### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### **FORM 10-Q**

(Mark One)

X

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

For the quarterly period ended June 30, 2020

OR

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

For the transition period from \_\_\_\_\_to \_\_\_\_ Commission file number 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	$\boxtimes$	Accelerated filer	
Non-accelerated filer		Smaller reporting company	
Emerging growth company			

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.  $\Box$ 

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 93,254,872 as of July 28, 2020.

### TABLE OF CONTENTS

	PAGE
Part I. Financial Information	3
Item 1. Financial Statements	3
Condensed Consolidated Balance Sheets as of June 30, 2020 and December 31, 2019	3
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and six months ended June 30, 2020 and 2019	4
Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2020 and 2019	5
Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2020 and 2019	6
Notes to the Condensed Consolidated Financial Statements	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	20
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	24
Part II. Other Information	25
Item 1A. Risk Factors	25
Item 6. Exhibits	46
Signatures	47

### Part I. Financial Information

### **Item 1. Financial Statements**

#### **NEUROCRINE BIOSCIENCES, INC.**

#### CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

(in millions, except per share data)		June 30, 2020	December 31, 2019		
Assets					
Current assets:					
Cash and cash equivalents	\$	415.1	\$	112.3	
Debt securities available-for-sale, at fair value (amortized cost \$530.3 million at June 30, 2020 and \$557.3 million at December 31, 2019)		533.2		558.2	
Accounts receivable		148.4		126.6	
Inventories		22.0		17.3	
Other current assets		27.5		16.6	
Total current assets		1,146.2		831.0	
Debt securities available-for-sale, at fair value (amortized cost \$193.5 million at June 30, 2020 and \$299.3 million at December 31, 2019)		195.2		299.7	
Right-of-use assets		72.1		74.3	
Equity securities		50.7		55.9	
Property and equipment, net		44.6		41.9	
Restricted cash		3.2		3.2	
Other long-term assets		3.6		_	
Total assets	\$	1,515.6	\$	1,306.0	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable and accrued liabilities	\$	137.1	\$	141.3	
Convertible senior notes		419.5		408.8	
Other current liabilities		16.4		15.2	
Total current liabilities		573.0	<u></u>	565.3	
Operating lease liabilities		84.3		86.7	
Other long-term liabilities		27.1		17.1	
Total liabilities	_	684.4		669.1	
Stockholders' equity:					
Preferred stock, \$0.001 par value; 5.0 shares authorized; no shares issued and outstanding at June 30, 2020 and December 31, 2019		_		_	
Common stock, \$0.001 par value; 220.0 shares authorized; issued and outstanding shares were 93.2 at June 30, 2020 and 92.3 at December 31, 2019	1	0.1		0.1	
Additional paid-in capital		1,842.2		1,768.1	
Accumulated other comprehensive income		4.6		1.4	
Accumulated deficit		(1,015.7)		(1,132.7)	
		831.2		636.9	
Total stockholders' equity		0011		00010	

See accompanying notes to the condensed consolidated financial statements.

#### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS) (unaudited)

	Three Mo Ju	nths Ei ie 30,	nded	Six Months Ended June 30,				
(in millions, except per share data)	 2020		2019	 2020		2019		
Revenues:								
Product sales, net	\$ 267.6	\$	180.5	\$ 498.7	\$	316.9		
Collaboration revenue	 34.8		3.0	40.8		5.0		
Total revenues	302.4		183.5	539.5		321.9		
Operating expenses:								
Cost of sales	2.4		1.6	4.5		2.7		
Research and development	80.9		61.7	139.2		99.4		
Acquired in-process research and development	46.0		5.0	46.0		118.1		
Selling, general and administrative	 96.5		80.8	214.3		168.3		
Total operating expenses	225.8		149.1	 404.0		388.5		
Operating income (loss)	 76.6		34.4	135.5		(66.6)		
Other income (expense):								
Interest expense	(8.3)		(7.9)	(16.5)		(15.8)		
Unrealized gain (loss) on equity securities	11.3		21.0	(5.2)		22.7		
Investment income and other, net	3.6		4.6	8.3		9.2		
Total other income (expense), net	 6.6		17.7	(13.4)		16.1		
Income (loss) before provision for income taxes	 83.2		52.1	122.1		(50.5)		
Provision for income taxes	3.6		0.8	5.1		0.3		
Net income (loss)	79.6		51.3	117.0		(50.8)		
Unrealized gain on debt securities available-for-sale, net of tax	6.0		0.9	3.2		2.6		
Comprehensive income (loss)	\$ 85.6	\$	52.2	\$ 120.2	\$	(48.2)		
Net income (loss) per share, basic	\$ 0.86	\$	0.56	\$ 1.26	\$	(0.56)		
Net income (loss) per share, diluted	\$ 0.81	\$	0.54	\$ 1.20	\$	(0.56)		
Weighted average common shares outstanding, basic	93.0		91.4	92.8		91.2		
Weighted average common shares outstanding, diluted	98.2		94.8	97.6		91.2		

See accompanying notes to the condensed consolidated financial statements.

# CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (unaudited)

	Comm	ion Ste	ock				cumulated Other			
(in millions)	Shares		Amount	. Ad	ditional Paid-In Capital	Com	prehensive Income (Loss)	Acc	umulated Deficit	Total
Balances at March 31, 2020	92.8	\$	0.1	\$	1,796.9	\$	(1.4)	\$	(1,095.3)	\$ 700.3
Net income	—		—		—		—		79.6	79.6
Unrealized gain on debt securities available-for-sale, net of tax	_		_		_		6.0		_	6.0
Share-based compensation expense	_		_		29.5				_	29.5
Issuance of common stock for vested restricted stock options	0.1		_		_		_		_	_
Issuance of common stock for stock options	0.3		_		15.8		_			15.8
Balances at June 30, 2020	93.2	\$	0.1	\$	1,842.2	\$	4.6	\$	(1,015.7)	\$ 831.2
		-		-						
Balances at March 31, 2019	91.3	\$	0.1	\$	1,681.3	\$	(0.3)	\$	(1,271.8)	\$ 409.3
Net income	—		_		_		_		51.3	51.3
Unrealized gain on debt securities available-for-sale, net of tax	_				_		0.9		_	0.9
Share-based compensation expense	_		_		17.9		_			17.9
Issuance of common stock for stock options	0.2		_		4.3		_			4.3
Balances at June 30, 2019	91.5	\$	0.1	\$	1,703.5	\$	0.6	\$	(1,220.5)	\$ 483.7
-						·				
Balance at December 31, 2019	92.3	\$	0.1	\$	1,768.1	\$	1.4	\$	(1,132.7)	\$ 636.9
Net income	_		_		_				117.0	117.0
Unrealized gain on debt securities available-for-sale, net of tax	_		_		_		3.2			3.2
Share-based compensation expense	_		_		52.3		_		_	52.3
Issuance of common stock for vested restricted stock										
options	0.5		_		_				_	_
Issuance of common stock for stock options	0.4		—		19.1		—		—	19.1
Issuance of common stock for employee stock purchase plan	_		_		2.7		_		_	2.7
Balances at June 30, 2020	93.2	\$	0.1	\$	1,842.2	\$	4.6	\$	(1,015.7)	\$ 831.2
		-		. —						
Balance at December 31, 2018	90.8	\$	0.1	\$	1,660.4	\$	(2.0)	\$	(1,177.7)	\$ 480.8
Net loss	—		—		—		—		(50.8)	(50.8)
Unrealized gain on debt securities available-for-sale, net of tax	_				_		2.6		_	2.6
Share-based compensation expense	_		_		33.7		_		_	33.7
Issuance of common stock for vested restricted stock										
options	0.4		—		—				_	—
Issuance of common stock for stock options	0.3		_		6.9				_	6.9
Issuance of common stock for employee stock purchase plan	_		_		2.5		_		_	2.5
Cumulative-effect adjustment to equity due to adoption of ASU 2016-02	_						_		8.0	8.0
Balance at June 30, 2019	91.5	\$	0.1	\$	1,703.5	\$	0.6	\$	(1,220.5)	\$ 483.7
		:		:		:				

See accompanying notes to the condensed consolidated financial statements.

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

	Six Months Ended June 30,								
(in millions)	 2020		2019						
Cash Flows from Operating Activities:									
Net income (loss)	\$ 117.0	\$	(50.8)						
Reconciliation of net income (loss) to net cash provided by (used in) operating activities:									
Share-based compensation expense	52.3		33.7						
Depreciation	4.2		3.4						
Amortization of debt discount	10.0		9.3						
Amortization of debt issuance costs	0.7		0.7						
Change in fair value of equity security investments	5.2		(22.7)						
Other	0.7		(0.6)						
Change in operating assets and liabilities:									
Accounts receivable	(21.8)		(39.1)						
Inventory	(4.7)		(1.2)						
Accounts payable and accrued liabilities	(5.1)		7.7						
Other assets and liabilities, net	(1.4)		11.3						
Net cash provided by (used in) operating activities	157.1		(48.3)						
Cash Flows from Investing Activities:									
Purchases of debt securities available-for-sale	(288.6)		(235.9)						
Sales and maturities of debt securities available-for-sale	421.2		339.7						
Purchases of equity securities	—		(54.7)						
Purchases of property and equipment	(6.0)		(8.4)						
Net cash provided by investing activities	 126.6		40.7						
Cash Flows from Financing Activities:									
Issuance of common stock	19.1		6.9						
Net cash provided by financing activities	 19.1	<u></u>	6.9						
Change in cash and cash equivalents and restricted cash	 302.8		(0.7)						
Cash and cash equivalents and restricted cash at beginning of period	115.5		147.2						
Cash and cash equivalents and restricted cash at end of period	\$ 418.3	\$	146.5						
Supplemental Disclosure:									
Non-cash capital expenditures	\$ 0.9	\$	0.9						
Cash paid for interest	\$ 5.8	\$	5.8						
Cash paid for income taxes	\$ _	\$	0.4						

See accompanying notes to the condensed consolidated financial statements.

# 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 commercial-stage biopharmaceutical company focused on discovering and developing innovative and life-changing treatments for patients with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. We specialize in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. Currently, we are primarily focused on the commercialization of INGREZZA<sup>®</sup> (valbenazine) in the United States, or US, our first US Food and Drug Administration, or FDA, approved product.

In April 2017, we received FDA approval of our first marketed product, INGREZZA, for the treatment of adults with tardive dyskinesia, or TD. Shortly after receiving FDA approval, we began commercializing INGREZZA in the US using a specialty sales force primarily focused on educating physicians who treat patients with TD, including psychiatrists and neurologists.

In addition to our first marketed product, our collaboration partner, AbbVie Inc., or AbbVie, received approval of ORILISSA<sup>®</sup> (elagolix) for the management of moderate to severe endometriosis pain in women from the FDA in July 2018 and Health Canada in October 2018. We receive royalties at tiered percentage rates on any net sales of ORILISSA.

In April 2020, we received FDA approval for ONGENTYS<sup>®</sup> (opicapone) as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients. FDA approval for ONGENTYS for Parkinson's disease triggered a milestone payment of \$20.0 million, which was expensed as research and development, or R&D, in the second quarter of 2020.

In May 2020, AbbVie received approval from the FDA for ORIAHNN<sup>TM</sup> (elagolix) for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. FDA approval for ORIAHNN for uterine fibroids resulted in the achievement of a \$30.0 million regulatory milestone, which was recognized as collaboration revenue in the second quarter of 2020. We are entitled to receive royalties at tiered percentage rates on any net sales of ORIAHNN.

Our late-stage pipeline includes crinecerfont (NBI-74788) for the treatment of congenital adrenal hyperplasia, or CAH, in adult patients, valbenazine for the treatment of chorea in adult patients with Huntington's disease, or HD, and NBIb-1817 (VY-AADC) for the treatment of advanced Parkinson's disease patients with motor fluctuations that are refractory to medical management. Our product candidate for advanced Parkinson's disease is partnered with Voyager Therapeutics, Inc., or Voyager.

Our early-stage clinical pipeline includes crinecerfont for the treatment of CAH in pediatric patients, elagolix for the treatment of polycystic ovary syndrome, or PCOS, in women, NBI-921352 (XEN901), a clinical-stage candidate with potential in epilepsy, and NBI-827104 (ACT-709478), a T-type calcium channel blocker in clinical development for the treatment of a rare pediatric epilepsy. Our product candidate for PCOS is partnered with AbbVie.

In May 2020, we entered into a collaboration and licensing agreement with Idorsia Pharmaceuticals Ltd, or Idorsia. In connection with the agreement, we paid Idorsia \$45.0 million upfront to gain a license 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. The agreement includes a research collaboration to discover and identify up to two additional novel T-type calcium channel blockers as development candidates.

In June 2020, we entered into an exclusive license agreement with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize certain compounds in Takeda's early to mid-stage psychiatry pipeline. The agreement became effective in July 2020, upon expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. In connection with the agreement, we paid Takeda \$120.0 million upfront (less an earnest money deposit paid by us to Takeda in the first quarter of 2020) to gain an exclusive license to seven of Takeda's pipeline programs, including three clinical-stage assets for schizophrenia, treatment-resistant depression, and anhedonia. The collaboration also includes a cost-sharing arrangement for associated collaboration activities.

*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, 2019, included in our Annual Report on Form 10-K, or the 2019 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, 2019, 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 2019 Form 10-K, except as set forth below.

**Debt Securities.** Debt securities consist of investments in certificates of deposit, corporate debt securities, and securities of government-sponsored entities. We classify debt securities as available-for-sale. Debt securities available-for-sale are recorded at fair value, with unrealized gains and losses included in other comprehensive income or loss, net of tax. We exclude accrued interest from both the fair value and amortized cost basis of debt securities. A debt security is placed on nonaccrual status at the time any principal or interest payments become 90 days delinquent. Interest accrued but not received for a debt security placed on nonaccrual status is reversed against interest income.

Interest income includes amortization of purchase premium or discount. Premiums and discounts on debt securities are amortized using the effective interest rate method. Gains and losses on sales of debt securities are recorded on the trade date in investment income and other, net, and determined using the specific identification method.

Allowance for Credit Losses. For debt securities available-for-sale in an unrealized loss position, we first assess whether we intend to sell, or it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through earnings. For debt securities available-for-sale that do not meet the aforementioned criteria, we evaluate whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, we consider the extent to which fair value is less than amortized cost, any changes in interest rates, and any changes to the rating of the security by a rating agency, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security is compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded, limited by the amount that the fair value is less than the amortized cost basis. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive income or loss, as applicable.

Accrued interest receivables on debt securities available-for-sale totaled \$3.7 million at June 30, 2020. 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 six months ended June 30, 2020.

*Fair Value of Financial Instruments.* We record cash equivalents, 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-forsale 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.

#### **Recently Adopted Accounting Pronouncements.**

ASU 2016-13. On January 1, 2020, we adopted Accounting Standards Update, or ASU, 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, using the modified retrospective transition method. For debt securities available-for-sale, the standard requires an investor to determine whether a decline in the fair value below the amortized cost basis of the investment is due to credit-related factors. Credit-related impairment is recognized as an allowance for credit loss on the balance sheet with a corresponding adjustment to earnings. Credit losses are limited to the amount by which the investment's amortized cost basis exceeds its fair value and may be subsequently reversed if conditions change. Any impairment that is not credit related is recognized in other comprehensive income or loss, as applicable, net of applicable taxes.

The adoption of ASU 2016-13 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.

#### **Recently Issued Accounting Pronouncements.**

ASU 2019-12. In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which 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. ASU 2019-12 is effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted in any interim period for which financial statements have not yet been made available for issuance. We are currently evaluating the effect that ASU 2019-12 will have on our condensed consolidated financial statements and related disclosures.

#### 2. Significant Collaboration and Licensing Agreements

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

AbbVie received approval of ORILISSA for the management of moderate to severe endometriosis pain in women from the FDA in July 2018 and Health Canada in October 2018.

In May 2020, AbbVie received approval from the FDA for ORIAHNN for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. FDA approval for ORIAHNN for uterine fibroids resulted in the achievement of a \$30.0 million regulatory milestone, which was recognized as collaboration revenue in the second quarter of 2020.

Since inception of the agreement, we have recognized revenue of \$75.0 million associated with the delivery of a technology license and existing know-how and \$165.0 million associated with the achievement of certain development and regulatory milestones. Pursuant to the terms of the agreement, we may also be entitled to receive payments of up to \$366.0 million upon the achievement of certain development, regulatory and commercial milestones.

Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing, and commercialization costs. We will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. AbbVie may terminate the collaboration at its discretion upon 180 days' written notice to us.

We evaluated the terms of this agreement under Topic 606, *Revenue from Contracts with Customers*, and determined that there is one performance obligation, the exclusive worldwide license with rights to develop, manufacture, and commercialize elagolix. At execution, the transaction price included only the \$75.0 million up-front consideration received. None of the development or regulatory milestones were included in the transaction price, as all milestone amounts were fully constrained. As part of our evaluation of the constraint, we considered numerous factors, including that achievement of the milestones is outside of our control and contingent upon success in future clinical trials and the licensee's efforts. Any consideration

related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to AbbVie and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

*BIAL* – *Portela & Ca, S.A.* In the first quarter of 2017, we entered into an exclusive license agreement with BIAL – Portela & Ca, S.A., or BIAL, for the development and commercialization of ONGENTYS for the treatment of human diseases and conditions, including Parkinson's disease, in the US and Canada.

In April 2020, we received FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients. FDA approval for ONGENTYS for Parkinson's disease triggered a milestone payment of \$20.0 million, which was expensed as R&D in the second quarter of 2020. Pursuant to the terms of the agreement, BIAL may also be entitled to receive up to \$75.0 million upon the achievement of certain commercial milestones.

Under the terms of the agreement, we are responsible for the commercialization of ONGENTYS in the US and Canada. Further, we will rely on BIAL for the commercial supply of ONGENTYS. Upon our written request prior to the estimated expiration of the term of a licensed product, the parties shall negotiate a good faith continuation of BIAL's supply of such licensed product after the term. After the term, and if BIAL is not supplying a certain licensed product, we shall pay BIAL a trademark royalty based on the net sales of such licensed product.

Upon commercialization of ONGENTYS, we will determine certain annual sales forecasts. In the event we fail to meet the minimum sales requirements for a particular year, we would be obligated to pay BIAL an amount equal to the difference between the actual net sales and minimum sales requirements for such year.

Unless earlier terminated, the agreement will continue on a licensed product-by-product and country-by-country basis until a generic product in respect of such licensed product under the agreement is sold in a country and sales of such generic product are greater than a specified percentage of total sales of such licensed product in such country.

Either party may terminate the agreement if the other party materially breaches the agreement and does not cure the breach within a specified notice period, or upon the other party's insolvency. BIAL may terminate the agreement if we fail to use commercially reasonable efforts to submit an NDA for a licensed product by a specified date, in the event we fail to meet the minimum sales requirements for any two years, or under certain circumstances involving a change of control of Neurocrine Biosciences. Under certain circumstances where BIAL elects to terminate the agreement in connection with a change of control of Neurocrine Biosciences, BIAL would be obligated to pay us a termination fee. We may terminate the agreement at any time for any reason upon nine months' written notice to BIAL.

*Voyager.* In the first quarter of 2019, we entered into a collaboration and license agreement with Voyager, a clinical-stage gene therapy company. The agreement is focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platform. The four programs consist of the NBIb-1817 program for Parkinson's disease, the Friedreich's ataxia program and the rights to two undisclosed programs.

In connection with the agreement, we paid Voyager \$115.0 million upfront and purchased \$50.0 million of Voyager's common stock at \$11.9625 per share, representing approximately 4.2 million shares. Pursuant to the terms of the agreement, Voyager may also be entitled to receive payments of up to \$1.7 billion upon the achievement of certain development, regulatory and commercial milestones, as well as receive royalties on the net sales of any collaboration product. We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. Our equity investment in Voyager was recorded at a fair value of \$54.7 million after considering Voyager's stock price on the date of closing and certain lock-up and voting provisions applicable to the acquired shares. The remaining \$113.1 million of the purchase price, which includes the applicable transaction costs, was expensed as in-process research and development, or IPR&D, in the second quarter of 2019.

In June 2019, we entered into an amendment to the collaboration and license agreement with Voyager. Under the terms of the amendment, we paid Voyager \$5.0 million upfront to obtain rights outside the US to the Friedreich's ataxia program in connection with the early return of those rights to Voyager pursuant to a restructuring of Voyager's gene therapy relationship with Sanofi Genzyme. The upfront payment was expensed as IPR&D in the second quarter of 2019.

Pursuant to development plans agreed to by us and Voyager, unless Voyager exercises its co-development and co-commercialization rights as provided for in the agreement, we will be responsible for all development costs. Further, upon the occurrence of a specified event for each program, we will assume responsibility for the development, manufacturing, and commercialization activities of such program.

We may terminate the collaboration and license agreement with Voyager upon 180 days' written notice to Voyager prior to the first commercial sale of any collaboration product or upon one year after the date of notice if such notice is provided after



the first commercial sale of any collaboration product. Unless terminated earlier, the agreement will continue in effect until the expiration of the last to expire royalty term with respect to any collaboration product or the last expiration or termination of any exercised co-development and co-commercialization rights by Voyager as provided for in the agreement.

*Xenon.* 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 and three preclinical candidates, which compounds we will have the exclusive right to further develop and commercialize under the terms and conditions set forth in the agreement.

We will be solely responsible, at our sole cost and expense, for all development and manufacturing of the compounds and any pharmaceutical product that contains a compound, subject to Xenon's right to elect to co-fund the development of one product in a major indication and thus receive a mid-single digit percentage increase in royalties owed on the net sales of such product in the US. If Xenon exercises such option, the parties will share equally all reasonable and documented costs and expenses incurred in connection with the development of such product in the applicable indication, except costs and expenses that are solely related to the development of such product for regulatory approval outside the US.

In connection with the agreement, we paid Xenon \$30.0 million upfront and purchased \$20.0 million of Xenon's common stock at \$14.196 per share, representing approximately 1.4 million shares. Pursuant to the terms of the agreement, Xenon may also be entitled to receive payments of up to \$1.7 billion upon the achievement of certain development, regulatory and commercial milestones, as well as receive royalties on the net sales of any collaboration product.

We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. Our equity investment in Xenon was recorded at a fair value of \$14.1 million after considering Xenon's stock price on the date of closing and certain lock-up and voting provisions applicable to the acquired shares. The remaining \$36.2 million of the purchase price, which includes the applicable transaction costs, was expensed as IPR&D in the fourth quarter of 2019.

Unless earlier terminated, the term of the license and collaboration agreement will continue on a product-by-product and country-by-country basis until the expiration of the royalty term for such product in such country. Upon the expiration of the royalty term for a particular product and country, the exclusive license granted by Xenon to us with respect to such product and country will become fully paid, royalty free, perpetual, and irrevocable. We may terminate the license and collaboration agreement by providing at least 90 days' written notice, provided that such unilateral termination will not be effective for certain products until we have used commercially reasonable efforts to complete certain specified clinical studies. Either party may terminate the agreement in the event of a material breach in whole or in part, subject to specified conditions.

*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 for movement disorders in Japan and other select Asian markets.

In the first six months of 2020, we recognized revenue of \$1.3 million in connection with the ongoing KINECT-HD study, a placebo-controlled Phase III study of valbenazine in adult Huntington's disease patients with chorea. In accordance with our continuing performance obligations, \$8.1 million of the \$30.0 million upfront payment received from MTPC in connection with the agreement is being deferred and will be recognized as revenue over the study period using an input method according to costs incurred to-date relative to estimated total costs associated with the study.

Since inception of the agreement, we have recognized revenue of \$19.8 million associated with the delivery of a technology license and existing knowhow, \$15.0 million associated with the achievement of a certain development milestones, and \$2.1 million associated with our performance of the ongoing KINECT-HD study. Pursuant to the terms of the agreement, we may also be entitled to receive payments of up to \$70.0 million upon the achievement of certain regulatory and commercial milestones, receive payments for the manufacture of certain pharmaceutical products, as well as receive royalties on the net sales of collaboration products in select territories in Asia.

Under the terms of the agreement, MTPC is responsible for all third-party development, marketing, and commercialization costs in Japan and other select Asian markets and we would be entitled to a percentage of sales of INGREZZA in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights. Further, the collaboration effort between the parties to advance INGREZZA towards commercialization in Japan and other select Asian markets is governed by joint steering and development committees with representatives from both parties. There are no performance, cancellation, termination, or refund provisions in the agreement that would have a material financial consequence to us. We do not directly control when event-based payments will be achieved or when royalty payments will begin. MTPC may terminate the agreement at its discretion upon 180 days' written notice to us. In such event, all INGREZZA product rights for Japan and other select Asian markets would revert to us.



We assessed this arrangement in accordance with Topic 606 and identified the following performance obligations: (i) INGREZZA technology license and existing know-how; and (ii) development activities to initiate a clinical study of INGREZZA for Huntington's chorea. We have the option to participate on the joint steering committee, but since participation is at our option it was deemed to not be a performance obligation. The option for MTPC to engage us to manufacture and supply pharmaceutical products, not at a discount, was not considered a material right and therefore not a performance obligation. Based on these assessments, we identified the license and the development activities as the only performance obligations at the inception of the agreement, which were both deemed to be distinct.

To evaluate the appropriate transaction price, we determined that the up-front payment received constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on our best estimate of their relative stand-alone selling prices. For the license, the stand-alone selling price was calculated using an income approach model and included the following key assumptions: the development timeline, revenue forecast, discount rate and probabilities of technical and regulatory success. The relative selling price of our development activities to initiate a clinical study of INGREZZA for Huntington's chorea was based on an assessment of costs to perform the study, based upon a peer company analysis for similar studies. We believe a change in the assumptions used to determine our stand-alone selling price for the license most likely would not have a significant effect on the allocation of consideration received (or receivable) to the performance obligations.

At execution, the transaction price included only the \$30.0 million up-front consideration received. None of the development or regulatory milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of our evaluation of the constraint, we considered numerous factors, including that achievement of the milestones is outside of our control and contingent upon success in future clinical studies and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to MTPC and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. Under the terms of the agreement, any payment we receive is generally non-refundable.

*Idorsia.* In January 2020, we announced a collaboration and optional licensing agreement with Idorsia, granting us an option to license NBI-827104, a potent, selective, orally active and brain penetrating T-type calcium channel blocker, in clinical development for the treatment of a rare pediatric epilepsy. The option also included a research collaboration to discover and identify up to two additional novel T-type calcium channel blockers as development candidates.

In May 2020, we exercised the option to license the global rights to NBI-827104. In connection with the exercise of the option, we paid Idorsia \$45.0 million upfront, which was expensed as IPR&D in the second quarter of 2020. Further, as part of the research collaboration, we provided Idorsia with an incremental \$7.2 million in funding, which was recorded as a prepaid asset to be expensed over the two-year research collaboration term.

Pursuant to the terms of the agreement, upon the achievement of certain development and regulatory milestones, Idorsia may be entitled to receive payments of up to \$365.0 million with respect to NBI-827104 and up to \$620.0 million with respect to the development candidates. In addition, Idorsia may also be entitled to receive payments of up to \$750.0 million upon the achievement of certain commercial milestones, as well as receive royalties on the net sales of any collaboration product. Further, we will be responsible for all manufacturing, development and commercialization costs of any collaboration product.

We may terminate the collaboration and licensing agreement, in its entirety or with respect to a particular compound or development candidate, by providing 90 days' written notice to Idorsia. Further, in the event a party commits a material breach and fails to cure such material breach within 90 days after receiving written notice thereof, the non-breaching party may terminate the agreement in its entirety immediately upon written notice to the breaching party.

