procedural rules for the conduct of the arbitration in accordance with the rules of arbitration of the LCIA.

5. Governing Law: This arbitration provision shall be governed by, and all rights and obligations specifically enforceable under and pursuant to, the laws of England and Wales.

6. Award: The arbitrator shall issue his or her decision by delivering written notice to each Party setting forth the arbitrator's decision regarding the terms of the proposed Co-Promotion Agreement and any other award of fees or expenses. Any award of fees or expenses rendered by the arbitrator shall be final. The arbitrator's decision shall be final.

7. **Confidentiality:** The Parties hereto will maintain the substance of any proceedings hereunder in confidence and the arbitrator, prior to any proceedings hereunder, will sign an agreement whereby the arbitrator agrees to keep the substance of any proceedings hereunder in confidence.

8. **Time Frame:** To the fullest extent practicable pre-hearing conferences and hearing procedures shall be expedited and the Parties shall use their best reasonable efforts to conclude the dispute resolution proceeding herein within [...***...] to the event feasible and practicable under the circumstances. Under no circumstances shall the conclusion of such dispute resolution proceeding extend beyond [...***...] except by mutual consent of each Party.

EXHIBIT 4

Certain Supply Terms

1.1 [...***...]

104-110 / 118

EXHIBIT 6.3(a)

[...***...]

111-114 / 118

EXHIBIT 6.4

BIAL Studies

[...***...]

EXHIBIT 8.3(e)

Assumptions (for the Agreed Sales Forecasts)

[...***...]

EXHIBIT 9.2(c)

Existing Licensees

[...***...]

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

I, Kevin C. Gorman, 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: May 5, 2021

/s/ Kevin C. Gorman

Kevin C. Gorman
Chief Executive Officer

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

I, Matthew C. Abernethy, 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: May 5, 2021

/s/ Matthew C. Abernethy

Matthew C. Abernethy
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, 2021 as filed with the Securities and Exchange Commission on the date hereof (Report), I, Kevin C. Gorman, 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.

May 5, 2021

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

In connection with the Quarterly Report of Neurocrine Biosciences, Inc. (Company) on Form 10-Q for the period ended March 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (Report), I, Matthew C. Abernethy, 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.

May 5, 2021

By: /s/ Matthew C. Abernethy
Name: Matthew C. Abernethy
Title: Chief Financial Officer