### 3. Debt Securities

The following table summarizes the amortized cost, unrealized gain and loss recognized in accumulated other comprehensive loss, allowance for credit losses, and fair value of debt securities available-for-sale at June 30, 2020, aggregated by major security type and contractual maturity:

(in millions)	Contractual Maturity	Α	mortized Cost	U	nrealized Gain	τ	J <b>nrealized</b> Loss	Allowance for Credit Losses	Fair Value
Commercial paper	Within 1 year	\$	140.0	\$	0.1	\$	_	_	\$ 140.1
Corporate debt securities	Within 1 year		287.8		2.0		—	—	289.8
Securities of government-sponsored entities	Within 1 year		102.5		0.8				103.3
		\$	530.3	\$	2.9	\$	_	\$ —	\$ 533.2
		-							
Corporate debt securities	1 to 2 years	\$	173.5	\$	1.7	\$	_	—	\$ 175.2
Securities of government-sponsored entities	1 to 2 years		20.0		—		—	—	20.0
		\$	193.5	\$	1.7	\$	_	\$ —	\$ 195.2

The following table summarizes the amortized cost, unrealized gain and loss recognized in accumulated other comprehensive income, and fair value of debt securities available-for-sale at December 31, 2019, aggregated by major security type and contractual maturity:

(in millions)	Contractual Maturity			Unrealized Gain		Unrealized Loss		Fair Value
Commercial paper	Within 1 year	\$	144.5	_		_	\$	144.5
Corporate debt securities	Within 1 year		270.5	0.5				271.0
Securities of government-sponsored entities	Within 1 year		142.3	0.4		_		142.7
		\$	557.3	\$ 0.9	\$		\$	558.2
Corporate debt securities	1 to 2 years	\$	250.5	\$ 0.5	\$	(0.1)	\$	250.9
Securities of government-sponsored entities	1 to 2 years		48.8			—		48.8
		\$	299.3	\$ 0.5	\$	(0.1)	\$	299.7

At June 30, 2020, debt securities available-for-sale in an unrealized loss position for which an allowance for credit losses had not been recorded were not significant. Further, at June 30, 2020, our security portfolio consisted of 158 securities related to investments in debt securities available-for-sale, of which 17 securities were in an unrealized loss position.

Our investments in commercial paper, corporate debt securities and securities of government-sponsored entities are of high credit quality (rated A1, A- and AA+ or higher, respectively). 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.

The following table summarizes debt securities available-for-sale in an unrealized loss position at December 31, 2019, aggregated by major security type and length of time in a continuous unrealized loss position:

		Less Than 12 Months			12 Month	onger	Total					
(in millions)	Fair Value		Unrealized Loss		 Fair Value		Unrealized Loss		Fair Value		Unrealized Loss	
Corporate debt securities	\$	186.1	\$	(0.1)	\$ _	\$	_	\$	186.1	\$	(0.1)	



### 4. Fair Value Measurements

Investments at June 30, 2020, which were measured at fair value on a recurring basis, consisted of the following:

		Fair Value Measurements Using							
(in millions)	Fair Value		Level 1		Level 2		Level 3		
Cash and cash equivalents:									
Cash and money market funds	\$ 415.1	\$	415.1	\$	—	\$	—		
Total cash and cash equivalents	 415.1		415.1		—		—		
Restricted cash:									
Certificates of deposit	3.2		3.2		—		—		
Total restricted cash	 3.2		3.2		_				
Debt securities available-for-sale:									
Commercial paper	140.1		—		140.1		_		
Corporate debt securities	465.0		—		465.0		—		
Securities of government-sponsored entities	123.3		—		123.3		—		
Total debt securities available-for-sale	 728.4				728.4				
Equity securities:									
Equity securities-biotechnology industry	50.7		—		—		50.7		
Total equity securities	 50.7						50.7		
Total recurring fair value measurements	\$ 1,197.4	\$	418.3	\$	728.4	\$	50.7		

Investments at December 31, 2019, which were measured at fair value on a recurring basis, consisted of the following:

		Fair Value Measurements Using								
(in millions)	Fair Value	 Level 1	Level 2		Level 3					
Cash and cash equivalents:										
Cash and money market funds	\$ 112.3	\$ 112.3	—		—					
Total cash and cash equivalents	 112.3	 112.3	_		_					
Restricted cash:										
Certificates of deposit	3.2	3.2	—		—					
Total restricted cash	 3.2	 3.2								
Debt securities available-for-sale:										
Commercial paper	144.5	—	144.5		_					
Corporate debt securities	521.9	—	521.9		—					
Securities of government-sponsored entities	191.5	—	191.5		—					
Total debt securities available-for-sale	 857.9	 _	857.9		_					
Equity securities:										
Equity securities-biotechnology industry	55.9	—	_		55.9					
Total equity securities	55.9				55.9					
Total recurring fair value measurements	\$ 1,029.3	\$ 115.5	\$ 857.9	\$	55.9					

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):

	Three Months Ended June 30,					Six Months Ended June 30,			
(in millions)	2020 2019					2020	2019		
Balance at beginning of period	\$	39.4	\$	56.4	\$	55.9	\$	—	
Purchases		—		_		—		54.7	
Unrealized gains (losses) included in earnings		11.3		21.0		(5.2)		22.7	
Balance at end of period	\$	50.7	\$	77.4	\$	50.7	\$	77.4	

At June 30, 2020, the discount for lack of marketability used in the valuation analysis of equity securities ranged from 17.5% to 31.5% (weighted average of 27.5%). 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 securities are included in other income (expense), net.

#### 5. Inventories

Inventories consisted of the following:

(in millions)	ıne 30, 2020	Decen	ıber 31, 2019
Raw materials	\$ 15.8	\$	14.1
Work in process	1.8		1.5
Finished goods	4.4		1.7
Total inventories	\$ 22.0	\$	17.3

#### 6. Restricted Cash

The following table presents a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows.

(in millions)	June 30, 2020	December 31, 2019	
Cash and cash equivalents	\$ 415.1	\$ 112.3	
Restricted cash	3.2	3.2	
Total cash and cash equivalents and restricted cash	\$ 418.3	\$ 115.5	

#### 7. Leases

At June 30, 2020, our operating leases consisted of the following:

Address	Туре	Square Feet	<b>Commencement Date</b>	Expiration Date
12780 El Camino Real <sup>(1)</sup>	Office/Laboratory	141,000	August 7, 2019	July 31, 2031
12790 El Camino Real, Suite 130 <sup>(1)</sup>	Office	2,000	December 1, 2019	July 31, 2031
12790 El Camino Real, Suite 150 <sup>(1)</sup>	Office	8,000	August 7, 2019	July 31, 2031
12790 El Camino Real, Suite 300 <sup>(1)</sup>	Office	28,000	December 1, 2019	July 31, 2031
12777 High Bluff Drive	Office	45,000	July 1, 2018	July 31, 2029
12790 El Camino Real, Suite 200 <sup>(1)</sup>	Office	28,000	February 1, 2021	July 31, 2031
12790 El Camino Real, Suite 100 (1)	Office	17,000	February 1, 2021	July 31, 2031

(1) Under the terms of the 12780/12790 El Camino Real master lease, we have two options to extend the term of the lease for a period of ten years each. We were not reasonably certain to exercise either of these options at lease commencement. As such, neither option was recognized as part of the associated operating lease right-of-use asset or liability. Note: 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 \$5.0 million and \$3.9 million for the six months ended June 30, 2020 and 2019, respectively. Cash paid for amounts in the measurement of lease liabilities for operating cash flows from operating leases was \$4.3 million and \$3.3 million for the six months ended June 30, 2020 and 2019, respectively.

Our operating leases had a weighted average remaining lease term of approximately 11 years and 10 years at June 30, 2020 and December 31, 2019, respectively, and a weighted average discount rate of 5.8% at June 30, 2020 and December 31, 2019, respectively.



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

(in millions)	June 30, 2020
Year ending December 31, 2020 (6 months remaining)	\$ 4.3
Year ending December 31, 2021	10.6
Year ending December 31, 2022	10.9
Year ending December 31, 2023	11.2
Year ending December 31, 2024	11.6
Thereafter	79.7
Total operating lease payments	128.3
Less accreted interest	34.8
Total operating lease liabilities	93.5
Less current operating lease liabilities	9.2
Noncurrent operating lease liabilities	\$ 84.3

Note: Amounts presented in the table above exclude \$28.3 million of non-cancelable future minimum lease payments for operating leases that have not yet commenced.

#### 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 2024 and entered into an indenture agreement, or the 2024 Indenture, with respect to the 2024 Notes. The 2024 Notes accrue interest at a fixed rate of 2.25% per year, payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2017. The 2024 Notes mature on May 15, 2024. The net proceeds from the issuance of the 2024 Notes were approximately \$502.8 million, after deducting commissions and the offering expenses payable by us.

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:

- 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.

As the conditional conversion feature described under (i) above had been triggered as of June 30, 2020, holders of the 2024 Notes may convert the 2024 Notes at any time during the period beginning on July 1, 2020 and ending at the close of business on September 30, 2020. Accordingly, the 2024 Notes have been classified as a current liability as of June 30, 2020. The future 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.

Upon conversion, holders will receive the principal amount of their 2024 Notes and any excess conversion value, calculated based on the per share volumeweighted 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 6.8 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 \$517.5 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.

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 June 30, 2020, the remaining period over which the discount on the liability component will be amortized was approximately 4 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:

(in millions)	June 30, 2020	December 31, 2019
Principal	\$ 517.5	\$ 517.5
Deferred financing costs	(6.2)	(6.9)
Debt discount, net	(91.8)	(101.8)
Net carrying amount	\$ 419.5	\$ 408.8

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 \$845.3 million at June 30, 2020 and \$596.8 million at December 31, 2019.

#### 9. Net Income (Loss) Per Share

Net income (loss) per share was calculated as follows:

Three Months Ended June 30,				nded	Six Months Ended June 30,					
(in millions, except per share data)		2020 2019			2020			2019		
Net income (loss) - basic and diluted	\$	79.6	\$	51.3	\$	117.0	\$	(50.8)		
Weighted-average common shares outstanding:										
Basic		93.0		91.4		92.8		91.2		
Effect of dilutive securities:										
Stock options		2.6		2.6		2.5		—		
Restricted stock		0.5		0.3		0.5		—		
2024 Notes		2.1		0.5		1.8		—		
Diluted		98.2		94.8		97.6		91.2		
Net income (loss) per share:										
Basic	\$	0.86	\$	0.56	\$	1.26	\$	(0.56)		
Diluted	\$	0.81	\$	0.54	\$	1.20	\$	(0.56)		

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 6.8 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 2.2 million and 1.4 million for the three and six months ended June 30, 2020, respectively, and 2.3 million and 8.5 million for the three and six months ended June 30, 2019, respectively.

#### **10. Subsequent Events**

*Takeda*. In June 2020, we entered into an exclusive license agreement with Takeda to develop and commercialize certain compounds in Takeda's early to mid-stage psychiatry pipeline. Specifically, Takeda granted us an exclusive license to the following seven assets: (i) NBI-1065844 (TAK-831) for schizophrenia, or the Phase II Asset, (ii) NBI-1065845 (TAK-653) for treatment-resistant depression, (iii) NBI-1065846 (TAK-041) for anhedonia (which together with the NBI-1065845 are referred to as the Phase II Ready Assets), and (iv) four non-clinical stage assets, or the Non-Clinical Assets. The agreement became effective in July 2020, upon expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

The Phase II Asset is deemed a royalty-bearing product under the license agreement pursuant to which we will be responsible for all costs and expenses associated with the development, manufacture, and commercialization of such asset, subject to certain exceptions, and Takeda will be eligible to receive development and commercial milestones and royalties with respect to such asset, or a Royalty-Bearing Product, and 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 related to such asset, subject to certain exceptions, in lieu of receiving milestones and royalties, or a Profit-Share Product. Subject to specified conditions, Takeda may elect to exercise such opt-in right for the Phase II Asset before we initiate a Phase III clinical trial for such Phase II Asset. Each of the Phase II Ready Assets is deemed a Profit-Share Product and Takeda will retain the right to opt-out of the profit-sharing arrangement for such asset pursuant to which such asset would become a Royalty-Bearing Product. Takeda may elect to exercise such opt-out rights with respect to a Phase II Ready Asset immediately following the completion of the second Phase II clinical trial for such Phase II Ready Asset. In addition, under certain circumstances related to the development and commercialization activities to be performed by us, Takeda may elect to opt-out of the profit-sharing arrangement for a Profit-Share Product before the initiation of a Phase III clinical trial for such product.

Each of the Non-Clinical Assets will be Royalty-Bearing Products pursuant to which we will be responsible for all costs and expenses associated with the development, manufacture, and commercialization of such assets, subject to certain exceptions.

In connection with the agreement, we paid Takeda \$120.0 million upfront (less an earnest money deposit paid by us to Takeda in the first quarter of 2020). Pursuant to the terms of the agreement, Takeda may also be entitled to receive payments of up to \$1.9 billion upon the achievement of certain development and commercial milestones associated with Royalty-Bearing Products, as well as receive royalties on future net sales of Royalty-Bearing Products. On a country-by-country and product-by-product basis, royalty payments would commence on the first commercial sale of a Royalty-Bearing Product and terminate on the later of (i) the expiration of the last patent covering such Royalty-Bearing Product in such country, (ii) a number of years from the first commercial sale of such Royalty-Bearing Product in such country and (iii) the expiration of regulatory exclusivity for Royalty-Bearing Product in such country.

Unless earlier terminated, the license agreement will continue on a licensed product-by-licensed product and country-by-country basis until the date on which, (i) for any Royalty-Bearing Product, the royalty term has expired in such country; and (ii) for any Profit-Share Product, for so long as we continue to develop, manufacture, or commercialize such licensed product. We may terminate the license agreement for convenience in its entirety or in one or more (but not all) of the United States, Japan, the European Union, and the United Kingdom, or the Major Markets, on 6 months' written notice to Takeda (i) with respect to all licensed products prior to the first commercial sale of the first licensed product for which first commercial sale occurs, or (ii) with respect to all licensed products in one or more given target classes, as defined in the agreement, prior to the first commercial sale of the first licensed product in such target class(es) for which first commercial sale occurs. We may terminate the license agreement for convenience in its entirety or in one or more (but not all) of the Major Markets on 12 months' written notice to Takeda (i) with respect to all licensed product for which first commercial sale occurs, or (ii) with first commercial sale or the first licensed product for which first commercial sale occurs, or (ii) with respect to all licensed product for which first commercial sale occurs, or (ii) with respect to all licensed product for which first commercial sale occurs, or (ii) with respect to all licensed product for which first commercial sale occurs, or (ii) with respect to all licensed product for which first commercial sale occurs, or (ii) with respect to all licensed product for which first commercial sale occurs, or (ii) with respect to all licensed product for which first commercial sale occurs, or (ii) with respect to all licensed product for which first commercial sale occurs, or (ii) with respect to all licensed product for which first commercial sale occurs, or (ii) with respec

#### 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, 2019 and the related Management's Discussion and Analysis of Financial Conditions, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2019 and our Quarterly Report on Form 10-Q for the three months ended March 31, 2020.

#### Overview

We are a commercial-stage biopharmaceutical company focused on discovering and developing innovative and life-changing treatments for patients with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. We specialize in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. Currently, we are primarily focused on the commercialization of INGREZZA<sup>®</sup> (valbenazine) in the United States, or US, our first US Food and Drug Administration, or FDA, approved product.

In April 2017, we received FDA approval of our first marketed product, INGREZZA, for the treatment of adults with tardive dyskinesia, or TD. Shortly after receiving FDA approval, we began commercializing INGREZZA in the US using a specialty sales force primarily focused on educating physicians who treat patients with TD, including psychiatrists and neurologists.

In addition to our first marketed product, our collaboration partner, AbbVie Inc., or AbbVie, received approval of ORILISSA<sup>®</sup> (elagolix) for the management of moderate to severe endometriosis pain in women from the FDA in July 2018 and Health Canada in October 2018. We receive royalties at tiered percentage rates on any net sales of ORILISSA.

In April 2020, we received FDA approval for ONGENTYS<sup>®</sup> (opicapone) as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients. FDA approval for ONGENTYS for Parkinson's disease triggered a milestone payment of \$20.0 million, which was expensed as research and development, or R&D, in the second quarter of 2020. We plan to commercialize ONGENTYS later in 2020 with our existing INGREZZA commercial infrastructure.

In May 2020, AbbVie received approval from the FDA for ORIAHNN<sup>TM</sup> (elagolix) for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. FDA approval for ORIAHNN for uterine fibroids resulted in the achievement of a \$30.0 million regulatory milestone, which was recognized as collaboration revenue in the second quarter of 2020. We are entitled to receive royalties at tiered percentage rates on any net sales of ORIAHNN.

Our late-stage pipeline includes crinecerfont (NBI-74788) for the treatment of congenital adrenal hyperplasia, or CAH, in adult patients, valbenazine for the treatment of chorea in adult patients with Huntington's disease, or HD, and NBIb-1817 (VY-AADC) for the treatment of advanced Parkinson's disease patients with motor fluctuations that are refractory to medical management. Our product candidate for advanced Parkinson's disease is partnered with Voyager Therapeutics, Inc., or Voyager.

Our early-stage clinical pipeline includes crinecerfont for the treatment of CAH in pediatric patients, elagolix for the treatment of polycystic ovary syndrome, or PCOS, in women, NBI-921352 (XEN901), a clinical-stage candidate with potential in epilepsy, and NBI-827104 (ACT-709478), a T-type calcium channel blocker in clinical development for the treatment of a rare pediatric epilepsy. Our product candidate for PCOS is partnered with AbbVie.

In May 2020, we entered into a collaboration and licensing agreement with Idorsia Pharmaceuticals Ltd, or Idorsia. In connection with the agreement, we paid Idorsia \$45.0 million upfront to gain a license to NBI-827104, a potent, selective, orally active and brain penetrating T-type calcium channel blocker, in clinical development for the treatment of a rare pediatric epilepsy. The agreement includes a research collaboration to discover and identify up to two additional novel T-type calcium channel blockers as development candidates.

In June 2020, we entered into an exclusive license agreement with Takeda Pharmaceutical Company Limited, or Takeda, to develop and commercialize certain compounds in Takeda's early to mid-stage psychiatry pipeline. The agreement became effective in July 2020, upon expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. In connection with the agreement, we paid Takeda \$120.0 million upfront to gain an exclusive license to seven of Takeda's pipeline programs, including three clinical-stage assets for schizophrenia, treatment-resistant depression, and anhedonia. The collaboration also includes a cost-sharing arrangement for associated collaboration activities.



Going forward, we expect to augment our product pipeline by acquiring, through license or otherwise, additional drug candidates for research and development, or R&D, and potential commercialization.

#### 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, their caregivers, healthcare providers and our employees; (2) ensuring patients with TD 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.

Due to the impact of COVID-19, we initially paused enrollment of new patients in several of our clinical trials and have recently begun enrolling patients in our HD and CAH studies. Although certain of our trials have begun enrolling, not all clinical trial sites are able to begin enrolling at this time. We will continue preparations to be well positioned to launch planned clinical studies in the second half of 2020. To date, we have not experienced any interruption of our supply of drug products needed to support our ongoing clinical studies, but we expect that completion and data readouts for several of our ongoing and planned studies will be delayed. In addition, in July 2020, we initiated the CAHtalyst study, a single, global registrational study of crinecerfont in adult patients with classic CAH.

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, should the COVID-19 pandemic and any associated recession or depression continue for a prolonged period, our results of operations, financial condition, liquidity and cash flows could be materially impacted by lower revenues and profitability and a lower likelihood of effectively and efficiently developing new medicines.

#### Results of Operations for the Three and Six Months Ended June 30, 2020 and 2019

#### Revenues

The following table presents revenues by category.

	Three Months Ended June 30,				Six Months Ended June 30,				
(in millions)		2020		2019		2020		2019	
INGREZZA product sales, net	\$	267.6	\$	180.5	\$	498.7	\$	316.9	
Collaboration revenue		34.8		3.0		40.8		5.0	
Total revenues	\$	302.4	\$	183.5	\$	539.5	\$	321.9	

*Product Sales, Net.* Net product sales were \$267.6 million and \$498.7 million for the three and six months ended June 30, 2020, respectively, compared with \$180.5 million and \$316.9 million in the comparable periods last year, primarily reflecting increased INGREZZA net product sales driven by new patient additions.

*Collaboration Revenue.* Collaboration revenue reflects the achievement of certain development, regulatory and commercial milestones, royalties received on any net sales of ORILISSA and license fees earned under our collaboration agreements with AbbVie and Mitsubishi Tanabe Pharma Corporation, or MTPC. Collaboration revenue was \$34.8 million and \$40.8 million for the three and six months ended June 30, 2020, respectively, compared with \$3.0 million and \$5.0 million in the comparable periods last year, primarily reflecting the achievement of a \$30.0 million regulatory milestone associated with AbbVie's receipt of FDA approval for ORIAHNN for uterine fibroids in May 2020.

#### **Operating Expenses**

*Cost of Sales*. Cost of sales was \$2.4 million and \$4.5 million for the three and six months ended June 30, 2020, respectively, compared with \$1.6 million and \$2.7 million in the comparable periods 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. Milestone expenses reflect payments made in connection with our collaborative and other relationships. 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:

Three Months Ended June 30,				ded	Six Months Ended June 30,				
(in millions)		2020		2019		2020		2019	
Late stage	\$	13.1	\$	14.1	\$	26.1	\$	19.1	
Early stage		5.7		5.9		10.3		12.6	
Research and discovery		10.6		5.4		19.8		10.8	
Milestone expenses		20.0		10.0		20.0		10.0	
Payroll and benefits		25.2		16.9		49.1		32.8	
Facilities and other		6.3		9.4		13.9		14.1	
Total R&D expense	\$	80.9	\$	61.7	\$	139.2	\$	99.4	

R&D expense was \$80.9 million and \$139.2 million for the three and six months ended June 30, 2020, respectively, compared with \$61.7 million and \$99.4 million in the comparable periods last year, primarily reflecting increased investment in our gene therapy programs in collaboration with Voyager, increased activity to support advancing our expanded clinical portfolio, increased personnel expenses on higher headcount, and milestone expenses of \$20.0 million associated with our receipt of FDA approval for ONGENTYS for Parkinson's disease in April 2020, offset by milestone expenses of \$10.0 million associated with the FDA's acceptance of the ONGENTYS new drug application for Parkinson's disease in June 2019.

Acquired In-Process Research and Development. In connection with the payment of the upfront fee pursuant to our collaboration and license agreement with Idorsia, we recorded a charge of \$46.0 million, accounted for as in-process research and development, or IPR&D, in the second quarter of 2020. In connection with the payment of the upfront fee pursuant to our collaboration and license agreement with Voyager, we recorded a charge of \$113.1 million, accounted for as IPR&D, in the first quarter of 2019. In the second quarter of 2019, we entered into an amendment to the collaboration and license agreement with Voyager, pursuant to which we paid Voyager \$5.0 million upfront, accounted for as IPR&D, to obtain outside the U.S. rights to the Friedreich's ataxia program.

*Sales, General and Administrative*. Sales, general and administrative, or SG&A, expense was \$96.5 million and \$214.3 million for the three months and six months ended June 30, 2020, respectively, compared with \$80.8 million and \$168.3 million in the comparable periods last year, primarily reflecting increased personnel expenses on higher headcount and continued investment in INGREZZA marketing.

#### Other Income (Expense), Net

Other income, net, was \$6.6 million and \$17.7 million for the three months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020, other expense, net, was \$13.4 million, compared with other income, net, of \$16.1 million in the comparable period last year. Periodic fluctuations in other income (expense), net, primarily reflect unrealized gains or losses recognized to adjust our equity investments in Voyager and Xenon Pharmaceuticals Inc. to fair value.

#### **Provision for Income Taxes**

Our provision for income taxes was \$3.6 million and \$5.1 million for the three and six months ended June 30, 2020, respectively, compared with \$0.8 million and \$0.3 million in the comparable periods last year. At June 30, 2020 and 2019, we had full valuation allowances against our net deferred tax assets as realization was uncertain. As a result, tax expense for the three and six months ended June 30, 2020 and 2019, respectively, varies from the statutory tax rate primarily due to changes



in our valuation allowances, net of other permanent book/tax differences, tax credits generated and impacts of changes in tax laws.

#### Net Income (Loss)

Net income was \$79.6 million, or \$0.81 diluted earnings per share, for the three months ended June 30, 2020, compared with \$51.3 million, or \$0.54 diluted earnings per share, in the comparable period last year. For the six months ended June 30, 2020, net income was \$117.0 million, or \$1.20 diluted earnings per share, compared with a net loss of \$50.8 million, or \$0.56 net loss per share, in the comparable period last year.

#### Liquidity and Capital Resources

At June 30, 2020, our cash and cash equivalents and debt securities available-for-sale totaled \$1.1 billion compared with \$970.2 million at December 31, 2019.

Net cash provided by operating activities was \$157.1 million for the six months ended June 30, 2020, compared with net cash used in operating activities of \$48.3 million in the comparable period last year, primarily reflecting increased INGREZZA net product sales, our achievement of a \$30.0 million regulatory milestone in May 2020 in connection with our collaboration with AbbVie, and upfront payments of \$118.1 million in the first six months of 2019 in connection with Voyager, partially offset by an upfront payment of \$45.0 million in May 2020 in connection with our collaboration with Idorsia.

Net cash provided by investing activities was \$126.6 million for the six months ended June 30, 2020, compared with \$40.7 million in the comparable period last year, reflecting timing differences related to purchases, sales and maturities of debt securities available-for-sale, changes in our portfolio-mix, and an equity investment of \$54.7 million in Voyager in March 2019.

Net cash provided by financing activities was \$19.1 million for the six months ended June 30, 2020, compared with \$6.9 million in the comparable period last year, reflecting proceeds from issuances of our common stock.

Convertible Senior Notes. In May 2017, we issued \$517.5 million of 2.25% convertible senior notes due May 15, 2024.

#### **Off-Balance Sheet Arrangements**

We did not have any off-balance sheet arrangements at June 30, 2020 or 2019.

#### **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, 2019.

#### **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 June 30, 2020, 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 June 30, 2020, 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, 2019.

#### **Risks Related to Our Company**

#### \*We may not be able to continue to successfully commercialize INGREZZA, 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 sell our products and secure adequate thirdparty reimbursement if and when they are approved by the FDA. 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 three 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 successfully commercialize INGREZZA, ONGENTYS or any product candidate approved by the FDA in the future.

In addition, our business could 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 and medical affairs personnel 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 course sales and marketing programs. 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 any of our other products, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.

The commercial success of INGREZZA, ONGENTYS or any of our other products, if approved for marketing, will depend upon the acceptance of those products as safe and effective by the medical community and patients.

The market acceptance of INGREZZA, ONGENTYS or any of our other products 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 gene therapy 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 ultimately 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 commercialize any products successfully, including INGREZZA and 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 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, COVID-19 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. 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 due to COVID-19 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 are temporarily pausing enrollment of new patients in the Phase III study of valbenazine for chorea in Huntington disease, the RESTORE-1 registrational study for NBIb-1817 in Parkinson's disease patients and the Phase IIa pediatric study of crinecerfont in CAH.

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.

# \*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 TD, ONGENTYS, which has been approved by the FDA for Parkinson's disease, ORILISSA (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. 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 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.

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 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 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 may be slower 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. For example, we recently announced that due to the impact of the COVID-19 pandemic, we are temporarily pausing enrollment of new patients in the Phase III study of valbenazine for chorea in Huntington disease, the RESTORE-1 registrational study for NBIb-1817 in Parkinson's disease patients and the Phase IIa pediatric study of crinecerfont in congenital adrenal hyperplasia, or CAH. 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.

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

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

- · does not successfully commercialize ORILISSA for endometriosis or ORIAHNN for uterine fibroids;
- does not conduct its collaborative activities in a timely manner;
- does not devote sufficient time and resources to our partnered programs;
- terminates its agreement with us;
- develops, either alone or with others, products that may compete with elagolix;
- · disputes our respective allocations of rights to any products or technology developed during our collaboration; or
- merges with a third party that wants to terminate our agreement.



In addition, we are a party to several other collaboration and license agreements, including our agreements with BIAL, MTPC, Voyager, Xenon, Idorsia and Takeda. These collaborations are subject to risks and uncertainties similar to those described above. In some situations, we may not be able to influence our collaboration partners' decisions regarding the development and collaboration of our partnered product products 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. We may also need to enter into other licensing collaborations to assist in the development and commercialization of other product candidates we are developing now or may develop in the future, and any such future collaborations would be subject to similar risks and uncertainties.

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

#### 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 August 2020, we announced that we planned to make ONGENTYS commercially available in the third quarter of 2020. The successful commercial launch of ONGENTYS is subject to many risks, and there are numerous examples of unsuccessful product launches and failures l, 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 launch 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 launch and 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, including INGREZZA, ONGENTYS, ORILISSA, and ORIAHNN could be associated with side effects or adverse events.

As with most pharmaceutical products, use of our approved products or those of our collaborators, including INGREZZA, ONGENTYS, ORILISSA, and ORIAHNN 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.

#### 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. As part of our collaboration and license agreement with Voyager, a Phase II clinical trial of NBIb-1817 is being conducted. There is no guarantee that this program or other collaboration gene therapy product candidates will not be placed on clinical hold by the FDA, as has been the case for many gene therapy clinical programs. 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 or negative public opinion related to gene therapy products may delay or impair the development and commercialization of our gene therapy product candidates or demand for any gene therapy products we develop.

# 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 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, TD, 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 TD, we compete with Teva Pharmaceutical Industries, which received FDA approval for AUSTEDO to treat TD in August 2017, and several clinical development-stage programs targeting TD and related movement disorders. Additionally, there are a number of commercially available medicines used to treat TD 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, ORILISSA 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 will compete 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 will 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 companies developing medicinal treatments for CAH.
- Our investigational therapies for potential use in epilepsy may in the future compete with numerous approved products and development-stage programs being pursued by several companies.
- Our development programs using Voyager's proprietary gene therapy platform (NBIb-1817 for Parkinson's disease and the Friedreich's ataxia program) may in the future compete with development-stage programs being pursued by numerous 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.

# \*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 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 commercialization activities, we depend 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 TD 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.

# \*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, or 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.

To date, we have sold \$517.5 million aggregate principal amount of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes. 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 may adversely affect our financial condition, operating results, or liquidity.

The conditional conversion feature of the 2024 Notes was triggered as of June 30, 2020, meaning holders of 2024 Notes are entitled to convert their 2024 Notes at any time during the period beginning on July 1, 2020, and ending at the close of business on September 30, 2020. The conditional conversion feature may also be triggered again in the future. 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, 2019, we had an accumulated deficit of \$1.1 billion as a result of historical operating losses.



In April 2017, we received FDA approval of INGREZZA for TD. In July 2018, our partner AbbVie received FDA approval for ORILISSA for the management of moderate to severe endometriosis pain in women. In April 2020, we received FDA approval of ONGENTYS for Parkinson's disease. In May 2020, our partner AbbVie received FDA approval for ORIAHNN for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. 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 launch 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 TD;
- launch the commercialization of 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 six months ended June 30, 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 June 30, 2020, we had approximately 780 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 of commercial sales of INGREZZA, timing of the commercial launch of ONGENTYS, 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 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 three months ended June 30, 2020, 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 ending 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, 2020, will be subject to a percentage limitation 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. 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.

#### \*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 \$72 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;
- timing 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.

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

We have entered into distribution agreements 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, 2019 and a significant majority of our accounts receivable balance at December 31, 2019. 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 effectively commercialize INGREZZA or ONGENTYS, to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, 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. 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 sales, general and administrative expenses and management time related to compliance activities. If we fail to comply with these laws, regulations and standards, our reputation may be



harmed, and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

#### **Risks Related to Our Industry**

#### \*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. 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 imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers are required to provide certain information regarding the drug product 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 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 remain 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. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs 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". The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a new final rule



permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. 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 eliminates 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 Cuts and Jobs 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. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

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 BBA, will remain in effect through 2030 unless additional Congressional action is taken. However, the Medicare sequester reductions under the BBA will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. 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 Meritbased 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 current presidential administration's budget proposal for the 2021 fiscal year includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses. provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the current presidential administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The US Department of Health and Human Services, or HHS, has solicited feedback on certain of these measures and, additionally, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, the Trump administration announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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 to address 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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 certain types of individuals and entities, 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, as defined by such law, 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; 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 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 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 other regulatory agencies, financial prospects, and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and regulations.

### 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 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 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 of data subjects 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, such as healthcare data or other personal information from our clinical trials, 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, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the US. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA, which went into effect on January 1, 2020, requires covered companies to provide new disclosures to California consumers, and provides such consumers new ways to opt-out of certain sales 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:

#### <u>Exhibit</u>

3.1	Description:	Certificate of Incorporation, as amended
5.1	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
	Reference:	Incorporated by reference to Exhibit 3.2 of the Company's Quarterly Report on Form 10-Q filed on November 5, 2018
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
4.4	Description:	Description of Common Stock of the Company
	Reference:	Incorporated by reference to Exhibit 4.4 of the Company's Annual Report on Form 10-K filed on February 7, 2020
10.1*	Description:	Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan
10.2*	Description:	Form of Stock Option Grant Notice and Option Agreement for use under the Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan, and Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement for use under the Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan
10.3**	Description:	Exclusive License Agreement dated June 12, 2020 between Takeda Pharmaceutical Company Limited 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)
_0.	_ comption.	

<sup>\*</sup> Management contract or compensatory plan or arrangement.\*\* Certain portions of this exhibit (indicated by "\*\*") have been omitted pursuant to confidential treatment. \*\*\* 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: August 3, 2020

/s/ Matthew C. Abernethy

Matthew C. Abernethy Chief Financial Officer (Duly authorized officer and Principal Financial Officer)

#### Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan

Adopted by the Compensation Committee: March 16, 2020 Approved by the Stockholders: May 19, 2020 Termination Date: March 15, 2030

Page
1
1
2
4
7
9
12
14
15
18
19
22
22
24

#### 1. General.

a. Successor to and Continuation of Prior Plan. The Plan is the successor to and continuation of the Prior Plan. As of the day immediately following the Effective Date: (i) no additional awards may be granted under the Prior Plan; (ii) the Prior Plan's Available Reserve, plus any Prior Plan's Returning Shares (as such shares become available from time to time), will become available for issuance pursuant to Awards granted under this Plan; and (iii) all Prior Plan Awards will remain subject to the terms of the Prior Plan (except that any Prior Plan's Returning Shares will become available for issuance pursuant to Awards granted under this Plan; and (iii) all Prior Plan Awards will remain subject to the terms of the Prior Plan. All Awards granted under this Plan will be subject to the terms of this Plan.

**b. Plan Purpose.** The Company, by means of the Plan, seeks to secure and retain the services of Employees, Directors and Consultants, to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate, and to provide a means by which such persons may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Awards.

**c. Available Awards.** The Plan provides for the grant of the following Awards: (i) Incentive Stock Options; (ii) Nonstatutory Stock Options; (iii) SARs; (iv) Restricted Stock Awards; (v) RSU Awards; (vi) Performance Awards; and (vii) Other Awards.

**d.** Adoption Date. The Plan will come into existence on the Adoption Date. No Award may be granted under the Plan prior to the Adoption Date. Any Award granted prior to the Effective Date is contingent upon timely receipt of stockholder approval to the extent required under applicable tax, securities and regulatory rules, and satisfaction of any other compliance requirements.

#### 2. Shares Subject to the Plan.

a. **Share Reserve.** Subject to adjustment in accordance with Section 2(b), any adjustment as necessary to implement any Capitalization Adjustment, and Section 3(d), the aggregate number of shares of Common Stock that may be issued pursuant to Awards will not exceed the sum of: (i) the Prior Plan's Available Reserve; (ii) 3,300,000 new shares; and (iii) the number of Prior Plan's Returning Shares, if any, as such shares become available from time to time.

#### b. Share Reserve Operation.

i. Limit Applies to Shares Issued Pursuant to Awards. For clarity, the Share Reserve is a limit on the number of shares of Common Stock that may be issued pursuant to Awards and does not limit the granting of Awards, except that the Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy its obligations to issue shares pursuant to such Awards. Shares may be issued in connection with a merger or acquisition as permitted by, as applicable, Nasdaq Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, NYSE American Company Guide Section 711 or other

applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

**ii.** Actions that Will Not Constitute Issuance of Shares and Will Not Reduce Share Reserve. The following actions will not result in an issuance of shares of Common Stock under the Plan and accordingly will not reduce the number of shares of Common Stock subject to the Share Reserve and available for issuance under the Plan: (1) the expiration or termination of any portion of an Award without the shares covered by such portion of the Award having been issued; and (2) the settlement of any portion of an Award in cash (*i.e.*, the Participant receives cash rather than shares of Common Stock).

#### iii. Reversion of Shares to the Share Reserve.

1. Shares Available for Subsequent Issuance. If any shares of Common Stock issued pursuant to an Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required for the vesting of such shares, then such shares will revert to the Share Reserve and become available again for issuance under the Plan.

2. Shares Not Available for Subsequent Issuance. The following shares of Common Stock will not become available again for issuance under the Plan: (i) any shares that are reacquired or withheld (or not issued) by the Company to satisfy the exercise, strike or purchase price of an Award or a Prior Plan Award (including any shares subject to such award that are not delivered because such award is exercised through a reduction of shares subject to such award (*i.e.*, "net exercised")); (ii) any shares that are reacquired or withheld (or not issued) by the Company to satisfy a tax withholding obligation in connection with an Award or a Prior Plan Award; (iii) any shares repurchased by the Company on the open market with the proceeds of the exercise, strike or purchase price of an Award or a Prior Plan Award; and (iv) in the event that a Stock Appreciation Right granted under the Plan or a stock appreciation right granted under the Prior Plan is settled in shares of Common Stock, the gross number of shares of Common Stock subject to such award.

#### 3. Eligibility and Limitations.

**a. Eligible Award Recipients.** Subject to the terms of the Plan, Employees, Directors and Consultants are eligible to receive Awards.

#### b. Specific Award Limitations.

**i. Limitations on Incentive Stock Option Recipients.** Incentive Stock Options may be granted only to Employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and (f) of the Code).

**ii. Incentive Stock Option \$100,000 Limitation.** To the extent that the aggregate Fair Market Value (determined at the time of grant) with respect to which Incentive

Stock Options are exercisable for the first time by any Participant during any calendar year (under all plans of the Company and any Affiliates) exceeds \$100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

**iii.** Limitations on Incentive Stock Options Granted to Ten Percent Stockholders. A Ten Percent Stockholder may not be granted an Incentive Stock Option unless (1) the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant of such Option and (2) such Option is not exercisable after the expiration of five years from the date of grant of such Option.

iv. Limitations on Nonstatutory Stock Options and SARs. Nonstatutory Stock Options and SARs may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any "parent" of the Company (as such term is defined in Rule 405) unless the stock underlying such Awards is treated as "service recipient stock" under Section 409A because such Awards are granted pursuant to a corporate transaction (such as a spin off transaction) or unless such Awards otherwise comply with the distribution requirements of Section 409A.

**c. Aggregate Incentive Stock Option Limit.** Notwithstanding anything to the contrary in Section 2(a) and subject to any adjustment as necessary to implement any Capitalization Adjustment, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options is 18,000,000 shares.

d. Limitation on Full Value Awards. Subject to adjustment in accordance with Section 2(b) and any adjustment as necessary to implement any Capitalization Adjustment, the aggregate number of shares of Common Stock that may be issued pursuant to Full Value Awards will not exceed 50% of the Share Reserve.

e. Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid, as applicable, by the Company to any individual for service as a Non-Employee Director with respect to any period commencing on the date of the Annual Meeting for a particular year and ending on the date of the Annual Meeting for the next subsequent year (the "Annual Period"), including Awards granted and cash fees paid by the Company to such Non-Employee Director, will not exceed \$1,250,000 in total value. In addition, the aggregate value of any equity award(s) granted under the Plan or otherwise by the Company to any individual for service as a Non-Employee Director upon or in connection with his or her initial election or appointment to the Board will not exceed \$2,000,000 in total value; for the avoidance of doubt, the aggregate compensation granted or paid, as applicable, by the Company to any individual for service as a Non-Employee Director with respect to an Annual Period in which such individual is first appointed or elected to the Board will not exceed the sum of the two preceding limitations in this Section 3(e). The value of any equity awards, for purposes of the limitations described in this Section 3(e), will be calculated based on the grant date fair value of such equity awards for financial reporting purposes. The limitations in this

Section 3(e) will apply beginning with the Annual Period in which the Annual Meeting in 2020 occurs.

#### 4. **Options and Stock Appreciation Rights.**

Each Option and SAR will have such terms and conditions as determined by the Board. Each Option will be designated in writing as an Incentive Stock Option or Nonstatutory Stock Option at the time of grant; *provided, however*, that if an Option is not so designated, then such Option will be a Nonstatutory Stock Option, and the shares purchased upon exercise of each type of Option will be separately accounted for. Each SAR will be denominated in shares of Common Stock equivalents. The terms and conditions of separate Options and SARs need not be identical; *provided, however*, that each Option Agreement and SAR Agreement will conform (through incorporation of the provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

**a. Term.** Subject to Section 3(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of ten years from the date of grant of such Award or such shorter period specified in the Award Agreement.

**b. Exercise or Strike Price.** Subject to Section 3(b) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will not be less than 100% of the Fair Market Value on the date of grant of such Award. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value on the date of grant of such Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Transaction and in a manner consistent with the provisions of Sections 409A and, if applicable, 424(a) of the Code.

c. Exercise Procedure and Payment of Exercise Price for Options. In order to exercise an Option, the Participant must provide notice of exercise to the Plan Administrator in accordance with the procedures specified in the Option Agreement or otherwise provided by the Company. The Board has the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The exercise price of an Option may be paid, to the extent permitted by Applicable Law and as determined by the Board, by one or more of the following methods of payment to the extent set forth in the Option Agreement:

i. by cash or check, bank draft or money order payable to the Company;

**ii.** pursuant to a "cashless exercise" program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the Common Stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the exercise price to the Company from the sales proceeds;

**iii.** by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock that are already owned by the Participant free and clear of any liens, claims, encumbrances or security interests, with a Fair Market Value on the date of exercise that does not exceed the exercise price, provided that (1) the Common Stock is publicly traded at the time of exercise, (2) any remaining balance of the exercise price not satisfied by such delivery is paid by the Participant in cash or other permitted form of payment, (3) such delivery would not violate any Applicable Law or agreement restricting the redemption of the Common Stock, (4) any certificated shares are endorsed or accompanied by an executed assignment separate from certificate, and (5) such shares have been held by the Participant for any minimum period necessary to avoid adverse accounting treatment as a result of such delivery;

**iv.** if the Option is a Nonstatutory Stock Option, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value on the date of exercise that does not exceed the exercise price, provided that (1) such shares used to pay the exercise price will not be exercisable thereafter and (2) any remaining balance of the exercise price not satisfied by such net exercise is paid by the Participant in cash or other permitted form of payment; or

Law.

**v.** in any other form of consideration that may be acceptable to the Board and permissible under Applicable

d. Exercise Procedure and Payment of Appreciation Distribution for SARs. In order to exercise a SAR, the Participant must provide notice of exercise to the Plan Administrator in accordance with the procedures specified in the SAR Agreement or otherwise provided by the Company. The appreciation distribution payable to a Participant upon the exercise of a SAR will not be greater than an amount equal to the excess of (i) the aggregate Fair Market Value on the date of exercise of a number of shares of Common Stock equal to the number of Common Stock equivalents that are vested and being exercised under such SAR, over (ii) the strike price of such SAR. Such appreciation distribution may be paid to the Participant in the form of Common Stock or cash (or any combination of Common Stock and cash) or in any other form of payment, as determined by the Board and specified in the SAR Agreement.

**e. Transferability.** Options and SARs may not be transferred to third party financial institutions for value. The Board may impose such additional limitations on the transferability of an Option or SAR as it determines. In the absence of any such determination by the Board, the following restrictions on the transferability of Options and SARs will apply, provided that except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration and *provided, further*, that if an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer:

i. **Restrictions on Transfer.** An Option or SAR will not be transferable, except by will or by the laws of descent and distribution, and will be exercisable during the lifetime of the Participant only by the Participant; *provided, however*, that the Board may permit transfer of an Option or SAR in a manner that is not prohibited by applicable tax and securities

laws upon the Participant's request, including to a trust if the Participant is considered to be the sole beneficial owner of such trust (as determined under Section 671 of the Code and applicable state law) while such Option or SAR is held in such trust, provided that the Participant and the trustee enter into a transfer and other agreements required by the Company.

**ii. Domestic Relations Orders.** Notwithstanding the foregoing, subject to the execution of transfer documentation in a format acceptable to the Company and subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to a domestic relations order.

**f. Vesting.** The Board may impose such restrictions on or conditions to the vesting and/or exercisability of an Option or SAR as determined by the Board. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, vesting of Options and SARs will cease upon termination of the Participant's Continuous Service.

**g. Termination of Continuous Service for Cause.** Except as explicitly otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service is terminated for Cause, the Participant's Options and SARs will terminate and be forfeited immediately upon such termination of Continuous Service, the Participant will be prohibited from exercising any portion (including any vested portion) of such Awards on and after the date of such termination of Continuous Service, and the Participant will have no further right, title or interest in the forfeited Award, the shares of Common Stock subject to the forfeited Award, or any consideration in respect of the forfeited Award.

h. Post-Termination Exercise Period Following Termination of Continuous Service for Reasons Other than for Cause. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, subject to Section 4(i), if a Participant's Continuous Service terminates for any reason other than for Cause, the Participant may exercise his or her Option or SAR to the extent vested, but only within the following period of time or, if applicable, such other period of time provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate; *provided*, *however*, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)):

**i.** three months following the date of such termination if such termination is a termination without Cause (other than any termination due to the Participant's Disability or death);

- **ii.** 12 months following the date of such termination if such termination is due to the Participant's Disability;
- iii. 18 months following the date of such termination if such termination is due to the Participant's death; or

**iv.** 18 months following the date of the Participant's death if such death occurs following the date of such termination but during the period such Award is otherwise exercisable (as provided in (i) or (ii) above).

Following the date of such termination or death, as applicable, to the extent the Participant does not exercise such Award within the applicable Post-Termination Exercise Period (or, if earlier, prior to the expiration of the maximum term of such Award), such unexercised portion of the Award will terminate, and the Participant will have no further right, title or interest in the terminated Award, the shares of Common Stock subject to the terminated Award, or any consideration in respect of the terminated Award.

i. Restrictions on Exercise; Extension of Exercisability. A Participant may not exercise an Option or SAR at any time that the issuance of shares of Common Stock upon such exercise would violate Applicable Law. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason other than for Cause and, at any time during the applicable Post-Termination Exercise Period: (i) the exercise of the Participant's Option or SAR would be prohibited solely because the issuance of shares of Common Stock upon such exercise would violate Applicable Law; or (ii) the immediate sale of any shares of Common Stock issued upon such exercise would violate the Company's Trading Policy, then the applicable Post-Termination Exercise Period will be extended to the last day of the calendar month that commences following the date the Award would otherwise expire, with an additional extension of the exercise period to the last day of the next calendar month to apply if any of the foregoing restrictions apply at any time during such extended exercise period, generally without limitation as to the maximum permitted number of extensions; *provided, however*, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)).

**j. Non-Exempt Employees.** No Option or SAR, whether or not vested, granted to an Employee who is a nonexempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, will be first exercisable for any shares of Common Stock until at least six months following the date of grant of such Award. Notwithstanding the foregoing, in accordance with the provisions of the Worker Economic Opportunity Act, any vested portion of such Award may be exercised earlier than six months following the date of grant of such Award in the event of (i) such Participant's death or Disability, (ii) a Transaction in which such Award is not assumed, continued or substituted, (iii) a Change in Control, or (iv) such Participant's retirement (as such term may be defined in the Award Agreement or another applicable agreement or, in the absence of any such definition, in accordance with the Company's then current employment policies and guidelines). This Section 4(j) is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay.

**k. Whole Shares.** Options and SARs may be exercised only with respect to whole shares of Common Stock or their equivalents.

#### 5. Awards Other Than Options and Stock Appreciation Rights.

a. **Restricted Stock Awards and RSU Awards.** Each Restricted Stock Award and RSU Award will have such terms and conditions as determined by the Board. The terms and conditions of separate Restricted Stock Awards and RSU Awards need not be identical; *provided, however*, that each Restricted Stock Award Agreement and RSU Award Agreement will conform (through incorporation of the provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

#### i. Form of Award.

1. **Restricted Stock Awards.** To the extent consistent with the Company's Bylaws, at the Board's election, shares of Common Stock subject to a Restricted Stock Award may be (i) held in book entry form subject to the Company's instructions until such shares become vested or any other restrictions lapse, or (ii) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. Unless otherwise determined by the Board, a Participant will have voting and other rights as a stockholder of the Company with respect to any shares subject to a Restricted Stock Award.

2. **RSU Awards.** A RSU Award represents a Participant's right to be issued on a future date the number of shares of Common Stock that is equal to the number of restricted stock units subject to the RSU Award. As a holder of a RSU Award, a Participant is an unsecured creditor of the Company with respect to the Company's unfunded obligation, if any, to issue shares of Common Stock in settlement of such Award and nothing contained in the Plan or any RSU Award Agreement, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between a Participant and the Company or an Affiliate or any other person. A Participant will not have voting or any other rights as a stockholder of the Company with respect to a RSU Award (unless and until shares are actually issued in settlement of a vested RSU Award).

#### ii. Consideration.

**1. Restricted Stock Awards.** A Restricted Stock Award may be granted in consideration for (A) cash or check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of consideration (including future services) as the Board may determine and permissible under Applicable Law.

2. **RSU Awards.** Unless otherwise determined by the Board at the time of grant, a RSU Award will be granted in consideration for the Participant's services to the Company or an Affiliate, such that the Participant will not be required to make any payment to the Company (other than such services) with respect to the grant or vesting of the RSU Award, or the issuance of any shares of Common Stock pursuant to the RSU Award. If, at the time of grant, the Board determines that any consideration must be paid by the Participant (in a form other than the Participant's services to the Company or an Affiliate) upon the issuance of any

shares of Common Stock in settlement of the RSU Award, such consideration may be paid in any form of consideration as the Board may determine and permissible under Applicable Law.

**iii. Vesting.** The Board may impose such restrictions on or conditions to the vesting of a Restricted Stock Award or RSU Award as determined by the Board. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, vesting of Restricted Stock Awards and RSU Awards will cease upon termination of the Participant's Continuous Service.

iv. Termination of Continuous Service. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason, (1) the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant under his or her Restricted Stock Award that have not vested as of the date of such termination as set forth in the Restricted Stock Award Agreement, and (2) any portion of the Participant's RSU Award that has not vested will be forfeited upon such termination and the Participant will have no further right, title or interest in the RSU Award, the shares of Common Stock issuable pursuant to the RSU Award, or any consideration in respect of the RSU Award.

v. Settlement of RSU Awards. A RSU Award may be settled by the issuance of shares of Common Stock or cash (or any combination thereof) or in any other form of payment, as determined by the Board and specified in the RSU Award Agreement. At the time of grant, the Board may determine to impose such restrictions or conditions that delay such delivery to a date following the vesting of the RSU Award.

**b. Performance Awards.** With respect to any Performance Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, the other terms and conditions of such Award, and the measure of whether and to what degree such Performance Goals have been attained will be determined by the Board. In addition, to the extent permitted by Applicable Law and set forth in the applicable Award Agreement, the Board may determine that cash or other property may be used in payment of Performance Awards. Performance Awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the Common Stock.

c. Other Awards. Other forms of Awards valued in whole or in part by reference to, or otherwise based on, Common Stock may be granted either alone or in addition to Awards provided for under Section 4 and the preceding provisions of this Section 5. Subject to the provisions of the Plan, the Board will have sole and complete discretion to determine the persons to whom and the time or times at which such Other Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Awards, and all other terms and conditions of such Other Awards.

#### 6. Adjustments upon Changes in Common Stock; Other Corporate Events.

a. **Capitalization Adjustments.** In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of shares of Common Stock subject to the Plan pursuant to Section 2(a); (ii) the class(es) and maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c); and (iii) the class(es) and number of shares of Common Stock and the exercise, strike or purchase price of Common Stock subject to outstanding Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive. Notwithstanding the foregoing, no fractional shares or rights for fractional shares of Common Stock will be created in order to implement any Capitalization Adjustment. The Board will determine an appropriate equivalent benefit, if any, for any fractional shares or rights to fractional shares that may be created by the adjustments referred to in the preceding provisions of this Section 6(a).

**b. Dissolution or Liquidation.** Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, in the event of a dissolution or liquidation of the Company, all outstanding Awards (other than Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to a forfeiture condition or the Company's right of repurchase may be reacquired or repurchased by the Company notwithstanding the fact that the holder of such Award is providing Continuous Service.

**c. Transaction.** In the event of a Transaction, the provisions of this Section 6(c) will apply to each outstanding Award unless otherwise provided in the instrument evidencing the Award, in any other written agreement between a Participant and the Company or an Affiliate, or in any director compensation policy of the Company.

i. Awards May Be Assumed. In the event of a Transaction, the Acquiring Entity may assume or continue any or all outstanding Awards or may substitute similar awards for any or all outstanding Awards (including but not limited to, awards to acquire the same consideration paid to the stockholders of the Company pursuant to the Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to outstanding Awards may be assigned by the Company to the Acquiring Entity. For clarity, in the event of a Transaction, the Acquiring Entity may choose to assume or continue only a portion of an outstanding Award, to substitute a similar award for only a portion of an outstanding Award, or to assume or continue, or substitute similar awards for, the outstanding Awards held by some, but not all, Participants. The terms of any assumption, continuation or substitution will be set by the Board.

**ii.** Awards Held by Current Employee and Director Participants. In the event of a Transaction in which the Acquiring Entity does not assume or continue outstanding Awards or substitute similar awards for outstanding Awards, then with respect to any such Awards that have not been assumed, continued or substituted and that are held by Participants

who are Employees or Directors and, in each case, whose Continuous Service has not terminated prior to the effective time of the Transaction (referred to as the "*Current Employee and Director Participants*"), the vesting (and exercisability, if applicable) of such Awards will be accelerated in full (and with respect to any such Awards that are subject to performance-based vesting conditions or requirements, vesting will be deemed to be satisfied at the greater of (x) the target level of performance or (y) the actual level of performance measured in accordance with the applicable performance goals as of the date of the Transaction) to a date prior to the effective time of such Transaction (contingent upon the effectiveness of the Transaction) as the Board determines (or, if the Board does not determine such a date, to the date that is 15 days prior to the effective time of the Transaction, and any reacquisition or repurchase rights held by the Company with respect to such Awards will lapse (contingent upon the effectiveness of the Transaction). With respect to the vesting of Awards that will accelerate upon the occurrence of a Transaction pursuant to this Section 6(c)(ii) and are settled in the form of a cash payment, such cash payment will be made no later than 30 days following the occurrence of the Transaction.

**iii.** Awards Held by Persons other than Current Participants. In the event of a Transaction in which the Acquiring Entity does not assume or continue outstanding Awards or substitute similar awards for outstanding Awards, then with respect to Awards that have not been assumed, continued or substituted and that are held by persons other than Current Employee and Director Participants, such Awards will terminate if not exercised (if applicable) at or prior to the effective time of the Transaction; *provided, however*, that any reacquisition or repurchase rights held by the Company with respect to such Awards will not terminate and may continue to be exercised notwithstanding the Transaction.

**iv. Payment for Awards in Lieu of Exercise.** Notwithstanding the foregoing, in the event an Award will terminate if not exercised at or prior to the effective time of a Transaction, the Board may provide that the holder of such Award may not exercise such Award but will receive a payment, in such form as may be determined by the Board, equal in value, at the effective time, to the excess, if any, of (1) the value of the property the Participant would have received upon the exercise of the Award, over (2) any exercise price payable by such holder in connection with such exercise.

**d. Involuntary Termination Upon or Following a Transaction.** Except as otherwise provided in the Award Agreement, in any other written agreement between a Participant and the Company or an Affiliate, or in any director compensation policy of the Company, in the event that an Employee or Director's Continuous Service is involuntarily terminated without Cause (including any such termination due to such Employee or Director's death or Disability) upon or within 12 months following the effective time of a Transaction, the vesting (and exercisability, if applicable) of any Assumed Awards (as defined in this Section 6(d)) held by such Employee or Director as of the date of such termination will be accelerated in full (and with respect to any such Awards that are subject to performance-based vesting conditions or requirements, vesting will be deemed to be satisfied at the greater of (x) the target level of performance or (y) the actual level of performance measured in accordance with the

applicable performance goals as of the date of such termination), effective as of the date of such termination. For purposes of this Section 6(d), an "*Assumed Award*" means any outstanding Award that was assumed or continued, or any outstanding similar award that was granted in substitution for an Award, in each case by the Acquiring Entity in connection with the applicable Transaction.

e. Appointment of Stockholder Representative. As a condition to the receipt of an Award, a Participant will be deemed to have agreed that the Award will be subject to the terms of any agreement governing a Transaction involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on the Participant's behalf with respect to any escrow, indemnities and any contingent consideration.

f. No Restriction on Right to Undertake Transactions. The grant of any Award and the issuance of shares of Common Stock pursuant to any Award does not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, rights or options to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

#### 7. Administration.

**a. Administration by Board.** The Board will administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in Section 7(c).

**b. Powers of Board.** The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

**i.** To determine from time to time: (1) which of the persons eligible under the Plan will be granted Awards; (2) when and how each Award will be granted; (3) what type or combination of types of Award will be granted; (4) the provisions of each Award (which need not be identical), including the time or times when a person will be permitted to receive an issuance of Common Stock or other payment pursuant to an Award; (5) the number of shares of Common Stock or cash equivalent with respect to which an Award will be granted to each such person; and (6) the Fair Market Value applicable to an Award.

**ii.** To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it deems necessary or expedient to make the Plan or Awards fully effective.

iii. To settle all controversies regarding the Plan and Awards granted under it.

**iv.** To accelerate the time at which an Award may first be exercised or the time during which an Award or any part thereof will vest, notwithstanding the provisions in the Award Agreement stating the time at which it may first be exercised or the time during which it will vest.

v. To prohibit the exercise of any Option, SAR or other exercisable Award during a period of up to 30 days prior to the consummation of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of Common Stock or the share price of the Common Stock, including any Transaction, for reasons of administrative convenience.

vi. To suspend or terminate the Plan at any time. Suspension or termination of the Plan will not Materially Impair a Participant's rights under any Award granted while the Plan is in effect unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

vii. To amend the Plan in any respect the Board deems necessary or advisable; *provided*, *however*, that stockholder approval will be required for any such amendment to the extent required by Applicable Law. Except as provided above, a Participant's rights under any Award granted before any amendment of the Plan will not be Materially Impaired by any such amendment unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

viii. To submit any amendment to the Plan for stockholder approval.

**ix.** To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided, however*, that a Participant's rights under any Award will not be Materially Impaired by any such amendment unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

**x.** Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

**xi.** To adopt such procedures and sub-plans as are necessary or appropriate to permit and facilitate participation in the Plan by, or take advantage of specific tax treatment for Awards granted to, Employees, Directors or Consultants who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement to ensure or facilitate compliance with the laws of the relevant foreign jurisdiction).

#### c. Delegation to Committee.

i. General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to another Committee or a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. Each Committee may retain the authority to concurrently administer the Plan with any Committee or subcommittee to which it has delegated its authority hereunder and may, at any time, revest in such Committee some or all of the powers previously delegated. The Board may retain the authority to concurrently administer the Plan with any Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

**ii. Rule 16b-3 Compliance.** To the extent an Award is intended to qualify for the exemption from Section 16(b) of the Exchange Act that is available under Rule 16b-3 of the Exchange Act, the Award will be granted by the Board or a Committee that consists solely of two or more Non-Employee Directors, as determined under Rule 16b-3(b)(3) of the Exchange Act, and thereafter any action establishing or modifying the terms of the Award will be approved by the Board or a Committee meeting such requirements to the extent necessary for such exemption to remain available.

**d. Effect of Board's Decision.** All determinations, interpretations and constructions made by the Board or any Committee in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

e. Cancellation and Re-Grant of Awards. Except in connection with a Transaction, as provided in Section 6(a) relating to Capitalization Adjustments, or unless the stockholders of the Company have approved such an action within 12 months prior to such an event, neither the Board nor any Committee will have the authority to: (i) reduce the exercise or strike price of any outstanding Option or SAR; or (ii) cancel any outstanding Option or SAR that has an exercise or strike price greater than the then-current Fair Market Value in exchange for cash or other Awards under the Plan.

**f. Delegation to an Officer.** The Board or any Committee may delegate to one or more Officers the authority to do one or both of the following: (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by Applicable Law, other types of Awards) and, to the extent permitted by Applicable Law, the terms thereof; and (ii) determine the number of shares of Common Stock to be subject to such Awards granted to such Employees; *provided, however*, that the resolutions or charter adopted by the Board or any Committee evidencing such delegation will specify the total number of shares of Common Stock that may be subject to the Awards granted by such Officer and that such Officer may not grant an Award to himself or herself. Any such Awards will be granted on the applicable form of Award Agreement most recently approved for use by the Board or the Committee, unless

otherwise provided in the resolutions approving the delegation authority. Notwithstanding anything to the contrary herein, neither the Board nor any Committee may delegate to an Officer who is acting solely in the capacity of an Officer (and not also as a Director) the authority to determine the Fair Market Value.

#### 8. Tax Withholding.

a. Withholding Authorization. As a condition to acceptance of any Award, a Participant authorizes withholding from payroll and any other amounts payable to such Participant, and otherwise agrees to make adequate provision for, any sums required to satisfy any U.S. federal, state, local and/or foreign tax or social insurance contribution withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise, vesting or settlement of such Award, as applicable. Accordingly, a Participant may not be able to exercise an Award even though the Award is vested, and the Company will have no obligation to issue shares of Common Stock subject to an Award, unless and until such withholding obligations are satisfied.

**b.** Satisfaction of Withholding Obligations. To the extent permitted by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any U.S. federal, state, local and/or foreign tax or social insurance contribution withholding obligations relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; (v) by allowing a Participant to effectuate a "cashless exercise" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board; or (vi) by such other method as may be set forth in the Award Agreement.

c. No Obligation to Notify or Minimize Taxes; No Liability to Claims. Except as required by Applicable Law, the Company has no duty or obligation to any Participant to advise such Participant as to the time or manner of exercising an Award. Furthermore, the Company has no duty or obligation to warn or otherwise advise such Participant of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to any Participant and will not be liable to any Participant for any adverse tax consequences to such Participant in connection with an Award. As a condition to accepting an Award, each Participant (i) agrees to not make any claim against the Company compensation and (ii) acknowledges that such Participant was advised to consult with his or her own personal tax, financial and other legal advisors regarding the tax consequences of the Award and has either done so or knowingly and voluntarily declined to do so. Additionally, each Participant acknowledges that any Option or SAR is exempt from Section 409A only if the exercise or strike price of such Option or SAR is at least equal to the "fair market value" of the Common Stock on the date of grant of such Option or SAR as determined

by the Internal Revenue Service and there is no other impermissible deferral of compensation associated with the Award. Additionally, as a condition to accepting an Option or SAR, each Participant agrees to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates in the event that the Internal Revenue Service asserts that the exercise or strike price of such Option or SAR is less than the "fair market value" of the Common Stock on the date of grant of such Option or SAR as subsequently determined by the Internal Revenue Service.

**d. Withholding Indemnification.** As a condition to accepting an Award, in the event that the amount of the Company's and/or its Affiliate's withholding obligations in connection with such Award was greater than the amount actually withheld by the Company and/or its Affiliates, each Participant agrees to indemnify and hold the Company and/or its Affiliates harmless from any failure by the Company and/or its Affiliates to withhold the proper amount.

#### 9. Miscellaneous.

**a. Dividends and Dividend Equivalents.** Dividends or dividend equivalents may not be paid or credited to any Awards.

**b. Source of Shares.** The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

c. Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Awards will constitute general funds of the Company.

d. Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (*e.g.*, Board consents, resolutions or minutes) documenting the corporate action approving the grant contain terms (*e.g.*, exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the Award Agreement or related grant documents.

e. **Stockholder Rights.** No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to an Award unless and until (i) such Participant has satisfied all requirements for exercise of the Award pursuant to its terms, if applicable, and (ii) the issuance of the Common Stock subject to such Award is reflected in the records of the Company.

f. No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award

granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or affect the right of the Company or an Affiliate to terminate at will and without regard to any future vesting opportunity that a Participant may have with respect to any Award (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate is incorporated, as the case may be. Further, nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award will constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or service or confer any right or benefit under the Award or the Plan unless such right or benefit has specifically accrued under the terms of the Award Agreement and/or Plan.

**g. Change in Time Commitment.** In the event a Participant's regular level of time commitment in the performance of his or her services for the Company or any Affiliate is reduced (for example, and without limitation, if the Participant is an Employee and has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board may determine, to the extent permitted by Applicable Law, to (i) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

**h. Execution of Additional Documents.** As a condition to accepting an Award, the Participant agrees to execute any additional documents or instruments necessary or desirable, as determined in the Plan Administrator's sole discretion, to carry out the purposes or intent of the Award, or facilitate compliance with securities and/or other regulatory requirements, in each case at the Plan Administrator's request.

i. Electronic Delivery and Participation. Any reference herein or in an Award Agreement to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access). By accepting any Award, the Participant consents to receive documents by electronic delivery and to participate in the Plan through any on-line electronic system established and maintained by the Plan Administrator or another third party selected by the Plan Administrator. The form of delivery of any Common Stock (*e.g.*, a stock certificate or electronic entry evidencing such shares) will be determined by the Company.

j. Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other Applicable Law, and any other clawback policy that the Company adopts. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a Participant's right to voluntary terminate employment upon a "resignation for good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

**k. Securities Law Compliance.** A Participant will not be issued any shares in respect of an Award unless either (i) the shares are registered under the Securities Act or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Each Award also must comply with other Applicable Law governing the Award, and a Participant will not receive such shares if the Company determines that such receipt would not be in material compliance with Applicable Law.

**I. Transfer or Assignment of Awards; Issued Shares.** Except as expressly provided in the Plan or an Award Agreement, Awards may not be transferred or assigned by the Participant. After the vested shares subject to an Award have been issued, or in the case of Restricted Stock and similar awards, after the issued shares have vested, the holder of such shares is free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, the terms of the Trading Policy and Applicable Law.

**m.** Effect on Other Employee Benefit Plans. The value of any Award, as determined upon grant, vesting or settlement, will not be included as compensation, earnings, salaries, or other similar terms used when calculating any Participant's benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

**n. Deferrals.** To the extent permitted by Applicable Law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may also establish programs and procedures for deferral elections to be made by Participants. Deferrals by will be made in accordance with the requirements of Section 409A.

**o. Section 409A.** Unless otherwise expressly provided for in an Award Agreement, the Plan and each Award Agreement will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A, and, to the extent not so exempt, in compliance with the requirements of Section 409A. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to

Section 409A, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A is a "specified employee" for purposes of Section 409A, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A without regard to alternative definitions thereunder) will be issued or paid before the date that is six months and one day following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment may be made in a manner that complies with Section 409A, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

**p. Choice of Law.** This Plan and any controversy arising out of or relating to this Plan will be governed by, and construed in accordance with, the internal laws of the State of California, without regard to conflict of law principles that would result in any application of any law other than the law of the State of California.

#### **10.** Covenants of the Company.

a. Compliance with Law. The Company will seek to obtain from each regulatory commission or agency, as may be deemed to be necessary, having jurisdiction over the Plan such authority as may be required to grant Awards and to issue and sell shares of Common Stock upon exercise or vesting of the Awards; *provided, however*, that this undertaking will not require the Company to register under the Securities Act the Plan, any Award or any Common Stock issued or issuable pursuant to any such Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary or advisable for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise or vesting of such Awards unless and until such authority is obtained. A Participant is not eligible for the grant of an Award or the subsequent issuance of Common Stock pursuant to the Award if such grant or issuance would be in violation of any Applicable Law.

#### 11. Additional Rules for Awards Subject to Section 409A.

**a. Application.** Unless the provisions of this Section 11 are expressly superseded by the provisions in an Award Agreement, the provisions of this Section 11 will apply and will supersede anything to the contrary set forth in the Award Agreement for a Non-Exempt Award.

**b. Non-Exempt Awards Subject to Non-Exempt Severance Arrangements.** To the extent a Non-Exempt Award is subject to Section 409A due to application of a Non-Exempt Severance Arrangement, the following provisions of this Section 11(b) will apply.

**i.** If the Non-Exempt Award vests in the ordinary course during the Participant's Continuous Service in accordance with the vesting schedule set forth in the Award Agreement, and does not accelerate vesting under the terms of a Non-Exempt Severance Arrangement, in no event will the shares be issued in respect of such Non-Exempt Award any later than the later of: (i) December 31<sup>st</sup> of the calendar year that includes the applicable vesting date; or (ii) the 60<sup>th</sup> day that follows the applicable vesting date.

**ii.** If vesting of the Non-Exempt Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with the Participant's Separation from Service, and such vesting acceleration provisions were in effect as of the date of grant of the Non-Exempt Award and, therefore, are part of the terms of such Non-Exempt Award as of the date of grant, then the shares will be earlier issued in settlement of such Non-Exempt Award upon the Participant's Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60<sup>th</sup> day that follows the date of the Participant's Separation from Service. However, if at the time the shares would otherwise be issued the Participant is subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such shares will not be issued before the date that is six months following the date of such Participant's Separation from Service, or, if earlier, the date of the Participant's death that occurs within such six month period.

**iii.** If vesting of a Non-Exempt Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with a Participant's Separation from Service, and such vesting acceleration provisions were not in effect as of the date of grant of the Non-Exempt Award and, therefore, are not a part of the terms of such Non-Exempt Award on the date of grant, then such acceleration of vesting of the Non-Exempt Award will not accelerate the issuance date of the shares, but the shares will instead be issued on the same schedule as set forth in the Grant Notice as if they had vested in the ordinary course during the Participant's Continuous Service, notwithstanding the vesting acceleration of the Non-Exempt Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).

c. Treatment of Non-Exempt Awards Upon a Transaction for Employees and Consultants. The provisions of this Section 11(c) will apply and will supersede anything to the contrary set forth in the Plan with respect to the permitted treatment of any Non-Exempt Award in connection with a Transaction if the Participant was either an Employee or Consultant upon the applicable date of grant of the Non-Exempt Award.

**i. Vested Non-Exempt Awards.** The following provisions will apply to any Vested Non-Exempt Award in connection with a Transaction:

**1.** If the Transaction is also a Section 409A Change in Control, then the Acquiring Entity may not assume, continue or substitute the Vested Non-Exempt Award. Upon the Section 409A Change in Control, the settlement of the Vested Non-Exempt Award will automatically be accelerated and the shares will be immediately issued in respect of the Vested Non-Exempt Award. Alternatively, the Company may instead provide that the Participant will

receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to the Participant upon the Section 409A Change in Control.

2. If the Transaction is not also a Section 409A Change in Control, then the Acquiring Entity must either assume, continue or substitute each Vested Non-Exempt Award. The shares to be issued in respect of the Vested Non-Exempt Award will be issued to the Participant by the Acquiring Entity on the same schedule that the shares would have been issued to the Participant if the Transaction had not occurred. In the Acquiring Entity's discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to the Participant on such issuance dates, with the determination of the Fair Market Value of the shares made on the date of the Transaction.

**ii. Unvested Non-Exempt Awards.** The following provisions will apply to any Unvested Non-Exempt Award unless otherwise determined by the Board pursuant to Section 11(e).

1. In the event of a Transaction, the Acquiring Entity will assume, continue or substitute any Unvested Non-Exempt Award. Unless otherwise determined by the Board, any Unvested Non-Exempt Award will remain subject to the same vesting and forfeiture restrictions that were applicable to the Award prior to the Transaction. The shares to be issued in respect of any Unvested Non-Exempt Award will be issued to the Participant by the Acquiring Entity on the same schedule that the shares would have been issued to the Participant if the Transaction had not occurred. In the Acquiring Entity's discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to the Participant on such issuance dates, with the determination of Fair Market Value of the shares made on the date of the Transaction.

2. If the Acquiring Entity will not assume, substitute or continue any Unvested Non-Exempt Award in connection with a Transaction, then such Award will automatically terminate and be forfeited upon the Transaction with no consideration payable to any Participant in respect of such forfeited Unvested Non-Exempt Award. Notwithstanding the foregoing, to the extent permitted and in compliance with the requirements of Section 409A, the Board may in its discretion determine to elect to accelerate the vesting and settlement of the Unvested Non-Exempt Award upon the Transaction, or instead substitute a cash payment equal to the Fair Market Value of such shares that would otherwise be issued to the Participant, as further provided in Section 11(e)(ii). In the absence of such discretionary election by the Board, any Unvested Non-Exempt Award will be forfeited without payment of any consideration to the affected Participants if the Acquiring Entity will not assume, substitute or continue the Unvested Non-Exempt Awards in connection with the Transaction.

**3.** The foregoing treatment will apply with respect to all Unvested Non-Exempt Awards upon any Transaction, and regardless of whether or not such Transaction is also a Section 409A Change in Control.

**d. Treatment of Non-Exempt Awards Upon a Transaction for Non-Employee Directors.** The following provisions of this Section 11(d) will apply and will supersede anything to the contrary that may be set forth in the Plan with respect to the permitted treatment of a Non-Exempt Director Award in connection with a Transaction.

i. If the Transaction is also a Section 409A Change in Control, then the Acquiring Entity may not assume, continue or substitute the Non-Exempt Director Award. Upon the Section 409A Change in Control, the vesting and settlement of any Non-Exempt Director Award will automatically be accelerated and the shares will be immediately issued to the Participant in respect of the Non-Exempt Director Award. Alternatively, the Company may provide that the Participant will instead receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to the Participant upon the Section 409A Change in Control pursuant to the preceding provision.

**ii.** If the Transaction is not also a Section 409A Change in Control, then the Acquiring Entity must either assume, continue or substitute the Non-Exempt Director Award. Unless otherwise determined by the Board, the Non-Exempt Director Award will remain subject to the same vesting and forfeiture restrictions that were applicable to the Award prior to the Transaction. The shares to be issued in respect of the Non-Exempt Director Award will be issued to the Participant by the Acquiring Entity on the same schedule that the shares would have been issued to the Participant if the Transaction had not occurred. In the Acquiring Entity's discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to the Participant on such issuance dates, with the determination of Fair Market Value made on the date of the Transaction.

**e.** If the RSU Award is a Non-Exempt Award, then the provisions in this Section 11(e) will apply and supersede anything to the contrary that may be set forth in the Plan or the Award Agreement with respect to the permitted treatment of such Non-Exempt Award:

**i.** Any exercise by the Board of discretion to accelerate the vesting of a Non-Exempt Award will not result in any acceleration of the scheduled issuance dates for the shares in respect of the Non-Exempt Award unless earlier issuance of the shares upon the applicable vesting dates would be in compliance with the requirements of Section 409A.

**ii.** The Company explicitly reserves the right to earlier settle any Non-Exempt Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A-3(j)(4)(ix).

**iii.** To the extent the terms of any Non-Exempt Award provide that it will be settled upon a Transaction, to the extent it is required for compliance with the requirements of Section 409A, the Transaction event triggering settlement must also constitute a Section 409A Change in Control. To the extent the terms of a Non-Exempt Award provide that it will be settled upon a termination of employment or termination of Continuous Service, to the extent it is required for compliance with the requirements of Section 409A, the termination event

triggering settlement must also constitute a Separation from Service. However, if at the time the shares would otherwise be issued to a Participant in connection with a "separation from service" such Participant is subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such shares will not be issued before the date that is six months following the date of the Participant's Separation from Service, or, if earlier, the date of the Participant's death that occurs within such six month period.

**iv.** The provisions in this Section 11(e) for delivery of the shares in respect of the settlement of a RSU Award that is a Non-Exempt Award are intended to comply with the requirements of Section 409A so that the delivery of the shares to the Participant in respect of such Non-Exempt Award will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.

#### 12. Severability.

If all or any part of the Plan or any Award Agreement is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of the Plan or such Award Agreement not declared to be unlawful or invalid. Any Section of the Plan or any Award Agreement (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

#### 13. Termination of the Plan.

The Board may suspend or terminate the Plan at any time. Unless terminated sooner by the Board, the Plan will automatically terminate on the day before the tenth anniversary of the earlier of: (i) the Adoption Date; or (ii) the Effective Date. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

#### 14. Definitions.

As used in the Plan, the following definitions apply to the capitalized terms indicated below:

**a.** "*Acquiring Entity*" means the surviving or acquiring corporation (or the surviving or acquiring corporation's parent company) in connection with a Transaction.

**b.** "Adoption Date" means the date the Plan is first approved by the Compensation Committee.

**c.** "*Affiliate*" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 promulgated under the Securities Act. The Board may determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

**d.** "Annual Meeting" means the first meeting of the Company's stockholders held each calendar year at which Directors are selected.

e. "Applicable Law" means any applicable securities, federal, state, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, listing rule, regulation, judicial decision, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (including under the authority of any applicable self-regulating organization such as the Nasdaq Stock Market, New York Stock Exchange, or the Financial Industry Regulatory Authority).

**f.** "*Award*" means any right to receive Common Stock, cash or other property granted under the Plan (including an Incentive Stock Option, a Nonstatutory Stock Option, a SAR, a Restricted Stock Award, a RSU Award, a Performance Award or any Other Award).

**g.** "*Award Agreement*" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award. The Award Agreement generally consists of the Grant Notice and the agreement containing the written summary of the general terms and conditions applicable to the Award and which is provided to a Participant along with the Grant Notice.

**h.** "*Board*" means the Board of Directors of the Company (or its designee). Any decision or determination made by the Board will be a decision or determination that is made in the sole discretion of the Board (or its designee), and such decision or determination will be final and binding on all Participants.

i. "*Capitalization Adjustment*" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Award after the Adoption Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

**j.** "*Cause*" has the meaning ascribed to such term in any written agreement between the Participant and the Company or an Affiliate defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's commission of any crime involving fraud, dishonesty or moral turpitude; (ii) such Participant's attempted commission of, or participation in, a fraud or act of dishonesty against the Company or an Affiliate that results in (or might have reasonably resulted in) material harm to the business of the Company or an Affiliate; (iii) such Participant's intentional, material violation of any contract or agreement between such Participant and the Company or an Affiliate, or of any statutory duty such Participant owes to the Company or an

Affiliate; or (iv) such Participant's conduct that constitutes gross insubordination, incompetence or habitual neglect of duties and that results in (or might have reasonably resulted in) material harm to the business of the Company or an Affiliate; *provided*, *however*, that the action or conduct described in clauses (iii) and (iv) above will constitute "*Cause*" only if such action or conduct continues after the Company has provided such Participant with written notice thereof and not less than five business days to cure the same. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Board with respect to Participants who are Officers and by the Chief Executive Officer of the Company with respect to Participants who are not Officers. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

**k.** "*Change in Control*" or "*Change of Control*" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events; *provided, however*, to the extent necessary to avoid adverse personal income tax consequences to the Participant in connection with an Award, such transaction also constitutes a Section 409A Change in Control:

i. any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the "*Subject Person*") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

**ii.** there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar

transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

**iii.** the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation;

iv. there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

v. individuals who, on the date the Plan is adopted by the Compensation Committee, are members of the Board (the "*Incumbent Board*") cease for any reason to constitute at least a majority of the members of the Board; *provided*, *however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that (1) if no definition of Change in Control (or any analogous term) is set forth in such an individual written agreement, the foregoing definition will apply; and (2) no Change in Control (or any analogous term) will be deemed to occur with respect to Awards subject to such an individual written agreement without a requirement that the Change in Control (or any analogous term) actually occur.

**I.** *"Code*" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

**m.** *"Committee*" means the Compensation Committee and any other committee of Directors to whom authority has been delegated by the Board or Compensation Committee in accordance with the Plan.

- **n.** "*Common Stock*" means the common stock of the Company.
- **o.** *"Company"* means Neurocrine Biosciences, Inc., a Delaware corporation.
- **p.** *"Compensation Committee"* means the Compensation Committee of the Board.

**q.** "Consultant" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

"Continuous Service" means that the Participant's service with the Company or an Affiliate, whether as an r. Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Director or Consultant or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; provided, however, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the Chief Executive Officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or Chief Executive Officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

s. "*Corporate Transaction*" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

**i.** a sale or other disposition of all or substantially all, as determined by the Board, of the consolidated assets of the Company and its Subsidiaries;

**ii.** a sale or other disposition of at least 90% of the outstanding securities of the Company;

**iii.** a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

**iv.** a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

t. "*determine*" or "*determined*" means as determined by the Board or the Committee (or its designee) in its sole discretion.

**u.** *"Director*" means a member of the Board of Directors of the Company.

v. "*Disability*" means, with respect to a Participant, such Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Section 22(e)(3) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

w. *"Effective Date"* means the date of the Annual Meeting in 2020, provided this Plan is approved by the Company's stockholders at such meeting.

**x.** *"Employee"* means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

- y. *"Employer"* means the Company or the Affiliate of the Company that employs the Participant.
- **z.** *"Entity"* means a corporation, partnership, limited liability company or other entity.

**aa.** *"Exchange Act"* means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

**bb.** "*Exchange Act Person*" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary, (ii) any employee benefit plan of the Company or any Subsidiary or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company, or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

**cc.** *"Fair Market Value"* means, as of any date, unless otherwise determined by the Board, the value of the Common Stock (as determined on a per share or aggregate basis, as applicable) determined as follows:

**i.** If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value will be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

**ii.** If there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing sales price on the last preceding date for which such quotation exists.

**iii.** In the absence of such exchange or market for the Common Stock, or if otherwise determined by the Board, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

**dd.** *"Full Value Award*" means any Award other than an Option or SAR with respect to which the exercise or strike price is at least 100% of the Fair Market Value on the date of grant of such Option or SAR.

**ee.** *"Governmental Body"* means any: (i) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (ii) federal, state, local, municipal, foreign or other government; (iii) governmental or regulatory body, or quasi-governmental body of any nature (including any governmental division, department, administrative agency or bureau, commission, authority, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or Entity and any court or other tribunal, and for the avoidance of doubt, any tax authority) or other body exercising similar powers or authority; or (iv) self-regulatory organization (including the Nasdaq Stock Market, New York Stock Exchange, and the Financial Industry Regulatory Authority).

**ff.** "*Grant Notice*" means the notice provided to a Participant that he or she has been granted an Award and which includes the name of the Participant, the type of Award, the date of grant of the Award, number of shares of Common Stock subject to the Award or potential cash payment right, (if any), the vesting schedule for the Award (if any) and other key terms applicable to the Award.

**gg.** "*Incentive Stock Option*" means an option granted pursuant to Section 4 that is intended to be, and qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code.

**hh.** "*Materially Impair*" means that a Participant's rights under an Award will be materially adversely affected by a suspension or termination of the Plan, an amendment of the Plan, or an amendment to the terms of the Award, as applicable. For purposes of the Plan, a Participant's rights under an Award will not be deemed to have been Materially Impaired by any

of the foregoing actions if the Board, in its sole discretion, determines that such action, taken as a whole, does not materially impair the Participant's rights under the Award. For example, an amendment to the terms of an Award in order to do any of the following, or that results in any of the following, will not be deemed to Materially Impair the Participant's rights under the Award: (i) an imposition of reasonable restrictions on the minimum number of shares subject to an Option that may be exercised; (ii) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (iii) a change in the terms of an Incentive Stock Option in a manner that disqualifies, impairs or otherwise affects the qualified status of the Award as an Incentive Stock Option under Section 422 of the Award as an Incentive Stock Option under Section 422 of the Award as an Incentive Stock Option under Section 422 of the Award as an Incentive Stock Option under Section 422 of the Award as an Incentive Stock Option under Section 422 of the Award as an Incentive Stock Option under Section 422 of the Award as an Incentive Stock Option under Section 422 of the Code; (iv) to clarify the manner of exemption from, or to bring the Award into compliance with or qualify it for an exemption from, Section 409A; or (v) to comply with other Applicable Laws.

**ii.** "*Non-Employee Director*" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("*Regulation S-K*")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K, or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

**jj.** "*Non-Exempt Award*" means any Award that is subject to, and not exempt from, Section 409A, including as the result of (i) a deferral of the issuance of the shares subject to the Award which is elected by the Participant or imposed by the Company, or (ii) the terms of any Non-Exempt Severance Agreement.

**kk.** *"Non-Exempt Director Award*" means a Non-Exempt Award granted to a Participant who was a Director but not an Employee on the applicable grant date.

**II.** "*Non-Exempt Severance Arrangement*" means a severance arrangement or other agreement between the Participant and the Company or an Affiliate that provides for acceleration of vesting of an Award and issuance of the shares in respect of such Award upon the Participant's termination of employment or separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (and without regard to any alternative definition thereunder) ("*Separation from Service*") and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4), 1.409A-1(b)(9) or otherwise.

**mm.** *"Nonstatutory Stock Option"* means any option granted pursuant to Section 4 that does not qualify as an Incentive Stock Option.

**nn.** *"Officer*" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

**oo.** *"Option"* means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock which is granted pursuant to the terms and conditions of Section 4.

**pp.** "*Option Agreement*" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Option grant. The Option Agreement includes the Grant Notice for the Option and the agreement containing the written summary of the general terms and conditions applicable to the Option and which is provided to a Participant along with the Grant Notice. Each Option Agreement will be subject to the terms and conditions of the Plan.

**qq.** *"Other Award*" means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 5(c).

**rr.** "*Other Award Agreement*" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Other Award grant. Each Other Award Agreement will be subject to the terms and conditions of the Plan.

**ss.** "*Own*," "*Owned*," "*Owner*," or "*Ownership*" means that a person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

**tt.** "*Participant*" means an Employee, Director or Consultant to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Award.

**uu.** "*Performance Award*" means an Award that may vest or may be exercised, or that may become earned and paid, contingent upon the attainment during a Performance Period of certain Performance Goals and which is granted pursuant to the terms and conditions of Section 5(b) and such terms as approved by the Board.

vv. "Performance Criteria" means the one or more criteria that the Board will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following, as determined by the Board: (1) earnings (including earnings per share and net earnings, in either case before or after any or all of: interest, taxes, depreciation and amortization, legal settlements or other income (expense), or stock-based compensation, other non-cash expenses and changes in deferred revenue); (2) total stockholder return; (3) return on equity or average stockholder's equity; (4) return on assets, investment, or capital employed; (5) stock price; (6) margin (including gross margin); (7) income (before or after taxes); (8) operating income; (9) operating income after taxes; (10) pre-tax profit; (11) operating cash flow; (12) sales, prescriptions, or revenue targets; (13) increases in revenue or product revenue; (14) expenses and cost reduction goals; (15) improvement in or attainment of working capital levels; (16) economic value added (or an equivalent metric); (17) market share; (18) cash flow;

(19) cash flow per share; (20) cash burn; (21) share price performance; (22) debt reduction; (23) implementation or completion of projects or processes (including, without limitation, discovery of a pre-clinical drug candidate, recommendation of a drug candidate to enter a clinical trial, clinical trial initiation, clinical trial enrollment and dates, clinical trial results, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals, presentation of studies and launch of commercial plans, compliance programs or education campaigns); (24) customer satisfaction; (25) stockholders' equity; (26) capital expenditures; (27) debt levels; (28) financings; (29) operating profit or net operating profit; (30) workforce diversity; (31) growth of net income or operating income; (32) billings; (33) employee hiring; (34) funds from operations; (35) budget management; (36) strategic partnerships or transactions (including acquisitions, joint ventures or licensing transactions); (37) engagement of thought leaders and patient advocacy groups; (38) enhancement of intellectual property portfolio, filing of patent applications and granting of patents; (39) litigation preparation and management; and (40) any other measure of performance selected by the Board.

"Performance Goals" means, for a Performance Period, the one or more goals established by the Board for the ww. Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board will appropriately make adjustments in the method of calculating the attainment of the Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated Performance Goals; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates: (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the Company's bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (12) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the U.S. Food and Drug Administration or any other regulatory body. In addition, the Board retains the discretion to define the manner of calculating the Performance Criteria it selects to use for a Performance Period and to reduce or eliminate the compensation or economic benefit due upon the attainment of any Performance Goal. Partial attainment of any

Performance Goal may result in payment or vesting corresponding to the degree of attainment as specified in the applicable Award Agreement or the written terms of a Performance Award.

**xx.** "*Performance Period*" means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to vesting or exercise of, or any payment under, an Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

yy. "Plan" means this Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan.

**zz.** "*Plan Administrator*" means the person, persons, and/or third-party administrator designated by the Company to administer the day to day operations of the Plan and the Company's other equity incentive programs.

**aaa.** *"Post-Termination Exercise Period"* means the period following termination of a Participant's Continuous Service within which an Option or SAR is exercisable, as specified in Section 4(h).

bbb. "Prior Plan" means the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan.

ccc. "Prior Plan Award" means an award granted under the Prior Plan that is outstanding as of the Effective Date.

**ddd.** *"Prior Plan's Available Reserve"* means the number of shares available for the grant of new awards under the Prior Plan as of immediately following the Effective Date.

**eee.** "*Prior Plan's Returning Shares*" means shares of Common Stock subject to a Prior Plan Award that following the Effective Date: (i) are not issued because such Prior Plan Award or any portion thereof expires or otherwise terminates without all of the shares covered by such Prior Plan Award having been issued; (ii) are not issued because such Prior Plan Award or any portion thereof is settled in cash; or (iii) are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required for the vesting of such shares.

fff. *"Prospectus"* means the document containing the Plan information specified in Section 10(a) of the Securities Act.

**ggg.** "*Restricted Stock Award*" means an Award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

**hhh.** "*Restricted Stock Award Agreement*" means a written agreement between the Company and a Participant evidencing the terms and conditions of a Restricted Stock Award grant. The Restricted Stock Award Agreement includes the Grant Notice for the Restricted Stock Award and the agreement containing the written summary of the general terms and conditions applicable to the Restricted Stock Award and which is provided to a Participant along with the Grant Notice. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

**iii.** *"RSU Award*" means an Award of restricted stock units representing the right to receive an issuance of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

**jjj.** "*RSU Award Agreement*" means a written agreement between the Company and a Participant evidencing the terms and conditions of a RSU Award grant. The RSU Award Agreement includes the Grant Notice for the RSU Award and the agreement containing the written summary of the general terms and conditions applicable to the RSU Award and which is provided to a Participant along with the Grant Notice. Each RSU Award Agreement will be subject to the terms and conditions of the Plan.

**kkk.** *"Rule 16b-3"* means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

III. "*Rule 405*" means Rule 405 promulgated under the Securities Act.

**mmm.** *"Section 409A"* means Section 409A of the Code and the regulations and other guidance thereunder.

**nnn.** "*Section 409A Change in Control*" means a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets, as provided in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

**000.** *"Securities Act"* means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

**ppp.** "*Share Reserve*" means the number of shares of Common Stock available for issuance under the Plan as set forth in Section 2(a).

**qqq.** *"SAR"* or *"Stock Appreciation Right"* means a right to receive the appreciation on Common Stock which is granted pursuant to the terms and conditions of Section 4.

**rrr.** "*SAR Agreement*" means a written agreement between the Company and a Participant evidencing the terms and conditions of a SAR grant. The SAR Agreement includes the Grant Notice for the SAR and the agreement containing the written summary of the general terms and conditions applicable to the SAR and which is provided to a Participant along with the Grant Notice. Each SAR Agreement will be subject to the terms and conditions of the Plan.

**sss.** "*Subsidiary*" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct

or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

**ttt.** "*Ten Percent Stockholder*" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any Affiliate.

**uuu.** "*Trading Policy*" means the Company's policy permitting certain individuals to sell Company shares only during certain "window" periods and/or otherwise restricts the ability of certain individuals to transfer or encumber Company shares, as in effect from time to time.

vvv. "Transaction" means a Corporate Transaction or a Change in Control.

www. "Unvested Non-Exempt Award" means the portion of any Non-Exempt Award that had not vested in accordance with its terms upon or prior to the date of any Transaction.

**xxx.** "*Vested Non-Exempt Award*" means the portion of any Non-Exempt Award that had vested in accordance with its terms upon or prior to the date of a Transaction.

# Neurocrine Biosciences, Inc.

## 2020 Equity Incentive Plan Option Grant Notice

Neurocrine Biosciences, Inc. (the "*Company*") has granted to you ("*Participant*") an option to purchase the number of shares of Common Stock set forth below (the "*Option*") under the Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan (the "*Plan*"). The Option is subject to all of the terms and conditions set forth in this Option Grant Notice (the "*Grant Notice*"), the Option Agreement (the "*Agreement*") and the Plan, all of which are available by logging into your E\*TRADE brokerage account and which are incorporated herein in their entirety. Capitalized terms not explicitly defined in this Grant Notice but defined in the Agreement or the Plan will have the meanings set forth in the Agreement or the Plan, as applicable.

Participant: Date of Grant: Vesting Commencement Date: Number of Shares of Common Stock: Exercise Price (Per Share): Total Exercise Price: Expiration Date:

**Type of Grant:** Incentive Stock Option Nonstatutory Stock Option

Vesting Schedule: Subject to Section 2 of the Agreement, the Option will vest as follows: [\_\_\_\_\_].

Exercise Schedule: Same as Vesting Schedule

Participant Acknowledgements: By your electronic acceptance of the Option via your E\*TRADE brokerage account, you understand and agree that:

- The Option is governed by this Grant Notice, the Agreement and the Plan, all of which are made a part of this document. Unless otherwise provided in the Plan, this Grant Notice and the Agreement may not be modified, amended or revised except in a writing signed by you and a duly authorized officer of the Company.
- If the Option is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options granted to you) cannot be first *exercisable* for more than \$100,000 in value (measured by exercise price) in any calendar year. Any excess over \$100,000 is a Nonstatutory Stock Option.
- Copies of this Grant Notice, the Agreement, the Plan and the Prospectus are available via your E\*TRADE brokerage account and may be viewed
  and printed by you. You consent to receive this Grant Notice, the Agreement, the Plan, the Prospectus and any other Plan-related documents by
  electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another
  third party designated by the Company.
- You have read and are familiar with the provisions of this Grant Notice, the Agreement, the Plan and the Prospectus. In the event of any conflict between the provisions in this Grant Notice, the Agreement or the Prospectus and the provisions of the Plan, the provisions of the Plan will control.
- As of the Date of Grant, this Grant Notice, the Agreement and the Plan set forth the entire understanding between you and the Company regarding the Option and supersede all prior oral and written agreements, promises and/or representations regarding the Option, with the exception of any written employment, offer letter, severance or other agreement, or any written severance plan or policy, in each case that specifies the terms that should govern the Option.

# **Neurocrine Biosciences, Inc.**

# 2020 Equity Incentive Plan Option Agreement

Pursuant to the accompanying Option Grant Notice (the "*Grant Notice*") and this Option Agreement (the "*Agreement*"), Neurocrine Biosciences, Inc. (the "*Company*") has granted you an option under the Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan (the "*Plan*") to purchase the number of shares of Common Stock set forth in the Grant Notice at the exercise price set forth in the Grant Notice (the "*Option*"). Capitalized terms not explicitly defined in this Agreement but defined in the Grant Notice or the Plan will have the meanings set forth in the Grant Notice or the Plan, as applicable.

The general terms and conditions applicable to your Option are as follows:

**1. Governing Plan Document.** Your Option is subject to all the provisions of the Plan, including but not limited to the provisions in:

**a.** Section 6 of the Plan regarding the impact of a Capitalization Adjustment, dissolution, liquidation, or Transaction on your Option;

**b.** Section 9(f) of the Plan regarding the Company's and any Affiliate's (if applicable) retained rights to terminate your Continuous Service notwithstanding the grant of your Option; and

**c.** Section 8(c) of the Plan regarding the tax consequences of your Option.

Your Option is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions in this Agreement or the Grant Notice and the provisions of the Plan, the provisions of the Plan will control.

### 2. Vesting.

**a.** Subject to the limitations contained in this Agreement, your Option will vest in accordance with the vesting schedule set forth in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service, except as otherwise explicitly provided in the Plan (in connection with a Transaction or certain terminations of Continuous Service following such Transaction) or this Agreement.

**b.** [For Employees and Directors, in the event of a termination of your Continuous Service due to your death or Disability, your Option will become vested, as of the date of such termination, in accordance with the vesting schedule set forth in the Grant Notice as if you had provided an additional six months of Continuous Service as of the date of such termination.]

**c.** [For Employees, in the event of a termination of your Continuous Service due to your Retirement, your Option will become fully vested as of the date of such Retirement. For purposes of this Agreement, "*Retirement*" means a termination of your Continuous Service upon or after you have reached age 60 with at least 5 years of Continuous Service, provided that you comply with any other requirements in the Company's then-current policy regarding Retirement.]

**d.** [For Directors, in the event of a Transaction during your Continuous Service, your Option will become fully vested as of the date of such Transaction.]

## 3. Exercise.

**a.** You may generally exercise the vested portion of your Option (and the unvested portion of your Option if permitted by the Grant Notice) for whole shares of Common Stock at any time during its term by delivery of payment of the exercise price and any Withholding Obligation, as set forth in Section 6, and other required documentation to the Plan Administrator in accordance with the exercise procedures established by the Plan Administrator, which may include an electronic submission. Please review Sections 4(i), 4(j) and 7(b)(v) of the Plan, which may restrict or prohibit your ability to exercise your Option during certain periods.

**b.** To the extent permitted by Applicable Law, you may pay the exercise price of your Option as follows:

**i.**by cash or check, bank draft or money order payable to the Company;

**ii**.pursuant to a "cashless exercise" program, as provided in Section 4(c)(ii) of the Plan, if at the time of exercise the Common Stock is publicly traded;

**iii.**by delivery of already owned shares of Common Stock, as provided in Section 4(c)(iii) of the Plan, if at the time of exercise the Common Stock is publicly traded; or

**iv.**subject to approval by the Company and/or the Committee, as applicable, at or prior to the time of exercise, if your Option is a Nonstatutory Stock Option, by a "net exercise" arrangement, as provided in Section 4(c)(iv) of the Plan.

4. **Term.** You may not exercise your Option before the commencement of its term or after its term expires. The term of your Option commences on the Date of Grant and expires upon the earliest of the following:

**a.** immediately upon the termination of your Continuous Service for Cause;

**b.** [for an Employee, three months after the termination of your Continuous Service for any reason other than Cause, Disability, death or Retirement;]

**c.** [for a Director, three years after the termination of your Continuous Service for any reason other than Cause;]

- d. [for a Consultant, 30 days after the termination of your Continuous Service for any reason other than
- Cause;]
- e. [for an Employee, 12 months after the termination of your Continuous Service due to your Disability;]
- f. [for an Employee, 18 months after your death if you die during your Continuous Service;]
- **g.** [for an Employee, 12 months after the termination of your Continuous Service due to your Retirement;]

**h.** immediately upon a Transaction if the Board has determined that your Option will terminate in connection with such Transaction;

- i. the Expiration Date set forth in the Grant Notice; or
- **j.** the day before the 10th anniversary of the Date of Grant.

[For an Employee, notwithstanding the foregoing, if you die during the period provided in Section 4(b) above, the term of your Option will not expire until the earlier of (i) 18 months after the termination of your Continuous Service, (ii) a Transaction if the Board has determined that your Option will terminate in connection with such Transaction, (iii) the Expiration Date set forth in the Grant Notice, or (iv) the day before the 10th anniversary of the Date of Grant.]

In addition, the Post-Termination Exercise Period of your Option may be extended as provided in Section 4(i) of the Plan.

To obtain the federal income tax advantages associated with an Incentive Stock Option, the Code requires that at all times beginning on the date of grant of your Option and ending on the day three months before the date of your Option's exercise, you must be an employee of the Company or an Affiliate, except in the event of your death or Disability. If the Company provides for the extended exercisability of your Option under certain circumstances for your benefit, your Option will not necessarily be treated as an Incentive Stock Option if you exercise your Option more than three months after the date your employment terminates.

5. **Transferability.** Except as otherwise provided in Section 4(e) of the Plan, your Option is not transferable, except by will or by the applicable laws of descent and distribution, and is exercisable during your life only by you. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, will thereafter be entitled to exercise your Option.

### 6. Withholding Obligations.

**a.** As provided in Section 8 of the Plan, at the time you exercise your Option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make

adequate provision for (including by means of a "cashless exercise" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations, if any, which arise in connection with your Option (the "*Withholding Obligation*") in accordance with the withholding procedures established by the Company.

**b.** Upon your request and subject to approval by the Company and/or the Committee, as applicable, and in compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon exercise of your Option a number of whole shares of Common Stock with a Fair Market Value on the date of exercise not in excess of the maximum amount of tax that may be required to be withheld by law (or such other amount as may be permitted while still avoiding classification of your Option as a liability for financial accounting purposes).

**c.** You may not exercise your Option unless the Withholding Obligation is satisfied. Accordingly, you may not be able to exercise your Option even though your Option is vested, and the Company will have no obligation to issue any shares of Common Stock subject to your Option, unless and until the Withholding Obligation is satisfied. In the event that the amount of the Withholding Obligation was greater than the amount actually withheld by the Company (or an Affiliate, if applicable), you agree to indemnify and hold the Company (and Affiliate, if applicable) harmless from any failure to withhold the proper amount.

7. Incentive Stock Option Disposition Requirement. If your Option is an Incentive Stock Option, you must notify the Company in writing within 15 days after the date of any disposition of any of the shares of Common Stock issued upon exercise of your Option that occurs within two years after the date of grant of your Option or within one year after such shares of Common Stock are transferred upon exercise of your Option.

**8. Transaction.** Your Option is subject to the terms of any agreement governing a Transaction involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on your behalf with respect to any escrow, indemnities and any contingent consideration.

9. No Liability for Taxes. As a condition to accepting your Option, you hereby (a) agree to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your Option or other Company compensation and (b) acknowledge that you were advised to consult with your own personal tax, financial and other legal advisors regarding the tax consequences of your Option and have either done so or knowingly and voluntarily declined to do so. Additionally, you acknowledge that your Option is exempt from Section 409A only if the exercise price of your Option is at least equal to the "fair market value" of the Common Stock on the date of grant as determined by the Internal Revenue Service and there is no other impermissible deferral of compensation associated with your Option. Additionally, as a condition to accepting your Option, you agree to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates in the event that the Internal Revenue Service asserts that such exercise price is less than the "fair market value"

of the Common Stock on the date of grant as subsequently determined by the Internal Revenue Service.

**10. Severability.** If any part of this Agreement, the Grant Notice or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement, the Grant Notice or the Plan not declared to be unlawful or invalid. Any Section of this Agreement, the Grant Notice or the Plan (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

**11. Other Documents.** You hereby acknowledge receipt of or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Prospectus. In addition, you acknowledge receipt of the Company's Trading Policy.

# Neurocrine Biosciences, Inc.

# 2020 Equity Incentive Plan RSU Award Grant Notice

Neurocrine Biosciences, Inc. (the "*Company*") has granted to you ("*Participant*") a restricted stock unit award for the number of restricted stock units ("*RSUs*") set forth below (the "*RSU Award*") under the Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan (the "*Plan*"). The RSU Award is subject to all of the terms and conditions set forth in this RSU Award Grant Notice (the "*Grant Notice*"), the RSU Award Agreement (the "*Agreement*") and the Plan, all of which are available by logging into your E\*TRADE brokerage account and which are incorporated herein in their entirety. Capitalized terms not explicitly defined in this Grant Notice but defined in the Agreement or the Plan will have the meanings set forth in the Agreement or the Plan, as applicable.

Participant: \_ Date of Grant: \_ Vesting Commencement Date: \_ Number of RSUs: \_

Vesting Schedule: Subject to Section 3 of the Agreement, the RSU Award will vest as follows: [\_\_\_\_\_].

Issuance Schedule: One share of Common Stock will be issued for each RSU which vests at the time set forth in Section 4 of the Agreement.

**Withholding Obligation:** To the fullest extent permitted under the Plan and Applicable Law, any Withholding Obligation (as set forth in Section 6 of the Agreement) will be satisfied through a "Sell to Cover" procedure as described in Section 6 of the Agreement. In order to effectuate such Sell to Cover, you must execute an election form and such other documents required by the Company and any applicable broker-dealer, authorizing and directing such Sell to Cover in accordance with the requirements of Rule 10b5-1(c) under the Exchange Act.

Participant Acknowledgements: By your electronic acceptance of the RSU Award via your E\*TRADE brokerage account, you understand and agree that:

- The RSU Award is governed by this Grant Notice, the Agreement and the Plan, all of which are made a part of this document. Unless otherwise provided in the Plan, this Grant Notice and the Agreement may not be modified, amended or revised except in a writing signed by you and a duly authorized officer of the Company.
- Copies of this Grant Notice, the Agreement, the Plan and the Prospectus are available via your E\*TRADE brokerage account and may be viewed and printed by you. You consent to receive this Grant Notice, the Agreement, the Plan, the Prospectus and any other Plan-related documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.
- You have read and are familiar with the provisions of this Grant Notice, the Agreement, the Plan and the Prospectus. In the event of any conflict between the provisions in this Grant Notice, the Agreement or the Prospectus and the provisions of the Plan, the provisions of the Plan will control.
- As of the Date of Grant, this Grant Notice, the Agreement and the Plan set forth the entire understanding between you and the Company regarding
  the RSU Award and supersede all prior oral and written agreements, promises and/or representations regarding the RSU Award, with the exception
  of any written employment, offer letter, severance or other agreement, or any written severance plan or policy, in each case that specifies the terms
  that should govern the RSU Award.

# Neurocrine Biosciences, Inc.

# 2020 Equity Incentive Plan RSU Award Agreement

Pursuant to the accompanying RSU Award Grant Notice (the "*Grant Notice*") and this RSU Award Agreement (the "*Agreement*"), Neurocrine Biosciences, Inc. (the "*Company*") has granted you a restricted stock unit award under the Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan (the "*Plan*") for the number of restricted stock units ("*RSUs*") set forth in the Grant Notice (the "*RSU Award*"). Capitalized terms not explicitly defined in this Agreement but defined in the Grant Notice or the Plan will have the meanings set forth in the Grant Notice or the Plan, as applicable.

The general terms and conditions applicable to your RSU Award are as follows:

**1. Governing Plan Document.** Your RSU Award is subject to all the provisions of the Plan, including but not limited to the provisions in:

**a.** Section 6 of the Plan regarding the impact of a Capitalization Adjustment, dissolution, liquidation, or Transaction on your RSU Award;

**b.** Section 9(f) of the Plan regarding the Company's and any Affiliate's (if applicable) retained rights to terminate your Continuous Service notwithstanding the grant of your RSU Award; and

**c.** Section 8(c) of the Plan regarding the tax consequences of your RSU Award.

Your RSU Award is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions in this Agreement or the Grant Notice and the provisions of the Plan, the provisions of the Plan will control.

2. **Grant of the RSU Award.** The RSU Award represents your right to be issued on a future date a number of shares of Common Stock that is equal to the number of RSUs set forth in the Grant Notice, as adjusted to reflect any Capitalization Adjustment, subject to your satisfaction of the vesting conditions set forth in the Grant Notice and this Agreement. Any additional RSUs that become subject to your RSU Award pursuant to any Capitalization Adjustment will be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of issuance as applicable to the other RSUs covered by your RSU Award. Your RSU Award was granted in consideration of your services to the Company or an Affiliate.

### 3. Vesting.

**a.** Subject to the limitations contained in this Agreement, your RSU Award will vest in accordance with the vesting schedule set forth in the Grant Notice, provided that

vesting will cease upon the termination of your Continuous Service, except as otherwise explicitly provided in the Plan (in connection with a Transaction or certain terminations of Continuous Service following such Transaction) or this Agreement. Upon such termination of your Continuous Service, you will forfeit (at no cost to the Company) any RSUs subject to your RSU Award that have not vested as of the date of such termination and you will have no further right, title or interest in such RSUs or the shares of Common Stock to be issued in respect of such RSUs.

**b.** [For Employees and Directors, in the event of a termination of your Continuous Service due to your death or Disability, your RSU Award will become vested, as of the date of such termination, in accordance with the vesting schedule set forth in the Grant Notice as if you had provided an additional six months of Continuous Service as of the date of such termination.]

**c.** [For Directors, in the event of a Transaction during your Continuous Service, your RSU Award will become fully vested as of the date of such Transaction.]

### 4. Date of Issuance.

a. The issuance of any shares of Common Stock in respect of your RSU Award is (i) subject to satisfaction of any Withholding Obligation, as set forth in Section 6, and (ii) intended to comply with Treasury Regulations Section 1.409A-1(b) (4) and will be construed and administered in such a manner.

**b.** In the event one or more RSUs subject to your RSU Award vests, the Company will issue to you, on the applicable vesting date, one share of Common Stock for each RSU that vests on such date (and for purposes of this Agreement, such issuance date is referred to as the "*Original Issuance Date*"); *provided, however*, that if the Original Issuance Date falls on a date that is not a business day, such shares will instead be issued to you on the next following business day.

**c.** Notwithstanding the foregoing, <u>if</u>:

i.your RSU Award is otherwise subject to a Withholding Obligation on the Original Issuance Date,

**ii.**the Original Issuance Date does not occur (x) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's Trading Policy, or (y) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market (including but not limited to under a previously established written trading plan that meets the requirements of Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "**10b5-1** Arrangement")), and

**iii.**the Company elects, prior to the Original Issuance Date, (x) not to satisfy such Withholding Obligation by withholding shares of Common Stock from the shares of

Common Stock otherwise due, on the Original Issuance Date, to you under your RSU Award, (y) not to permit you to enter into a "same day sale" commitment with a broker-dealer in order to satisfy such Withholding Obligation (including but not limited to a commitment under a 10b5-1 Arrangement), and (z) not to permit you to pay such Withholding Obligation in cash,

then the shares of Common Stock that would otherwise be issued to you on the Original Issuance Date will not be issued to you on the Original Issuance Date and will instead be issued to you on the first business day when you are not prohibited from selling shares of Common Stock on an established stock exchange or stock market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the year following the year in which the shares of Common Stock in respect of your RSU Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

**d.** To the extent your RSU Award is a Non-Exempt Award, the provisions of Section 11 of the Plan will apply.

**5. Transferability.** Except as otherwise provided in the Plan, your RSU Award is not transferable, except by will or by the applicable laws of descent and distribution.

## 6. Withholding Obligations.

**a.** As provided in Section 8 of the Plan, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for, any sums required to satisfy the federal, state, local and foreign tax withholding obligations, if any, which arise in connection with your RSU Award (the "*Withholding Obligation*") in accordance with the withholding procedures established by the Company. Additionally, the Company may, in its sole discretion, satisfy all or any portion of the Withholding Obligation by any of the following means or by a combination of such means: (i) causing you to tender a cash payment; (ii) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "*FINRA Dealer*") whereby you irrevocably elect to sell a portion of the shares to be issued in connection with your RSU Award to satisfy the Withholding Obligation and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Obligation directly to the Company and/or its Affiliates (a "*Sell to Cover*" arrangement); or (iii) such other method permitted under the Plan.

**b.** Upon your request and subject to approval by the Company and/or the Committee, as applicable, and in compliance with any applicable legal conditions or restrictions, the Company may withhold from the shares of Common Stock otherwise issuable to you in connection with your RSU Award a number of whole shares of Common Stock with a Fair Market Value on the date of issuance not in excess of the maximum amount of tax that may be required to be withheld by law (or such other amount as may be permitted while still avoiding classification of your RSU Award as a liability for financial accounting purposes).

**c.** Unless the Withholding Obligation is satisfied, the Company will have no obligation to issue to you any shares of Common Stock in respect of your RSU Award. In the event the Withholding Obligation arises prior to the issuance to you of any shares of Common Stock or it is determined after such issuance that the amount of the Withholding Obligation was greater than the amount actually withheld by the Company (or an Affiliate, if applicable), you agree to indemnify and hold the Company (and Affiliate, if applicable) harmless from any failure to withhold the proper amount.

7. **Dividends.** You will receive no dividends or dividend equivalents with respect to your RSU Award; *provided*, *however*, that this sentence will not apply with respect to any shares of Common Stock that are issued to you in connection with your RSU Award after such shares have been issued to you.

**8. Transaction.** Your RSU Award is subject to the terms of any agreement governing a Transaction involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on your behalf with respect to any escrow, indemnities and any contingent consideration.

**9. No Liability for Taxes.** As a condition to accepting your RSU Award, you hereby (a) agree to not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your RSU Award or other Company compensation and (b) acknowledge that you were advised to consult with your own personal tax, financial and other legal advisors regarding the tax consequences of your RSU Award and have either done so or knowingly and voluntarily declined to do so.

**10. Severability.** If any part of this Agreement, the Grant Notice or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Agreement, the Grant Notice or the Plan not declared to be unlawful or invalid. Any Section of this Agreement, the Grant Notice or the Plan (or part of such a Section) so declared to be unlawful or invalid will, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

**11. Other Documents.** You hereby acknowledge receipt of or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Prospectus. In addition, you acknowledge receipt of the Company's Trading Policy.

#### CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED.

CONFIDENTIAL

**Execution Version** 

**Exclusive License Agreement** 

by and Between

# **Takeda Pharmaceutical Company Limited**

and

Neurocrine Biosciences, Inc.

June 12, 2020

### TABLE OF CONTENTS

1. DEFINITIONS	1
2. LICENSE GRANT	27
2.1. License Grant to Neurocrine	27
2.2. Sublicensing Terms	27
2.3. Subcontractors	28
2.4 [***]	29
2.5 [***]	30
2.6. In-Licenses	30
2.7. Knowledge and Technology Transfer.	31
2.8. No Other Rights and Retained Rights	32
2.9. License to Takeda.	32
3. PROFIT AND LOSS SHARE OPTIONS	32
3.1. Takeda's Phase I Asset Opt-Out Right	32
3.2. Takeda's Phase II Asset Opt-In Right	33
3.3. Takeda Right to Opt-Out of Profit Sharing	34
4. DEVELOPMENT	34
4.1. Development Program of Certain Licensed Products	34
4.2. Development Diligence Obligations	37
4.3. Neurocrine Development Responsibilities	39
4.4. Scientific Records	39
5. REGULATORY MATTERS	39
5.1. Regulatory Responsibilities	39
5.2. Assignment of Regulatory Submissions	39
5.3. Regulatory Submissions, Study Reports and Data not Controlled by Takeda.	42
5.4. Neurocrine Obligations	42
5.5. Costs of Regulatory Affairs.	42
6. COMMERCIALIZATION	42
6.1. Commercialization of the Licensed Products.	42
6.2. Commercialization Diligence Obligations	43
6.3. Licensed Products Commercialization Reporting	43
6.4. Licensed Products Commercialization Expenses	44
6.5. Recalls, Market Withdrawals, or Corrective Actions	44
7. MEDICAL AFFAIRS	44
7.1. Co-Funded Medical Affairs Plan	44
7.2. Medical Affairs Reports	45
7.3. Profit-Share Products Medical Affairs Expenses	45
8. GOVERNANCE	45
8.1. Alliance Manager	45
8.2. Joint Steering Committee	46

8.3. Decisions of the JSC	49
8.4. Resolution of JSC Disputes	50
8.5. JSC Termination	53
9. PAYMENTS	53
9.1. Upfront Payment	53
9.2. Payments for the Licensed Assets and Licensed Products	53
9.3. Other Amounts Payable	58
9.4. Payment Terms	58
10. CONFIDENTIALITY AND PUBLICATION	62
10.1. Nondisclosure and Non-Use Obligations	62
10.2. Publication and Publicity	64
11. REPRESENTATIONS, WARRANTIES AND COVENANTS	65
11.1. Mutual Representations and Warranties as of the Execution Date	65
11.2. Representations and Warranties by Takeda	66
11.3. Warranty Disclaimer	68
11.4. Certain Covenants	69
12. INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE	70
12.1. Indemnification by Takeda	70
12.2. Indemnification by Neurocrine	70
12.3. Third Party Losses for Profit-Share Products.	71
12.4. Indemnification Procedure	72
12.5. Limitation of Liability	72
12.6. Insurance	73
13. INTELLECTUAL PROPERTY	73
13.1. Inventions.	73
13.2. Prosecution and Maintenance of Patent Rights	74
13.3. Third Party Infringement and Defense	76
13.4. Patent Right Extensions	78
13.5. Third Party Rights	78
13.6. Orange Book Listing.	78
13.7. Trademarks.	78
13.8. Common Interest	78
14. TERM AND TERMINATION	79
14.1. Term	79
14.2. Termination for Convenience	79
14.3. Termination for Cause	79
14.4. Effects of Termination	81
14.5. Survival	87
15. EFFECTIVENESS	88
15.1. Effective Date	88
15.2. Filings	88

#### **SCHEDULES**

SCHEDULE 1.45 Defensive Patent Rights SCHEDULE 1.89 Licensed Assets SCHEDULE 1.188 Takeda Know-How SCHEDULE 2.7 Transferred Inventory SCHEDULE 4.1.1 Preliminary Co-Funded Development Plan SCHEDULE 4.2.3(d) Phase II Ongoing Activities Plan and Budget SCHEDULE 5.2.3 Regulatory Submissions Dates SCHEDULE 9.2.1 Profit and Loss Share SCHEDULE 9.4.1 Wire Instructions SCHEDULE 10.2.3 Joint Press Release SCHEDULE 10.2.3 Joint Press Release SCHEDULE 11.2.1 Takeda Patent Rights SCHEDULE 11.2.2 Takeda Technology SCHEDULE 11.2.4 Ownership of Takeda Technology SCHEDULE 11.4.4 Domain Names SCHEDULE 13.2.1(a) Annuities and Maintenance Fees SCHEDULE 14.4.3 [\*\*\*] Dispute Resolution

4

#### EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT (this "**Agreement**"), entered into as of June 12, 2020 (the "**Execution Date**"), is entered into by and between Takeda Pharmaceutical Company Limited, a Japanese corporation ("**Takeda**"), and Neurocrine Biosciences, Inc., a corporation organized and existing under the Laws of Delaware ("**Neurocrine**"). Takeda and Neurocrine are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

#### RECITALS

**WHEREAS**, Takeda is a global pharmaceutical company with expertise in developing and commercializing neuroscience therapeutics;

**WHEREAS**, Neurocrine is a biopharmaceutical company focused on advancing therapies for neurological, psychiatric, and endocrine-related disorders;

WHEREAS, Takeda Controls certain Patent Rights, Know-How, and other intellectual property rights related to the Licensed Assets and Licensed Products; and

**WHEREAS**, Neurocrine wishes to obtain, and Takeda desires to grant, a license under certain Patent Rights, Know-How, and other intellectual property rights Controlled by Takeda to Exploit the Licensed Assets and Licensed Products on the terms and conditions set forth herein.

NOW, THEREFORE, the Parties hereby agree as follows:

#### 1. **DEFINITIONS**

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, will have the respective meanings set forth below:

- **1.1.** "Accounting Standards" means International Financial Reporting Standards (IFRS), with respect to Takeda, and U.S. Generally Accepted Accounting Principles (GAAP), with respect to Neurocrine, or GAAP or IFRS, as applicable, in each case, as generally and consistently applied throughout the Party's organization.
- **1.2.** "Affiliate" means, with respect to a Person, any other Person that controls, is controlled by, or is under common control with such Person. For purposes of this Agreement, a Person will be deemed to control another Person if it owns or controls, directly or indirectly, more than 50% of the equity securities of such other Person entitled to vote in the election of directors (or, in the case that such other Person is not a corporation, for the election of the corresponding managing authority), or otherwise has the power to direct the management and policies of such other Person. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than 50%, and that in such case such lower percentage will be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management and policies of such other solely as a result of their entering into this Agreement.
- **1.3.** "**Agreement**" has the meaning set forth in the preamble.

- **1.4.** "Alliance Manager" has the meaning set forth in Section 8.1 (Alliance Manager).
- **1.5.** "Allowable Overruns" means, for Licensed Assets that are Profit-Share Products, on a Licensed Asset-by Licensed Asset basis, any amount that is [\*\*\*] above the total budgeted or approved amounts for a Calendar Year on a year to date basis set forth in any Co-Funded Development Budget, Co-Funded Commercialization Budget, or Co-Funded Medical Affairs Budget for such Calendar Year for all Profit-Share Products that comprise the same Licensed Asset,[\*\*\*] for all Profit-Share Products comprising the same Licensed Asset in the applicable budget (*i.e.*, either the Co-Funded Development Budget, Co-Funded Commercialization Budget, or Co-Funded Medical Affairs Budget) for any Calendar Year], *provided* that, subject to [\*\*\*] such amount is not incurred as a result of [\*\*\*].
- **1.6.** "Antitrust Clearance Date" means the earliest date on which all applicable waiting periods and approvals required under Antitrust Laws in the U.S. with respect to the transactions contemplated under this Agreement have expired or have been terminated (in the case of waiting periods) or been received (in the case of approvals), in each case, without the imposition of any conditions.
- **1.7. "Antitrust Filing"** means any filing with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice and any applicable Governmental Authority in the Territory, as required under any Antitrust Laws with respect to the transactions contemplated under this Agreement, together with all required documentary attachments thereto.
- **1.8.** "Antitrust Laws" means any federal, state or foreign law, regulation, or decree, including the HSR Act, designed to prohibit, restrict, or regulate actions for the purpose or effect of monopolization or restraint of trade.
- **1.9.** "Assigned Regulatory Submissions" means all INDs, MAAs, and other Regulatory Approvals or Regulatory Submissions assigned by Takeda to Neurocrine pursuant to Section 5.2 (Assignment of Regulatory Submissions).
- **1.10.** "Auditor" has the meaning set forth in Section 9.4.3 (Records and Audits).
- **1.11.** [\*\*\*]
- 1.12. "Briefing Book Event" means [\*\*\*].
- **1.13.** "Budget Dispute Officers" has the meaning set forth in Section 8.4.1 (Referral to Executive Officers).
- **1.14.** "Business Day" means a calendar day other than a Saturday, Sunday, or a bank or other public holiday in Boston, Massachusetts or San Diego, California in the United States, or Tokyo in Japan.
- **1.15.** "Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30, and December 31 of each Calendar Year.

1.16. "Calendar Year" means each successive period of twelve months commencing on January 1 and ending on December 31.

- **1.17.** "**cGMP**" means the then-current good manufacturing practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including those as set forth in FDA regulations in 21 C.F.R. Parts 210 and 211 and all applicable FDA rules, regulations, orders, and guidances, and the requirements with respect to current good manufacturing practices prescribed by the European Community under provisions of "The Rules Governing Medicinal Products in the European Community, Volume 4, Good Manufacturing Practices, Annex 13, Manufacture of Investigational Medicinal Products, July 2003," or as otherwise required by applicable Laws.
- **1.18.** "Change of Control" means, with respect to a Party, (a) a merger, consolidation, recapitalization, or reorganization of such Party with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies for purposes of management voting on matters as directed by beneficial owners) of the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to hold beneficial ownership of more than 50% of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger, consolidation, recapitalization, or reorganization, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than 50% of the combined voting power of the ransfer to a Third Party of all or substantially all of such Party's and its controlled Affiliates' assets. Notwithstanding the foregoing, any transaction or series of transactions effected for the purpose of financing the operations of the applicable Party or changing the form or jurisdiction of organization of such Party (such as an initial public offering or other offering of equity securities to non series or corporate reorganization) will not be deemed a "Change of Control" for purposes of this Agreement.
- **1.19.** "Clinical Trial" means any study in humans (including a non[interventional study) conducted to obtain information regarding a pharmaceutical or biologic product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging, or efficacy of such pharmaceutical or biologic product.
- 1.20. "CMO" means a contract manufacturing organization or a contract testing organization.
- **1.21.** "Co-Funded Commercialization Activities" has the meaning set forth in Section 6.1.1 (Co-Funded Commercialization Plan).
- 1.22. "Co-Funded Commercialization Budget" has the meaning set forth in Section 6.1.1 (Co-Funded Commercialization Plan).
- 1.23. "Co-Funded Commercialization Plan" has the meaning set forth in Section 6.1.1 (Co-Funded Commercialization Plan).
- **1.24.** "Co-Funded Development Activities" has the meaning set forth in Section 4.1.1 (Co-Funded Development Plan).
- **1.25.** "Co-Funded Development Budget" has the meaning set forth in Section 4.1.1 (Co-Funded Development Plan).

- **1.26.** "Co-Funded Development Plan" has the meaning set forth in Section 4.1.1 (Co-Funded Development Plan).
- 1.27. "Co-Funded Medical Affairs Activities" has the meaning set forth in Section 7.1 (Co-Funded Medical Affairs Plan).
- **1.28.** "Co-Funded Medical Affairs Budget" has the meaning set forth in Section 7.1 (Co-Funded Medical Affairs Plan).
- 1.29. "Co-Funded Medical Affairs Plan" has the meaning set forth in Section 7.1 (Co-Funded Medical Affairs Plan).
- **1.30.** [\*\*\*]
- **1.31.** "Code" means the Internal Revenue Code of 1986, as amended.
- **1.32.** "**Combination Product**" means a Licensed Product that is (a) sold in the form of a combination that contains or comprises one or more additional therapeutically active pharmaceutical agents (whether coformulated or copackaged or otherwise sold for a single price) other than a Licensed Asset; (b) sold for a single price together with any delivery device (each of the therapeutically active pharmaceutical agents in clause (a) and the delivery device in clause (b), an "**Other Component**"); or (c) defined as a "combination product" by the FDA pursuant to 21 C.F.R. §3.2(e) or its foreign equivalent, where such "combination product" is sold for a single price.
- **1.33.** "Commercialization" or "Commercialize" means any and all activities directed to the marketing, promotion, distribution matters, offering for sale, sale, having sold, importing, having imported, exporting, having exported or other commercialization of a pharmaceutical or biologic product (including pricing matters), but expressly excluding activities directed to Manufacturing, Development, or performance of Medical Affairs. "Commercialize," "Commercializing," and "Commercialized" will be construed accordingly.
- **1.34.** "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party or its Affiliates with respect to any objective or activity under this Agreement by a Party, those efforts and resources, including [\*\*\*], in each case, [\*\*\*], taking into account [\*\*\*]. [\*\*\*].
- **1.35.** "**Competitive Infringement**" means (a) the making, using, selling, offering for sale, importing, or exporting by a Third Party of a pharmaceutical or biologic product in a country that actually or potentially infringes a Valid Claim of a Takeda Patent Right or Program Patent Right in such country or (b) the filing of an ANDA under Section 505(j) of the FD&C Act or an application under Section 505(b)(2) of the FD&C Act naming a Licensed Product as a reference listed drug and including a certification under Section 505(j)(2)(A)(Vii)(IV) or 505(b)(2)(A)(IV), respectively.
- **1.36. "Confidential Information**" means (a) any and all confidential or proprietary information and data, including scientific, preclinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, unpublished patent applications and information related thereto and set forth therein, in each case, that is or has been provided by or on behalf of one Party to the other Party or its Affiliates in connection with this Agreement or any related negotiations, discussions, or diligence, whether communicated in writing or orally or by any other method, and (b) the terms of this Agreement. Notwithstanding the foregoing, "Confidential Information"

excludes any information that the receiving Party can show by competent evidence (i) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records; (ii) is known to the public before its receipt from the disclosing Party, or thereafter becomes generally known to the public through no breach of this Agreement by the receiving Party; (iii) is subsequently disclosed to the receiving Party without obligation of confidentiality by a Third Party who has rightfully obtained such information and who is not under an obligation of confidentiality or other contractual obligation with respect to such information; or (iv) is developed by the receiving Party independently of Confidential Information received from the disclosing Party, as documented by the receiving Party's business records.

- **1.37.** "**Control**" means the possession by a Party (whether by ownership, license, or otherwise), other than pursuant to this Agreement, of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, or (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property on the terms set forth herein, in each case ((a) and (b)), (i) without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense or (ii) with respect to Know-How or Patent Rights developed, acquired, or licensed by a Party after the Effective Date, without incurring any additional payment obligations to a Third Party that are not subject to an agreed allocation between the Parties. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "Control" any of the foregoing (a)-(b) that (1) [\*\*\*], (2) [\*\*\*], and (3) [\*\*\*].
- **1.38.** "**Cover**," "**Covering**," or "**Covered**" means, with respect to a particular subject matter at issue and a relevant Patent Right or individual claim in such Patent Right, as applicable, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in such Patent Right.
- **1.39.** [\*\*\*]
- 1.40. [\*\*\*]
- 1.41. [\*\*\*]
- 1.42. [\*\*\*]
- 1.43. "CRO" means a contract research organization.
- 1.44. "Data Read-Out" means, with respect to a Clinical Trial, [\*\*\*].
- **1.45.** "Defensive Patent Right" means any Patent Right set forth on Schedule 1.45 (Defensive Patent Rights) or claiming priority to any such Patent Right.

- **1.46.** "Develop" and "Development" means all internal and external research, discovery, development, and regulatory activities related to pharmaceutical or biologic products, including (a) research, non-clinical testing, toxicology, testing and studies, non-clinical and preclinical activities, and Clinical Trials, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biologic product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical or biologic product regarding the foregoing, but expressly excluding activities directed to Manufacturing, performance of Medical Affairs, or Commercialization. Development will include development and regulatory Approval of such product (including label expansion), including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved formulation or indication (such as observational studies, implementation and management of registries and analysis thereof, in each case, if required by any Regulatory Authority in any region in the Territory to support or maintain Regulatory Approval for a pharmaceutical or biologic product in such region). "Developing," and "Developed" will be construed accordingly.
- **1.47. "Disputes**" has the meaning set forth in Section 16.3.1 (Exclusive Dispute Resolution Mechanism).
- 1.48. "Dollars" or "\$" means the legal tender of the United States of America.
- **1.49.** "Effective Date" has the meaning set forth in Section 15.1 (Effective Date).
- **1.50.** "Eligible Commercialization Expenses" means, with respect to a Profit-Share Product and a period of the PSP P&L Share for such Profit-Share Product, all FTE Costs, Out-of-Pocket Costs, and other costs and expenses incurred by or on behalf of a Party or its Affiliates that are directly attributable to Commercialization activities for such Profit-Share Product in accordance with the applicable Co-Funded Commercialization Plan, including the following:
  - a. [\*\*\*]; and
  - b. [\*\*\*];
    - c. in each case, to the extent such costs are consistent with the applicable Co-Funded Commercialization Budget, *plus* applicable Allowable Overruns and [\*\*\*], but expressly excluding [\*\*\*].
    - d. Eligible Commercialization Expenses specifically exclude the cost of [\*\*\*].
    - e. If any FTE Cost, Out-of-Pocket Cost, or other cost or expense is specifically identifiable or reasonably allocable to more than one Commercialization cost category set forth above, then such cost or expense will only be counted once (*i.e.*, as an Eligible Commercialization Expense with respect to only one such category). No FTE Cost, Out-of-Pocket Cost, or other cost or expense included as an Eligible Commercialization

Expense will also be included as an Eligible Development Expense or an Eligible Medical Affairs Expense. Eligible Commercialization Expenses will be recognized and calculated in accordance with the applicable Accounting Standards.

- **1.51.** "Eligible Development Expenses" means, with respect to a Profit-Share Product and a period of the PSP P&L Share for such Profit-Share Product, all FTE Costs, Out-of-Pocket Costs, and other costs and expenses incurred by or on behalf of a Party or its Affiliates that are directly attributable to Development activities for such Profit-Share Product in accordance with the applicable Co-Funded Development Plan, including the following:
  - a. [\*\*\*];
  - b. [\*\*\*];
  - C. [\*\*\*];
  - d. [\*\*\*]; and
  - e. [\*\*\*];
    - f. in each case to the extent such costs are consistent with the applicable Co-Funded Development Budget, *plus* applicable Allowable Overruns and [\*\*\*], but expressly excluding [\*\*\*]. In addition, Eligible Development Expenses specifically *exclude* [\*\*\*].
    - g. If any FTE Cost, Out-of-Pocket Cost, or other cost or expense is specifically identifiable or reasonably allocable to more than one Development cost category above, then such cost or expense will only be counted once. No expense included as an Eligible Development Expense will also be included as an Eligible Commercialization Expense or an Eligible Medical Affairs Expense. Eligible Development Expenses will be recognized and calculated in accordance with the applicable Accounting Standards.
- **1.52.** "Eligible Medical Affairs Expenses" means, with respect to a Profit-Share Product and a period of the PSP P&L Share for such Profit-Share Product, all FTE Costs, Out-of-Pocket Costs, and other costs and expenses incurred by or on behalf of a Party or its Affiliates that are directly attributable to the Medical Affairs activities for the applicable Profit-Share Products in accordance with the Co-Funded Medical Affairs Plan and Co-Funded Medical Affairs Budget, *plus* applicable Allowable Overruns and [\*\*\*], but expressly excluding [\*\*\*]. Eligible Medical Affairs Expenses specifically *exclude* [\*\*\*]. No expense included as an Eligible Medical Affairs Expense or Eligible Commercialization Expense. Eligible Medical Affairs Expenses will be recognized and calculated in accordance with the applicable Accounting Standards.
- **1.53.** "Eligible Shared Expenses" means the Eligible Commercialization Expenses, Eligible Development Expenses, Eligible Medical Affairs Expenses, and Other Operating Expenses.
- **1.54.** "EU" means the European Union, as its membership may be constituted from time to time, and any successor thereto.
- **1.55. "Execution Date"** has the meaning set forth in the preamble.

7

- **1.56.** "Executive Officer" means, for Neurocrine, an executive officer, and for Takeda, its president-level officer of Research and Development or Commercialization, as applicable, or another senior executive officer or their respective designee with appropriate responsibilities, seniority, and decision-making authority; *provided* that any of the foregoing individuals may designate appropriate financial officers as his/her designee for financial related matters, which will be (a) for Neurocrine, the Vice President of Finance, and (b) for Takeda, (i) Director of Research and Development Finance, for any Development-related financial matters, and (ii) Head of Finance for the Neuroscience Business Unit, for any Commercialization-related financial matters or, in each case (a) and (b), his or her respective designee with appropriate responsibilities, seniority, and decision-making authority. If the position of any of the Executive Officers identified in this Section 1.56 (Executive Officer) no longer exists due to a Change of Control, corporate reorganization, corporate restructuring, or the like of a Party that results in the elimination of the identified position, then the applicable Party will replace the applicable Executive Officer with another executive officer with responsibilities and seniority comparable to the eliminated Executive Officer.
- **1.57.** "Exploit" or "Exploitation" means to make, have made, import, have imported, export, have exported, distribute, have distributed, use, have used, sell, have sold, offer for sale, or have offered for sale, including to Develop, Manufacture, Commercialize, and perform Medical Affairs activities.
- 1.58. "FD&C Act" means the United States Federal Food, Drug, and Cosmetic Act, as amended.
- **1.59. "FDA"** means the United States Food and Drug Administration or any successor Governmental Authority having substantially the same function.
- 1.60. "Field" means all fields of use.
- 1.61. "Finance Officer" has the meaning set forth in Schedule 9.2.1 (Profit and Loss Share).
- **1.62.** "First Commercial Sale" means, [\*\*\*].
- 1.63. "Force Majeure" has the meaning set forth in Section 16.12 (Force Majeure).
- **1.64. "FTE**" means the equivalent of a full-time person's work time, carried out by an appropriately qualified employee of a Party or its Affiliates, on the performance of Development, Manufacturing, Commercialization, or Medical Affairs activities, based on [\*\*\*] person-hours per year, pro-rated as necessary. Overtime, and work on weekends, holidays, and the like [\*\*\*].
- **1.65. "FTE Costs"** means, for any period, the FTE Rate multiplied by the number of FTEs in such period.
- **1.66. "FTE Rate**" means (a) for personnel other than those described in clause (b), \$[\*\*\*] per one full FTE per full 12-month Calendar Year, which rate includes all direct and indirect costs of the performing Party's FTE, including personnel and travel expenses, and (b) [\*\*\*]. Each such rate, [\*\*\*].
- **1.67.** "**GCP**" means the then-current good clinical practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including those as

set forth in FDA regulations in 21 C.F.R. Parts 11, 50, 54, 56, 312, 314, and 320 and all related FDA rules, regulations, orders, and guidances, and by the International Conference on Harmonization E6: Good Clinical Practices Consolidated Guideline (the "ICH Guidelines").

- **1.68.** "Generic Product" means with respect to a given Licensed Product in a given country in the Territory, a product that (a) (i) contains the same active pharmaceutical ingredient as such Licensed Product [\*\*\*] and is approved in reliance on a prior Regulatory Approval of such Licensed Product and (ii) is [\*\*\*], and (b) is sold or marketed for sale in such country by a Third Party that has not obtained the rights to market or sell such product as a Sublicensee, subcontractor, or Third Party Distributor of Neurocrine or any of its Affiliates, Sublicensees, or subcontractors with respect to such Licensed Product.
- **1.69.** "**GLP**" means the then-current good laboratory practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including those as set forth in FDA regulations in 21 C.F.R. Part 58 and all applicable FDA rules, regulations, orders, and guidances, and the requirements with respect to good laboratory practices prescribed by the European Community, the OECD (Organization for Economic Cooperation and Development Council) and the ICH Guidelines.
- **1.70.** "Governmental Authority" means any applicable government authority, court, council, tribunal, arbitrator, agency, department, bureau, branch, office, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city, or other political subdivision thereof, or (c) any supranational body.
- **1.71.** "Grantback IP" has the meaning set forth in Section 14.4.3 (Intellectual Property License to Takeda).
- **1.72.** "H-W Suit Notice" has the meaning set forth in Section 13.3.2(c) (Hatch-Waxman).
- **1.73. "Hatch-Waxman Act"** means rights conferred in the U.S. under the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. §355, as amended (or any successor statute or regulation).
- 1.74. "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules promulgated thereunder.
- 1.75. "ICH Guidelines" has the meaning set forth in Section 1.67 (GCP).
- **1.76. "IND**" means an Investigational New Drug Application (as defined in the FD&C Act), clinical trial application, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority anywhere in the world in conformance with the requirement of such Regulatory Authority, and any amendments thereto.
- **1.77. "IND Effective Date"** means, with respect to an IND for a Royalty-Bearing Product, (a) in the U.S., the date that is 30 days (or any different time period pursuant to a change in applicable Laws after the Effective Date) following the filing of such IND for such Royalty-Bearing Product, [\*\*\*]; *provided* that, [\*\*\*] (i) [\*\*\*], and (ii) [\*\*\*].
  - 9

- 1.78. "IND Transfer Date" has the meaning set forth in Section 5.2.1(a) (Clinical Trial Regulatory Submissions).
- **1.79.** "Indemnified Party" has the meaning set forth in Section 12.4.1 (Notice).
- **1.80.** "Indemnifying Party" has the meaning set forth in Section 12.4.1 (Notice).
- **1.81.** "**Initiation**" means, with respect to a Clinical Trial of a pharmaceutical or biologic product, the first dosing of the first human subject pursuant to the applicable protocol for such Clinical Trial.
- **1.82.** "Joint Program Know-How" means any and all Program Know-How made jointly by or on behalf of the Parties or their respective Affiliates.
- 1.83. "Joint Program Patent Rights" means the Program Patent Rights Covering any Joint Program Know-How.
- 1.84. "Joint Program Technology" means the Joint Program Know-How and Joint Program Patent Rights.
- **1.85.** "JSC" has the meaning set forth in Section 8.2.1 (Joint Steering Committee: Purpose; Formation).
- **1.86.** "Know-How" means all commercial, technical, scientific, and other know-how and information, inventions, discoveries, trade secrets, knowledge, technology, methods, processes, practices, formulae, amino acid sequences, nucleotide sequences, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and know-how, including regulatory data, study designs and protocols), and materials, in all cases, whether or not confidential, proprietary, patentable, in written, electronic or any other form now known or hereafter developed, but expressly excluding all Patent Rights.
- **1.87. "Knowledge**" means, with respect to Takeda, the actual knowledge of a fact or other matter, after reasonable inquiry of intellectual property counsel, of the applicable Global Program Leader for the applicable Licensed Asset, and the transition leader for the Licensed Assets.
- **1.88.** "Laws" means all applicable laws, statutes, rules, regulations, orders, judgments, injunctions, ordinances, codes, principles of common law, or other pronouncements having the binding effect of law of any Governmental Authority, including if either Party is or becomes subject to a legal obligation to a Regulatory Authority or other Governmental Authority (such as a corporate integrity agreement or settlement agreement with a Governmental Authority).
- **1.89.** "Licensed Asset" means any of the Phase I Assets, the Phase II Asset, and the Nonclinical Assets.
- **1.90.** "Licensed Product" means (a) any Profit-Share Product, (b) any Royalty-Bearing Product, and (c) any other pharmaceutical or biologic product comprising a Licensed Asset, either alone or as a Combination Product.
  - 10

- **1.91.** "Loss of Market Exclusivity" means an event where, with respect to any Royalty-Bearing Product in any country: (a) [\*\*\*]; and (b) [\*\*\*].
- **1.92.** "Losses" has the meaning set forth in Section 12.1 (Indemnification by Takeda).
- **1.93.** "LP Commercialization Report" has the meaning set forth in Section 6.3 (Licensed Products Commercialization Reporting).
- **1.94.** "LP Development Report" has the meaning set forth in Section 4.2.4 (Licensed Products Development Reports).
- **1.95.** "**MAA**" means any new drug application or other marketing authorization application, in each case, filed with the applicable Regulatory Authority in a country or other regulatory jurisdiction (and all supplements and amendments thereto), which application is required to commercially market or sell a pharmaceutical or biologic product in such country or jurisdiction, including all New Drug Applications submitted to the FDA in the United States in accordance with the FD&C Act with respect to a pharmaceutical product or any analogous application or submission with any Regulatory Authority in any other country or regulatory jurisdiction.
- **1.96.** "Major Market" means each of the U.S., Japan, the EU, and the United Kingdom.
- **1.97.** "**Manufacturing**" or "**Manufacture**" means activities directed to process, analytical and formulation development, manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, or storage of any pharmaceutical or biologic product (or any components or process steps involving any product or any companion diagnostics), placebo, or comparator agent, as the case may be, including process development, qualification, and validation, scale-up, preclinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but expressly excluding activities directed to Development, performance of Medical Affairs, or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.
- **1.98.** "**Manufacturing Costs**" means, with respect to the Profit-Share Products, the consolidated fully burdened Manufacturing costs in accordance with the applicable Accounting Standards, which will be the sum of:
  - a. [\*\*\*]; and
  - b. [\*\*\*].
- **1.99.** "**Medical Affairs**" means activities conducted by a Party's medical affairs departments (or, if a Party does not have a medical affairs department, the equivalent function thereof), including patient advocacy, medical science liaisons, medical directors, health economics and outcomes research, communications with key opinion leaders (including key opinion leader selection and management, health care professional and patient speakers programs), medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries and other medical programs and communications, including investigator sponsored studies, educational grants, research grants, and charitable donations to the extent related to medical affairs and not to other activities that are not conducted by a Party's medical affairs (or equivalent) departments.

- **1.100.** "NDA" means a New Drug Application, as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or any analogous application or submission with any Regulatory Authority outside of the U.S.
- **1.101.** "**Net Sales**" means with respect to a Licensed Product, the gross amount invoiced in a country by [\*\*\*] (each of the foregoing Persons, a "**Selling Party**") for the sale or other disposition of such Licensed Product in such country to Third Parties [\*\*\*], *less* the following deductions calculated in accordance with the applicable Accounting Standards, consistently applied throughout the Territory by the relevant Selling Party. [\*\*\*]:
  - a. [\*\*\*]
  - b. [\*\*\*]
  - C. [\*\*\*]
  - d. [\*\*\*]
  - e. [\*\*\*]
  - f. [\*\*\*]
  - g. [\*\*\*].
  - [\*\*\*].

Notwithstanding the foregoing, and subject to the remainder of this paragraph, [\*\*\*].

Net Sales will not include [\*\*\*].

In the case of any Combination Product sold in a given country in the Territory in any Calendar Year, Net Sales for the purpose of determining RBP Royalties and RBP Commercial Milestone Events of the Combination Product in such country will be calculated by multiplying actual Net Sales of such Combination Product in such country by the fraction A/(A+B), where A is the invoice price of the Licensed Asset included in such Combination Product if sold separately as a stand-alone product in such country during the same Calendar Year, and B is the total invoice price of the Other Components in the Combination Product, if sold separately in such country during the same Calendar Year.

If, on a country-by-country basis, the Licensed Asset included in such Combination Product is sold separately as a stand-alone product in a country during the same Calendar Year, but the Other Components in the Combination Product are not sold separately in such country during the same Calendar Year, then Net Sales for the purpose of determining RBP Royalties and RBP Commercial Milestone Events of the Combination Product for such country will be calculated by multiplying actual Net Sales of the Combination Product in such country by the fraction A/C, where A is the invoice price of the Licensed Asset if sold separately as a stand-alone product in such country during the same Calendar Year, and C is the invoice price of the Combination Product in such country during the applicable Calendar Quarter.

If, on a country-by-country basis, the Licensed Asset included in the Combination Product is not sold separately as a stand-alone product in such country during the same Calendar Year, but the Other Components included in the Combination Product are sold separately in such country during the same Calendar Year, then Net Sales for the purpose of determining RBP Royalties and RBP Commercial Milestone Events of the Combination Product for such country will be calculated by multiplying actual Net Sales of the Combination Product in such country by the fraction C-B/C, where B is the invoice price of the Other Components included in such Combination Product if sold separately in such country during the same Calendar Year, and C is the invoice price of the Combination Product in such country during the same Calendar Year, and C is the invoice price of the Combination Product in such country during the applicable Calendar Quarter.

If neither the Licensed Asset nor the Other Components included in the Combination Product are sold separately in a given country during the same Calendar Year, then Net Sales for the purpose of determining RBP Royalties and RBP Commercial Milestone Events in such country will be calculated [\*\*\*].

[\*\*\*].

1.102. "Neurocrine Prosecuted Patent Rights" has the meaning set forth in Section 13.2.1(a) (Neurocrine's Right).

- **1.103.** "Neurocrine Sole Program Patent Rights" means Program Patent Rights Covering inventions within the Program Know-How made solely by or on behalf of Neurocrine or its Affiliates.
- **1.104.** "New License Agreement" has the meaning set forth in Section 14.4.5 (New License Agreements).
- 1.105. "Nonclinical Asset" means:

a. (i) any Nonclinical Asset listed on Schedule 1.89 (Licensed Assets), (ii) any salt, hydrate, isotope, solvate, ester, free acid or base, polymorph, enantiomer, metabolite or prodrug of any compound in the preceding clause (i), and (iii) any isotope, ester, enantiomer, metabolite or prodrug of any Phase II Asset,

- b. (i) [\*\*\*] and
- c. [\*\*\*] (i) is a [\*\*\*] and (ii) [\*\*\*]
- **1.106.** "**Operating Profits or Losses**" means, for all Profit-Share Products, the profits or losses calculated in accordance with Schedule 9.2.1 (Profit and Loss Share).
- **1.107.** "Other Component" has the meaning set forth in Section 1.32 (Combination Product).

### **1.108.** "Other Operating Expenses" means [\*\*\*]:

- a. [\*\*\*]
- b. [\*\*\*]
- C. [\*\*\*]

- 1. [\*\*\*]
- 1. [\*\*\*]
- 2. [\*\*\*]

No expense included as an Eligible Development Expense, an Eligible Commercialization Expense, or an Eligible Medical Affairs Expense will also be included as an Other Operating Expense. Other Operating Expenses will be recognized and calculated in accordance with the applicable Accounting Standards.

- **1.109.** "Out-of-Pocket Costs" means, with respect to certain activities for a Profit-Share Product hereunder, [\*\*\*].
- 1.110. "Overhead Costs" means costs incurred by a Party or for its account that are attributable to the performing Party's [\*\*\*].
- 1.111. "Party" or "Parties" has the meaning set forth in the preamble.
- **1.112.** "**Patent Challenge**" means any challenge to the validity or enforceability of a Patent Right by commencing any opposition proceeding, post-grant review, *inter partes* review, or declaratory action, or any foreign equivalent thereof, in any court, arbitration proceeding, or other tribunal, including any Patent Office, but excluding (a) any reexamination, reissue or similar proceeding intended to improve the validity, enforceability or scope of a Patent Right, or (b) complying with any applicable Laws (including court order), including responding to compulsory discovery, subpoenas, or other requests for information in a judicial or arbitration proceeding.
- **1.113.** "Patent Costs" means [\*\*\*].
- 1.114. "Patent Offices" has the meaning set forth in Section 11.2.5 (Validity and Enforceability).
- **1.115.** "**Patent Right**" means any patent (including any utility or design patent) or patent application (including any provisional, utility, continued prosecution, continuation, continuations-in-part, divisional, or substitution application), or other filing claiming priority thereto or sharing any common priority therewith, whether directly or indirectly, as well as any patent that issues or has issued with respect to any such patent application, reissue, reexamination, renewal, or extension (including any patent term adjustment, patent term extension, or supplemental protection certificate, or the equivalent thereof), registration or confirmation patent, patent resulting from a post-grant proceeding, patent of addition, revalidation, restoration or extension thereof, or any inventor's certificate, utility model (including any petty patent, innovation patent, utility certificate, functional design, short-term patent, minor patent, or small patent), or any equivalent or counterpart thereof in any country or jurisdiction. For clarity, a patent filing (a patent or a patent application) is considered to have been made (or to be pending or in force) within a selected time period if the filing itself, or any other filing to which it claims priority or with which it shares any common priority, was made, within (or was pending, or in force within) the time period.
- **1.116.** "Payments" has the meaning set forth in Section 9.4.5(b) (Withholding Taxes).

- **1.117.** "**Person**" means any natural person, corporation, unincorporated organization, partnership, association, sole proprietorship, joint stock company, joint venture, limited liability company, trust or government, Governmental Authority, or any other similar entity.
- **1.118.** "**Phase I Asset**" means (a) any of the Phase I Assets listed on Schedule 1.89 (Licensed Assets) as of the Execution Date, and (b) any salt, hydrate, solvate, free acid or base, or polymorph of any compound in the preceding clause.
- **1.119. "Phase I Clinical Trial**" means a Clinical Trial (or any arm thereof) of an investigational product in subjects that satisfies the requirements of U.S. regulation 21 C.F.R. 312.21(a) and its successor regulation, or an equivalent Clinical Trial prescribed by the relevant Regulatory Authority in a country other than the United States.
- **1.120. "Phase I Opt-Out**" has the meaning set forth in Section 3.1.1 (Exercise of Opt-Out).
- **1.121.** "Phase I Opt-Out Date" has the meaning set forth in Section 3.1.1 (Exercise of Opt-Out).
- 1.122. "Phase I Opt-Out Right" has the meaning set forth in Section 3.1.1 (Exercise of Opt-Out).
- 1.123. "Phase I Profit-Share Product" has the meaning set forth in Section 3.1.1 (Exercise of Opt-Out).
- 1.124. "Phase I Royalty Product" has the meaning set forth in Section 3.1.1 (Exercise of Opt-Out).
- 1.125. "Phase Ib Product" has the meaning set forth in Section 4.1.2 (Phase II Asset Development).
- **1.126.** "**Phase II Asset**" means (a) any of the Phase II Assets listed on Schedule 1.89 (Licensed Assets) as of the Execution Date or (b) any salt, hydrate, solvate, free acid or base, or polymorph of any compound in the preceding clause.
- **1.127. "Phase II Clinical Trial**" means a Clinical Trial (or any arm thereof) of an investigational product that satisfies the requirements of U.S. federal regulation 21 C.F.R. § 312.21(b) and its successor regulation, or an equivalent Clinical Trial prescribed by the relevant Regulatory Authority in a country other than the United States.
- **1.128.** "**Phase II Expiration Date**" has the meaning set forth in Section 4.1.2 (Phase II Asset Development).
- **1.129.** "**Phase II Ongoing Activities**" means all Development activities in support of the clinical program for the Phase II Asset through the Phase II Ongoing Trials Data Read-Out, including the activities set forth on Schedule 4.2.3(d) (Phase II Ongoing Activities Plan and Budget).
- **1.130.** "**Phase II Ongoing Trials**" means the two clinical studies entitled (a) "A Study to Evaluate Efficacy, Tolerability, Pharmacodynamic and Pharmacokinetics of Multiple Oral Doses of TAK-831 in Adults with Schizophrenia" and (b) "A Study to Evaluate Efficacy, Safety, Tolerability, and Pharmacokinetics of 3 Dose Levels of TAK-831 in Adjunctive Treatment of Adult Participants with Negative Symptoms of Schizophrenia," in each case ((a) and (b)), being conducted by Takeda. Each such clinical study is separately a "**Phase II Ongoing Trial**."

- **1.131.** "**Phase II Ongoing Trials Data Read-Out**" means the Data Read-Out for each of the Phase II Ongoing Trials.
- **1.132.** "**Phase II Ongoing Trials Regulatory Submissions**" means all INDs, MAAs, and other Regulatory Submissions in the Territory Controlled by Takeda or any of its Affiliates related to the Phase II Ongoing Trials.
- 1.133. "Phase II Opt-In" has the meaning set forth in Section 3.2.1 (Exercise of Opt-In).
- 1.134. "Phase II Opt-In Date" has the meaning set forth in Section 3.2.1 (Exercise of Opt-In).
- 1.135. "Phase II Opt-In Right" has the meaning set forth in Section 3.2.1 (Exercise of Opt-In).
- 1.136. "Phase II Profit-Share Product" has the meaning set forth in Section 3.2.1 (Exercise of Opt-In).
- 1.137. "Phase II Royalty Product" has the meaning set forth in Section 3.2.1 (Exercise of Opt-In).
- **1.138.** "Phase II Supplemental Studies" has the meaning set forth in Section 4.1.2 (Phase II Asset Development).
- **1.139. "Phase III Clinical Trial**" means a Clinical Trial (or any arm thereof) of an investigational product on a sufficient number of patients that satisfies the requirements of U.S. federal regulation 21 C.F.R. § 312.21(c) and its successor regulation or an equivalent Clinical Trial prescribed by the relevant Regulatory Authority in a country other than the United States.
- **1.140.** "Potential PSP In-License Term Sheet" has the meaning set forth in Section 2.6.2 (Potential PSP In-Licenses by Neurocrine for Profit-Share Products).
- **1.141. "Pricing Approval"** means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical or biologic products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).
- 1.142. "Profit-Share Product" means (a) any Phase I Profit-Share Product or (b) the Phase II Profit-Share Product.
- **1.143.** "**Program Know-How**" means any Know-How generated during the Term by or on behalf of a Party, any of its Affiliates or Sublicensees, either alone or jointly, in the performance of activities relating to the Exploitation of Licensed Products under this Agreement.
- **1.144.** "**Program Patent Rights**" means any Patent Right that (a) has a priority date after the Effective Date, and (b) Covers any Program Know-How.
- **1.145.** "**Prosecution and Maintenance**" or "**Prosecute and Maintain**" means, with regard to a particular Patent Right, the preparation, filing, prosecution (including any oppositions, interferences, reissue proceedings, reexaminations, post-grant proceedings, supplemental examinations, post grant review proceedings, *inter partes* review proceedings, patent interference proceedings, opposition proceedings, reissue and reexamination,

maintenance (including paying maintenance fees and annuities) and defense) of such Patent Right.

- 1.146. "PSP In-License" has the meaning set forth in Section 2.6.1 (PSP In-Licenses).
- **1.147.** "**PSP P&L Share**" means the Parties' equal sharing of the Operating Profits or Losses for Profit-Share Products pursuant to Section 9.2.1 (Profit and Loss Share).
- 1.148. "RBP Annual Ex-US Net Sales" has the meaning set forth in Section 9.2.3 (Royalty-Bearing Product Royalties).
- 1.149. "RBP Annual Net Sales" means the RBP Annual US Net Sales and the RBP Annual Ex-US Net Sales.
- 1.150. "RBP Annual US Net Sales" has the meaning set forth in Section 9.2.3 (Royalty-Bearing Product Royalties).
- **1.151.** "**RBP Commercial Milestone Event**" has the meaning set forth in Section 9.2.2(b) (Royalty-Bearing Product Commercial Milestones).
- **1.152.** "**RBP Commercial Milestone Payment**" has the meaning set forth in Section 9.2.2(b) (Royalty-Bearing Product Commercial Milestones).
- **1.153.** "**RBP Development Milestone Event**" has the meaning set forth in Section 9.2.2(a) (Royalty-Bearing Product Development Milestones).
- **1.154.** "**RBP Development Milestone Payment**" has the meaning set forth in Section 9.2.2(a) (Royalty-Bearing Product Development Milestones).
- 1.155. "RBP Ex-US Royalty" has the meaning set forth in Section 9.2.3 (Royalty-Bearing Product Royalties).
- 1.156. "RBP Milestone Events" has the meaning set forth in Section 9.2.2(b) (Royalty-Bearing Product Commercial Milestones).
- 1.157. "RBP Milestone Payments" has the meaning set forth in Section 9.2.2(b) (Royalty-Bearing Product Commercial Milestones).
- 1.158. "RBP Royalty" means any RBP US Royalty and any RBP Ex-US Royalty.
- 1.159. [\*\*\*]
- 1.160. [\*\*\*]
- 1.161. [\*\*\*]
- 1.162. [\*\*\*]
- 1.163. [\*\*\*]

- 1.164. "RBP US Royalty" has the meaning set forth in Section 9.2.3 (Royalty-Bearing Product Royalties).
- **1.165.** "Redacted Agreement" has the meaning set forth in Section 10.1.3(b) (Confidential Treatment).
- **1.166.** "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any approval of a MAA or other approval, product, or establishment license, registration, or authorization of any Regulatory Authority necessary for the commercial marketing or sale of a pharmaceutical or biologic product in such country or other regulatory jurisdiction, excluding, in each case, Pricing Approval.
- **1.167.** "**Regulatory Authority**" means any Governmental Authority responsible for granting Regulatory Approvals of pharmaceutical or biologic products.
- **1.168.** "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Licensed Product in a country or jurisdiction in the Territory, other than a Patent Right, that prohibits a Person from (a) relying on safety or efficacy data generated by or on behalf of a Party with respect to such Licensed Product in an application for Regulatory Approval of an Generic Product, or (b) Commercializing a Licensed Product or a Generic Product, including pediatric exclusivity (as set forth in Section 505(A) of the FD&C Act), orphan drug exclusivity, rights conferred in the U.S. under the Hatch-Waxman Act, or rights similar thereto in other countries or regulatory jurisdictions.
- 1.169. "Regulatory Lead" means:
  - a. Takeda, for the Phase II Asset until the IND Transfer Date; and
  - b. Neurocrine, (i) for the Phase II Asset on and after the IND Transfer Date, and (ii) for all other Licensed Products from and after the Effective Date.
- **1.170.** "**Regulatory Submissions**" means any regulatory application, submission, notification, communication, correspondence, registration, Regulatory Approval, or other filing made to, received from or otherwise conducted with a Regulatory Authority related to Developing, Manufacturing, or obtaining marketing authorization for a pharmaceutical or biologic product in a particular country or jurisdiction.
- **1.171.** "**Royalty Patent Rights**" means, collectively, with respect to a Royalty-Bearing Product, any and all Takeda Patent Rights, Defensive Patent Rights, or Joint Program Patent Rights that have any Valid Claim(s) Covering such Royalty-Bearing Product.
- **1.172.** "**Royalty Rates**" means the applicable royalty rate set forth in Table 9.2.3(a) (Royalty-Bearing Product Royalty Payments (US)) or Table 9.2.3(b) (Royalty-Bearing Product Royalty Payments (Ex-US)).
- 1.173. "Royalty Report" has the meaning set forth in Section 9.4.2 (Reports and Royalty Payments).
- **1.174.** "**Royalty Term**" means, with respect to a Royalty-Bearing Product and a country in the Territory, the period extending from the First Commercial Sale of such Royalty-Bearing Product in such country until the latest of (a) expiration of the last Valid Claim of the last-to-expire Royalty Patent Right Covering such Royalty-Bearing Product in such country, (b) [\*\*\*] years

after the First Commercial Sale of such Royalty-Bearing Product in such country, or (c) expiration of all Regulatory Exclusivities for such Royalty-Bearing Product in such country.

- 1.175. "Royalty-Bearing Product" means any Phase II Royalty Product, Phase I Royalty Product, Phase Ib Product, or Nonclinical Asset.
- **1.176.** "Safety Concern" means, with respect to any Licensed Product, (a) any safety concern required to be reported under 21 C.F.R. § 312.32 ("IND Safety Reporting") if an IND with respect to such Licensed Product was open at the time of the observation (or that would be so reportable if an IND was not open at such time), or (b) a toxicity or drug safety issue or a Serious Adverse Event reasonably related to or observed in connection with Development or Commercialization activities with respect to a Licensed Product.
- **1.177.** "Safety or Recall Response Event" has the meaning set forth in Section 12.2.4 (Indemnification by Neurocrine).
- **1.178.** "Sales and Marketing Costs" means, for a Profit-Share Product, the FTE Costs and Out-of-Pocket Costs incurred by or on behalf of a Party or its Affiliates that are [\*\*\*].
- 1.179. "Sales Force Expenses" means[\*\*\*].
- 1.180. "SEC" has the meaning set forth in Section 10.1.2 (Permitted Disclosures).
- **1.181.** "Selling Party" has the meaning set forth in Section 1.101 (Net Sales).
- **1.182.** "Serious Adverse Event" means an adverse drug experience or circumstance, whether or not considered drug related, that results in any of the following outcomes (a) death, (b) life threatening condition, (c) inpatient hospitalization or a prolongation of existing hospitalization, (d) persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions, (e) a congenital anomaly/birth defect, (f) significant intervention required to prevent permanent impairment or damage, or (g) a medical event that may not result in death, be life threatening, or require hospitalization but, based on appropriate medical judgment, that may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes described in clauses (a) through (f).
- **1.183.** "**Subcontractor**" means a Third Party contractor engaged by Neurocrine or its Affiliate to perform certain obligations or exercise certain rights of a Party under this Agreement (including all Third Party Distributors, contract research organizations, clinical research organizations or CMOs), but excluding all Sublicensees.
- **1.184.** "Sublicense Revenue" means revenue recognized by [\*\*\*].
- **1.185.** "**Sublicensee**" means a Third Party to which Neurocrine or its Affiliate has granted or grants a sublicense, option to sublicense or similar right under the Takeda Technology to Exploit any Licensed Product, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights), beyond the mere right to purchase any Licensed Product from or to provide services on behalf of Neurocrine or its Affiliates, but expressly excluding CMOs, CROs, and contract sales forces.
- **1.186.** "**Takeda**" has the meaning set forth in the preamble.

- **1.187.** "Takeda Indemnitees" has the meaning set forth in Section 12.2 (Indemnification by Neurocrine).
- **1.188.** "**Takeda Know-How**" means Know-How, other than Joint Program Know-How, Controlled by Takeda or its Affiliates as of the Effective Date or during the Term that (a) is necessary to Exploit any Licensed Product (excluding any active pharmaceutical ingredient therein that is not a Licensed Asset) in the Field in the Territory, (b) is reasonably useful to Exploit one or more Licensed Products in the Field in the Territory, but, in the case of this clause (b), excluding any Know-How that was [\*\*\*], or (ii) to the extent related to any active pharmaceutical ingredient Controlled by Takeda or any of its Affiliates that is not a Licensed Asset, or (c) is described on Schedule 1.188 (Takeda Know-How). For clarity, Takeda Know-How includes Program Know-How owned solely by Takeda.
- **1.189. "Takeda Patent Right**" means any Patent Right, other than any Joint Program Patent Right or Defensive Patent Right, Controlled by Takeda or its Affiliates as of the Effective Date or during the Term that (a) is necessary to Exploit any Licensed Product (excluding any active pharmaceutical ingredient therein that is not a Licensed Asset) in the Field in the Territory, or (b) is reasonably useful to Exploit one or more Licensed Products in the Field in the Territory, but, in the case of this clause (b), excluding any Patent Right that was [\*\*\*], or (ii) to the extent related to any active pharmaceutical ingredient Controlled by Takeda or any of its Affiliates that is not a Licensed Asset. The Takeda Patent Rights as of the Execution Date are set forth on Schedule 11.2.1 (Takeda Patent Rights). For clarity, Takeda Patent Rights includes Program Patent Rights owned solely by Takeda.
- **1.190. "Takeda Technology**" means, collectively, (a) the Takeda Patent Rights, (b) the Defensive Patent Rights, (c) the Takeda Know-How, and (d) Takeda's interest in the Joint Program Technology.
- **1.191.** "**Target Class**" means the group of all Licensed Products the mechanism of action of which is one of the following (in the case of Licensed Assets identified on Schedule 1.89 (Licensed Assets), as identified on such schedule as of the Execution Date): (a) a DAAO inhibitor, (b) an AMPA potentiator, (c) a GPR139 agonist, (d) [\*\*\*], or (e) [\*\*\*].
- **1.192.** "**Tax**" and "**Taxation**" means any U.S. and non-U.S. federal, state, local, regional, municipal, or other tax or taxation, levy, duty, charge, withholding, or other assessment of any kind (including any related fine, penalty, addition to tax, surcharge, or interest) imposed by, or payable to, a Governmental Authority, including sales, use, excise, stamp, transfer, property, value added, goods and services, withholding, and franchise taxes.
- 1.193. "Term" has the meaning set forth in Section 14.1 (Term).
- **1.194.** "**Terminated Product**" means any Licensed Product for which this Agreement has been terminated in accordance with Article 14 (Term and Termination), in the form that each such Licensed Product exists as of the date of notice of such termination, and any improvements, modifications, or enhancements thereof. All Licensed Products in the same Target Class will be deemed Terminated Products if this Agreement is terminated with respect to such Target Class. All Licensed Products will be deemed Terminated Products if this Agreement is terminated in its entirety.

- **1.195.** "**Terminated Target Class**" means any Target Class for which this Agreement has been terminated in accordance with Article 14 (Term and Termination). All Target Classes will be deemed Terminated Target Classes if this Agreement is terminated in its entirety.
- **1.196.** "**Terminated Territory**" means, on a Target Class-by-Target Class basis, those countries with respect to which this Agreement has been terminated in accordance with Article 14 (Term and Termination) in relation to such Target Class. The Terminated Territory will be worldwide if this Agreement is terminated in its entirety.
- **1.197.** "**Territory**" means worldwide, but excluding, with respect to any Licensed Product, any then-current Terminated Territory for such Licensed Product.
- 1.198. "Third Party" means any Person other than Takeda, Neurocrine, or their respective Affiliates.
- **1.199.** "**Third Party Distributor**" means, with respect to a country, any Third Party that purchases Licensed Products in such country from the Selling Party or its Affiliates and is appointed as a distributor to distribute, market, and resell such Licensed Product in such country, even if such Third Party is granted ancillary sublicensed rights under the Takeda Technology to package, distribute, market, or sell such Licensed Product in such country.
- 1.200. "Third Party Payment" has the meaning set forth in Section 2.6 (In-Licenses).
- **1.201.** "**Trademark**" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.
- **1.202.** "**Trigger Event**" means, with regard to any matter involving any activity for one or more Profit-Share Products to be performed under any Co-Funded Development Plan, Co-Funded Commercialization Plan, or Co-Funded Medical Affairs Plan prior to the Initiation of the first Phase III Clinical Trial for the applicable Profit Share Product(s), if [\*\*\*].
- 1.203. "Trigger Event Activity" means [\*\*\*]
- 1.204. "Trigger Event Opt-Out" has the meaning set forth in Section 3.3 (Trigger Event Opt-Out).
- 1.205. "Trigger Event Opt-Out Effective Date" has the meaning set forth in Section 3.3 (Takeda Right to Opt-Out of Profit Sharing).
- **1.206.** "United States" or "U.S." means the United States and its territories, possessions and commonwealths.
- **1.207.** "Valid Claim" means: (a) a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension or the like) that has not been revoked, held invalid, or unenforceable by a Patent Office or other Governmental Authority of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and which claim has not been disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, or disclaimer or otherwise; or (b) a pending claim of an unissued, pending patent application, which application has not been pending for the longer of (i) [\*\*\*] since [\*\*\*] or (ii) [\*\*\*] from the date of [\*\*\*].

**1.208.** "VAT" means, within the EU, such Tax as may be charged in accordance with (but subject to derogations from) Directive 2006/112/EC and, outside the EU, value added Tax or any form of consumption Tax, as well as all other forms of Taxes charged on the supply of a good or a service, including sales Tax and goods and services Tax.

**1.209.** [\*\*\*]

# 2. LICENSE GRANT

- 2.1. License Grant to Neurocrine. Subject to the terms and conditions of this Agreement, during the Term, Takeda hereby grants to Neurocrine an exclusive (even as to Takeda and its Affiliates, except as set forth in Section 2.8 (No Other Rights and Retained Rights)), non-transferable (except as provided in Section 16.1 (Assignment)), sublicensable (solely as provided in Section 2.2 (Sublicensing Terms)) license in the Field and in the Territory under the Takeda Technology to Exploit the Licensed Products.
- **2.2. Sublicensing Terms**. Subject to the terms and conditions of [\*\*\*], Neurocrine may grant sublicenses (through multiple tiers of sublicense) in accordance with the terms of this Section 2.2 (Sublicensing Terms).

### 2.2.1. Neurocrine Sublicensing Rights.

- a. **Profit-Share Products.** Subject to the requirements of this Section 2.2 (Sublicensing Terms), Section 2.3 (Subcontractors), and [\*\*\*], with respect to any Profit-Share Product, Neurocrine may grant sublicenses under the rights granted to it under Section 2.1 (License Grant to Neurocrine) [\*\*\*].
- b. **Royalty-Bearing Products**. Subject to the requirements of this Section 2.2 (Sublicensing Terms) and [\*\*\*], with respect to any Royalty-Bearing Product, Neurocrine will have the right to grant sublicenses under the rights granted to it under Section 2.1 (License Grant to Neurocrine) [\*\*\*].
- Sublicensing Agreements. Each sublicense granted by Neurocrine pursuant to this Section 2.2 (Sublicensing Terms) will be 222 subject and subordinate to the applicable terms of this Agreement. Any such sublicense (a) will be consistent with the terms of this Agreement, including intellectual property terms and confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement, and (b) to the extent Neurocrine engages a Sublicensee to Commercialize a Licensed Product, include an obligation of such Sublicensee to account for and report its Net Sales (in local currency and Dollars) on a country-by-country and Licensed Product-by-Licensed Product basis and any other information necessary for Neurocrine to comply with its obligation to provide Royalty Reports in accordance with Section 9.4.2 (Reports and Royalty Payments). In addition, unless agreed otherwise by the JSC, Neurocrine will include in each agreement under which it grants a sublicense an obligation of the Sublicensee to assign or grant a sublicensable license to Neurocrine, upon termination of such agreement or with respect to any territory that is not within the scope of the sublicense, of all Know-How generated by the Sublicensee and all Patent Rights owned or controlled by such Sublicensee Covering any such Know-How, in each case, that are necessary to Exploit any Licensed Product subject to such agreement. Neurocrine will provide Takeda with a written notice of any sublicense granted by Neurocrine or its Affiliates pursuant to this Section 2.2 (Sublicensing Terms) to any Third Party no later than [\*\*\*] after the effective date thereof and will provide Takeda with a copy of each Third Party sublicense agreement, from which copy Neurocrine may redact any confidential information that is not necessary for Takeda to confirm compliance with the terms of this Agreement.

- **2.2.3.** Liability of Neurocrine. Notwithstanding any sublicense, Neurocrine will remain primarily liable to Takeda for the performance of all of its obligations under, and Neurocrine's compliance with all provisions of, this Agreement, and for the performance of all obligations of its Affiliates and Sublicensees as required under this Agreement.
- 2.3. Subcontractors. Neurocrine may perform any of its obligations under this Agreement through one or more subcontractors, [\*\*\*], *provided* that: (a) Neurocrine will not engage any subcontractor that has been debarred by any Regulatory Authority, (b) Neurocrine remains fully responsible for the work allocated to, and payment to, such subcontractors to the same extent it would be if Neurocrine had done such work itself, (c) the subcontractor undertakes in writing obligations of confidentiality and non-use applicable to the Confidential Information that are at least as stringent as those set forth in Article 10 (Confidentiality and Publication), (d) unless agreed otherwise by the JSC, the subcontractor agrees in writing to assign or grant a sublicensable license (or in the case of a subcontractor that is an academic or nonprofit institution, a right to negotiate a license) to Neurocrine to all Know-How generated by the subcontractor and all Patent Rights owned or controlled by the subcontractor Covering any such Know-How, in each case, that are necessary to Exploit any Licensed Product, but excluding [\*\*\*], and (e) Neurocrine will be liable for any act or omission of any subcontractor that is a breach of any of Neurocrine's obligations under this Agreement as though the same were a breach by Neurocrine, and Takeda will have the right to proceed directly against Neurocrine without any obligation to first proceed against such subcontractor. Neurocrine will be solely responsible for the direction of and communications with each such subcontractor engaged by Neurocrine, and Neurocrine will provide Takeda, through the JSC, with updates regarding such activities performed by its subcontractors under this Agreement as part of its reports under Section 4.2.4 (Licensed Products Development Reports).

## 2.4. [\*\*\*]

2.4.1 [\*\*\*]

2.4.2 [\*\*\*]

- 2.5. [\*\*\*]
- **2.6. In-Licenses**. The Parties agree that all upfront, milestone, royalty, and other payments to any Third Party in respect of any PSP In-License will be deemed a **"Third Party Payment"** and subject to this Section 2.6 (In-Licenses).
  - **2.6.1. PSP In-Licenses**. Subject to Section 2.6.2 (Potential PSP In-Licenses by Neurocrine for Profit-Share Products), Neurocrine may enter into any agreement for rights (whether by acquisition or license) under any Patent Rights or Know-How Controlled by a Third Party for the specific purpose of Exploiting any Profit-Share Product (a **"PSP In-License"**). [\*\*\*]
  - **2.6.2. Potential PSP In-Licenses by Neurocrine for Profit-Share Products.** Only with respect to the Exploitation of any Profit-Share Product, prior to entering into any potential PSP In-License, Neurocrine will present the proposed material terms of such potential PSP In-License (the "**Potential PSP In-License Term Sheet**") to the JSC to review, discuss, and determine whether to approve such terms. The JSC will have [\*\*\*] to determine whether to approve (a) [\*\*\*], or (b) any other Potential PSP In-License

Term Sheet. If the JSC so approves a Potential PSP In-License Term Sheet, then Neurocrine may enter into such agreement on terms substantially consistent with such terms approved by the JSC in the applicable Potential PSP In-License Term Sheet and such agreement will be a PSP In-License. If, within the applicable [\*\*\*] period, the JSC does not approve a Potential PSP In-License Term Sheet, then any such potential PSP In-License will not be a PSP In-License for purposes of this Agreement unless and until the JSC approves a revised version of such Potential PSP In-License Term Sheet or except as otherwise approved in accordance with this Section 2.6.2 (Potential PSP In-Licenses by Neurocrine for Profit-Share Products). [\*\*\*].

- **2.6.3.** Non-Approved Potential PSP In-Licenses. Except as provided in the last two sentences of Section 2.6.2 (Potential PSP In-Licenses by Neurocrine for Profit-Share Products) with respect to [\*\*\*], if the JSC does not approve a Potential PSP In-License Term Sheet for a potential PSP In-License, then such potential PSP In-License will not be a PSP In-License hereunder. Neurocrine will have the right, but not the obligation, to negotiate a license from such Third Party under the Patent Rights or Know-How that are subject to such non-approved potential PSP In-License for a Profit-Share Product at its sole cost and discretion.
- **2.6.4. Copies of PSP In-Licenses.** Neurocrine agrees, upon Takeda's reasonable request, to provide Takeda with copies of PSP In-Licenses to which Neurocrine is a party, *provided* that Confidential Information of Neurocrine or confidential information of its counterparty may be redacted from such copies, except to the extent that such information is required in order to enable Takeda to comply with its obligations to Neurocrine under this Agreement with respect to such PSP In-License or to verify economic terms thereunder.

# 2.6.5. PSP In-License Payments. [\*\*\*]

- 2.7. Knowledge and Technology Transfer. Subject to Section 5.2 (Assignment of Regulatory Submissions), (a) within [\*\*\*] after the Effective Date, Takeda will deliver to Neurocrine copies of the written Takeda Know-How that are available in the site hosted for purposes of this Agreement on Intralinks as of the Effective Date, and (b) within [\*\*\*] after the Effective Date, Takeda will deliver to Neurocrine (i) copies of all other written Takeda Know-How not previously provided pursuant to clause (a) and (ii) that supply of Licensed Products held in inventory by Takeda in accordance with the timeline set forth on Schedule 2.7 (Transferred Inventory), other than any such inventory relating to the Phase II Asset, which will be transferred promptly after the IND Transfer Date or otherwise in accordance with the timeline set forth on Schedule 2.7 (Transferred Inventory). Thereafter, if requested by Neurocrine during the Term, Takeda will promptly disclose to Neurocrine all additional Takeda Know-How in existence as of the Effective Date or that comes into existence as a result of performance by or behalf of Takeda of activities under this Agreement and not previously transferred to Neurocrine. Takeda will provide any assistance as reasonably requested by Neurocrine in connection with its Exploitation of the Takeda Know-How in accordance with this Agreement for a period up to [\*\*\*] after the date on which Takeda delivers to Neurocrine such Takeda Know-How and inventory of Licensed Products. [\*\*\*], and Neurocrine will pay the undisputed invoiced amounts within [\*\*\*] after the date of such invoice. Notwithstanding any provision to the contrary set forth in this Agreement, after the initial [\*\*\*] FTE hours, Takeda will not be obligated to provide any additional assistance under this Section 2.8 (Knowledge and Technology Transfer) and Section 5.2.1(a) (Clinical Trial
  - 25

Regulatory Submissions) beyond that which can be provided in accordance with the amounts included in the budget agreed by the Parties (as such budget may be updated from time to time by agreement of the Parties).

- 2.8. No Other Rights and Retained Rights. Except as otherwise expressly provided in this Agreement, under no circumstances will a Party or any of its Affiliates, as a result of this Agreement, obtain any ownership interest, license, or other right in or to any Know-How, Patent Rights, or other intellectual property of the other Party, including tangible or intangible items owned, controlled, or developed by the other Party, or provided by the other Party to the receiving Party at any time, pursuant to this Agreement. Neurocrine will not, and will cause its Affiliates and Sublicensee to not, use or practice any Takeda Technology outside the scope of or otherwise not in compliance with the rights and licenses granted to Neurocrine Under this Agreement. Takeda will not, and will cause its Affiliates and licenses granted to Takeda under Section 14.4(Effects of Termination). Any rights not expressly granted by a Party under this Agreement are hereby retained by such Party. [\*\*\*].
- **2.9.** License to Takeda. Subject to the terms and conditions of this Agreement, Neurocrine hereby grants to Takeda and its Affiliates a non-exclusive, non-transferable, non-sublicensable license under the Neurocrine Sole Program Patent Rights and any Program Know-How owned solely by Neurocrine, [\*\*\*].

## 3. PROFIT AND LOSS SHARE OPTIONS

#### 3.1. Takeda's Phase I Asset Opt-Out Right.

- **3.1.1.** Exercise of Opt-Out. On a Phase I Asset-by-Phase I Asset basis, Takeda may elect to opt-out of the PSP P&L Share set forth in Section 9.2.1(a) (Profit and Loss Share before Takeda's Phase I Opt-Out) with respect to a Phase I Asset in accordance with this Section 3.1 (Takeda's Phase I Asset Opt-Out Right) (a "Phase I Opt-Out," and each such right to opt out, a "Phase I Opt-Out Right"). Takeda may elect to exercise the Phase I Opt-Out Right with respect to a Phase I Asset no later than [\*\*\*] following the Data Read-Out of the second Phase II Clinical Trial [\*\*\*] for such Phase I Asset, by providing written notice to Neurocrine prior to the expiration of such [\*\*\*] period for the applicable Phase I Asset. The date on which Takeda exercises the Phase I Opt-Out Right with respect to a Phase I Opt-Out Right with respect to a Phase I Asset, by providing will be deemed the "Phase I Opt-Out Date" with respect to such Phase I Asset. Prior to Takeda's exercise of the Phase I Opt-Out Right with respect to a Phase I Asset, the applicable Phase I Asset. Prior to Takeda's exercise of the Phase I Opt-Out Right with respect to a Phase I Asset, the applicable Phase I Asset, such Phase I Profit-Share Product," and after Takeda exercises the Phase I Opt-Out Right for such Phase I Asset, such Phase I Asset will no long be a Phase I Profit-Share Product but will instead be deemed a "Phase I Royalty Product."
- **3.1.2.** Effect of Phase I Asset Opt-Out. If Takeda exercises the Phase I Opt-Out Right pursuant to Section 3.1.1 (Exercise of Opt-Out) resulting in a Phase I Royalty Product, then from and after the applicable Phase I Opt-Out Date, with respect to such Phase I Royalty Product, (a) [\*\*\*], (b) [\*\*\*] Neurocrine will be solely responsible for any and all costs and expenses incurred in connection with the Exploitation of such Phase I Royalty Product, (c) [\*\*\*] Takeda will not have any funding obligations under any Co-Funded Development Plan, Co-Funded Commercialization Plan, or Co-Funded Medical Affairs
  - 26

Plan, or any rights or obligations pursuant to Section 9.2.1 (Profit and Loss Share), (d) Neurocrine will pay Takeda the applicable RBP Milestone Payments pursuant to Section 9.2.2 (Royalty-Bearing Product Milestone Payments) and the applicable RBP Royalties pursuant to Section 9.2.3 (Royalty-Bearing Product Royalties), and (e) the Parties will otherwise have the rights and obligations with respect to such Phase I Royalty Product as set forth in this Agreement.

### 3.2. Takeda's Phase II Asset Opt-In Right.

- **3.2.1.** Exercise of Opt-In. Takeda may elect to opt-in to the PSP P&L Share set forth in Section 9.2.1(d) (Profit and Loss Share after Takeda's Phase II Opt-In) with respect to the Phase II Asset throughout the Territory pursuant to the terms of this Section 3.2.1 (Exercise of Opt-In) (the "Phase II Opt-In," and such right to opt in, the "Phase II Opt-In Right"). If Takeda elected to co-fund the Phase II Supplemental Studies pursuant to Section 4.1.2 (Phase II Asset Development), if applicable, or if no Phase II Supplemental Studies were conducted, then Takeda may elect to exercise the Phase II Opt-In Right within [\*\*\*] following the Briefing Book Event by providing written notice of such election to Neurocrine within such [\*\*\*] period. The date on which Takeda exercises its Phase II Opt-In Right as set forth in this Section 3.2.1 (Exercise of Opt-In) will be deemed the "Phase II Opt-In Date." Prior to Takeda's exercise of the Phase II Opt-In Right, the Phase II Asset is deemed a "Phase II Royalty Product," and after Takeda exercises the Phase II Opt-In Right, such Phase II Asset will be deemed a "Phase II Profit-Share Product."
- **3.2.2.** Effect of Phase II Asset Opt-In. If Takeda exercises its Phase II Opt-In Right pursuant to Section 3.2.1 (Exercise of Opt-In) resulting in a Phase II Profit-Share Product, then (a) [\*\*\*] and (b) from and after the Phase II Opt-In Date, with respect to such Phase II Profit-Share Product, (i) Takeda will have the funding obligations under any Co-Funded Development Plan, Co-Funded Commercialization Plan, and Co-Funded Medical Affairs Plan and the rights and obligations pursuant to Section 9.2.1(d) (Profit and Loss Share after Takeda's Phase II Opt-In) with respect to the Phase II Profit-Share Product throughout the Territory, (ii) Neurocrine will not have any obligations to make payments pursuant to Section 9.2.2 (Royalty-Bearing Product Milestone Payments) and Section 9.2.3 (Royalty-Bearing Product Royalties), and (iii) the Parties will otherwise have the rights and obligations with respect to such Phase II Profit-Share Product as set forth in this Agreement. Notwithstanding anything to the contrary herein, [\*\*\*].
- **3.3. Takeda Right to Opt-Out of Profit Sharing**. In the event of a Trigger Event for one or more Profit Share Products, Takeda may, upon written notice to Neurocrine to be provided within [\*\*\*] days after [\*\*\*] that results in the Trigger Event for such Profit Share Product(s), elect to opt-out of the PSP P&L Share with respect to such Profit-Share Products with respect to which the Trigger Event relates (the "**Trigger Event Opt-Out**")[\*\*\*] (the "**Trigger Event Opt-Out Effective Date**")]. Notwithstanding any other provision to the contrary set forth in this Agreement, from and after the Trigger Event Opt-Out Effective Date, (a) for all purposes of this Agreement (including under Section 12.2.3 (Indemnification by Neurocrine)), any Profit-Share Product that was the subject of the Trigger Event Activity (i) that was a Phase I Profit-Share Product will no longer be a Phase I Profit-Share Product and will instead be a Phase II Royalty Product, (b) Neurocrine will be solely responsible
  - 27

for any and all costs and expenses incurred in connection with the Exploitation of such Royalty-Bearing Products, (c) Takeda will not have any funding obligations under any Co-Funded Development Plan, Co-Funded Commercialization Plan, or Co-Funded Medical Affairs Plan, or any rights or obligations pursuant to Section 9.2.1 (Profit and Loss Share), with respect to such Royalty-Bearing Products, and (d) Neurocrine will pay Takeda the applicable RBP Milestone Payments pursuant to Section 9.2.2 (Royalty-Bearing Product Milestone Payments) and the applicable RBP Royalties pursuant to Section 9.2.3 (Royalty-Bearing Product Royalties) with respect to such Royalty-Bearing Products only to the extent arising after the effective date for the Trigger Event Opt-Out.

## 4. DEVELOPMENT

#### 4.1. Development Program of Certain Licensed Products.

4.1.1. Co-Funded Development Plan. A preliminary development plan for all activities to be conducted by Neurocrine with respect to the Development of the Phase I Assets until completion of Phase II Clinical Trials is attached hereto as Schedule 4.1.1 (Preliminary Co-Funded Development Plan), and within [\*\*\*] after the Effective Date, Neurocrine will prepare a detailed plan based on such preliminary plan and submit such plan to the JSC to review, discuss, and determine whether to approve such plan. The development plan for the Phase I Assets and, solely in the case that the Phase II Asset becomes a Profit-Share Product, the Phase II Asset, as may be updated by the Parties from time to time, is referred to as the "Co-Funded Development Plan," and the Development activities described in the Co-Funded Development Plan are referred to as the "Co-Funded Development Activities." The Co-Funded Development Plan will include: (a) [\*\*\*] (b) [\*\*\*] (c) [\*\*\*] (d) [\*\*\*] (e) a detailed written budget, on an activity-by-activity basis, of expected FTE Costs, Out-of-Pocket Costs, and other costs and expenses within Eligible Shared Expenses for all activities under the Co-Funded Development Plan on a Calendar Year-by-Calendar Year basis for the subsequent [\*\*\*] Calendar Years, including a Calendar Quarter forecast for the first [\*\*\*] Calendar Quarters and an aggregate forecast for the final [\*\*\*] Calendar Quarters, which will include [\*\*\*] (as may be updated by the Parties from time to time, the "Co-Funded Development Budget"). The Co-Funded Development Budget must also include, [\*\*\*]. The Co-Funded Development Plan and Co-Funded Development Budget will initially also include the plan and budget for the Phase II Ongoing Activities attached hereto as Schedule 4.2.3(d) (Phase II Ongoing Activities Plan and Budget). Neurocrine, through the JSC, will propose updates to the Co-Funded Development Plan on an annual basis, and will prepare (i) a proposed Co-Funded Development Budget for the subsequent [\*\*\*] Calendar Years no later than December of the then-current Calendar Year and (ii) no later than June of the following Calendar Year, an updated proposed Co-Funded Development Budget for the same [\*\*\*]-Calendar Year period. In addition, Neurocrine may update the Co-Funded Development Plan and the Co-Funded Development Budget as necessary, including to add the Phase II Supplemental Studies, if applicable, and upon Takeda's exercise of the Phase II Opt-In Right to add the Phase II Assets. The JSC will review, discuss, and determine whether to approve the Co-Funded Development Plan, including the [\*\*\*] Calendar Year of the Co-Funded Development Budget, and each annual update and any other such update that is material.

#### 4.1.2. Phase II Asset Development.

- a. Takeda will be solely responsible for conducting the Phase II Ongoing Trials and all associated Phase II Ongoing Activities. [\*\*\*]. Any Clinical Trial with respect to the Phase II Asset that Neurocrine chooses to initiate prior to the Phase II Opt-In Date will be conducted at Neurocrine's sole cost and expense, and no such study will be a Phase II Supplemental Study.
- b. If the Phase II Ongoing Trials are[\*\*\*], then Takeda will have the option to fund, on an equal basis (50:50) with Neurocrine, any additional Phase II Clinical Trials that are necessary to advance the Phase II Asset to Phase III Clinical Trials (such trials, the "Phase II Supplemental Studies") by providing written notice to Neurocrine of its election to fund such additional Phase II Clinical Trials within [\*\*\*] after [\*\*\*]. Upon receipt of notice of such election, Neurocrine will prepare an update to the Co-Funded Development Plan and Co-Funded Development Budget to include such Phase II Supplemental Studies and submit such plan to the JSC to review, discuss, and determine whether to approve such updated plan. If Takeda elects to fund such Phase II Supplemental Studies on an equal basis (50:50) with Neurocrine, then the Phase II Asset will remain classified as a Phase II Royalty Product, subject to Takeda's Phase II Opt-In Right as set forth in Section 3.2.1 (Exercise of Opt-In). If Takeda does not elect to fund such Phase II Supplemental Studies, but the Briefing Book Event occurs within [\*\*\*] after Takeda's receipt of the tables, figures, and listings for both of the Phase II Ongoing Trials (the "Phase II Expiration Date"), then the Phase II Asset will remain classified as a Phase II Royalty Product, but Takeda will not have a Phase II Opt-In Right with respect to such Phase II Royalty Product. If (a) Takeda does not elect to fund the Phase II Supplemental Studies and the Briefing Book Event does not occur within [\*\*\*] after the Phase II Expiration Date, or (b) the Phase II Asset, in the JSC's determination, fails in either of the Phase II Ongoing Trials, due to efficacy or safety, then in either case ((a) or (b)), the Phase II Asset will be reclassified as a "Phase Ib Product" and will be subject to the RBP Milestone Payments set forth in Section 9.2.2 (Royalty-Bearing Product Milestone Payments) and the RBP Royalties set forth in Section 9.2.3 (Royalty-Bearing Product Royalties). In any event, Neurocrine will use Commercially Reasonable Efforts to achieve the Briefing Book Event.
- c. Notwithstanding the foregoing, should the TAK-2002 study as outlined in Schedule 4.2.3(d) (Reimbursement for Phase II Ongoing Trials) [\*\*\*], Neurocrine shall have the right to terminate such study. In such event, the preceding Section 4.1.2(b) (Phase II Asset Development) will apply, except that (i) the JSC will make its determination based on the terminated TAK-2002 study, and (ii) if Takeda elects to co-fund the Phase II Supplemental Studies, then [\*\*\*].
  - 29

## 4.2. Development Diligence Obligations.

- **4.2.1.** Neurocrine Development Diligence Obligations. Neurocrine will use Commercially Reasonable Efforts to Develop and seek Regulatory Approval and, as applicable, Pricing Approval for (a) at least one Licensed Product that comprises a Phase I Asset and at least one Licensed Product that comprises a Phase II Asset, in each case, in each of the Major Markets and (b) at least one Licensed Product that comprises a Nonclinical Asset in the [\*\*\*] Target Class and at least one Licensed Product that comprises a Nonclinical Asset in the [\*\*\*] Target Class, in each case, in at least one Major Market. In addition, Neurocrine will use Commercially Reasonable Efforts to perform the Co-Funded Development Activities under the Co-Funded Development Plan.
- **4.2.2. Takeda Development Diligence Obligations**. Takeda will use Commercially Reasonable Efforts to conduct the Phase II Ongoing Trials and all associated Phase II Ongoing Activities in accordance with the plan set forth in Schedule 4.2.3(d) (Phase II Ongoing Activities Plan and Budget) and the protocols for such trials as in existence as of the Execution Date or as may be amended by written agreement of the Parties as required by a Regulatory Authority.

## 4.2.3. Development and Manufacturing Expenses.

- a. **Phase I Assets**. Unless and until Takeda exercises the Phase I Opt-Out Right in accordance with Section 3.1 (Takeda's Phase I Asset Opt-Out Right) with respect to a Phase I Asset, the Parties will share the Eligible Development Expenses incurred for such Phase I Profit-Share Product as set forth in Section 9.2.1 (Profit and Loss Share). Upon Takeda's exercise of the Phase I Opt-Out Right with respect to a Phase I Asset, Neurocrine will be solely responsible for all ongoing costs and expenses associated with further Exploitation of such Phase I Royalty Product and incurred after the applicable Phase I Opt-Out Date, except for the [\*\*\*].
- b. **Phase II Assets**. Prior to Takeda's exercise of the Phase II Opt-In Right in accordance with Section 3.2 (Takeda's Phase II Asset Opt-In Right), Neurocrine will be solely responsible for all costs and expenses associated with the Development of the Phase II Royalty Products, subject to Section 4.2.3(d) (Reimbursement for Phase II Ongoing Trials) with respect to Phase II Ongoing Trials, other than [\*\*\*]. Upon Takeda's exercise of the Phase II Opt-In Right, the Parties will share the Eligible Development Expenses incurred for the Phase II Profit-Share Product as set forth in Section 3.2.2 (Effect of Phase II Asset Opt-In) and Section 9.2.1 (Profit and Loss Share).
- c. **Nonclinical Assets**. Neurocrine will be solely responsible for all costs and expenses associated with the Development of all Nonclinical Assets.
- d. **Reimbursement for Phase II Ongoing Trials.** Starting from the Effective Date, after the end of each Calendar Quarter, Takeda will submit an invoice to Neurocrine for all costs and expenses incurred by Takeda in the preceding Calendar Quarter in connection with the conduct of the Phase II Ongoing Activities in accordance with the plan and budget attached hereto as Schedule
  - 30

4.2.3(d) (Phase II Ongoing Activities Plan and Budget), *plus* [\*\*\*], *plus* [\*\*\*]. Neurocrine will pay the undisputed portion of such invoiced amount to Takeda no later than [\*\*\*] after its receipt of such invoice. In the event of any disagreement with respect to the calculation of payments owed, Neurocrine will pay any undisputed portion of such payment in accordance with the foregoing timetable and will pay the remaining, disputed portion within [\*\*\*] after the date on which the Parties, using good faith efforts, resolve the Dispute, which Dispute, at the request of either Party, will be resolved in accordance with Section 16.3 (Dispute Resolution) of the Agreement. Takeda will bear all costs and expenses incurred by Takeda in connection with the conduct of the Phase II Ongoing Activities that exceed the amount equal to [\*\*\*].

- **4.2.4.** Licensed Products Development Reports. Neurocrine will keep the JSC informed regarding the progress of the Development of the Licensed Products. In addition, Neurocrine will provide to the JSC reasonably in advance of each meeting of the JSC a report (by means of a slide presentation or otherwise) summarizing results and, (a) for the Profit-Share Products, describing progress made against timelines in the Co-Funded Development Plan, and Co-Funded Development Activities planned to be undertaken for the Profit-Share Products (including, for example, updates regarding regulatory matters and Co-Funded Development Activities for the next Calendar Quarter), and (b) for each Licensed Product, a reasonable summary of results, information, and data generated from Clinical Trials for such Licensed Product, and updates regarding intellectual property issues (each such report, a "LP Development Report"). Neurocrine will promptly share with Takeda all other material developments and information that it comes to possess relating to the Development of the Licensed Products, including any additional information regarding the Development of the Licensed Products reasonably requested by Takeda through the JSC from time to time to the extent and in the form readily available to Neurocrine and able to be disclosed to Takeda. All such reports and information will be the Confidential Information of Neurocrine, and subject to the terms of Article 10 (Confidentiality and Publication).
- **4.3. Neurocrine Development Responsibilities.** For each Licensed Product, except as otherwise agreed by the Parties in writing, Neurocrine will be principally responsible for performing all Development of such product, including preparing Clinical Trial designs and protocols, sponsoring Clinical Trials, engaging CROs, and being primarily responsible for managing activities at Clinical Trial sites.
- **4.4. Scientific Records**. Takeda (with respect to the Phase II Ongoing Activities) and Neurocrine (with respect to all other Development activities hereunder) will maintain scientific records in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with GLP, cGMP, and GCP with respect to activities intended to be submitted in regulatory filings (including INDs), all of which records will fully and accurately reflect all work done and results achieved in the performance of the Development activities and Clinical Trials by or on behalf of such Party with respect to Licensed Products.

# 5. REGULATORY MATTERS

**5.1. Regulatory Responsibilities**. Subject to Section 5.2 (Assignment of Regulatory Submissions), Neurocrine (itself or through its Affiliate or Sublicensee) will be solely responsible as the

Regulatory Lead for all regulatory matters in the Territory relating to the Licensed Products. Subject to Section 5.2 (Assignment of Regulatory Submissions), Neurocrine (itself or through its Affiliate or Sublicensee) will own all INDs, MAA, Regulatory Approvals, other Regulatory Submissions, and related regulatory documents, in the Territory with respect to such Licensed Products (in each case, as applicable).

## 5.2. Assignment of Regulatory Submissions.

## 5.2.1. Phase II Asset Clinical Trial Regulatory Submissions.

- a. Clinical Trial Regulatory Submissions. Takeda will remain the Regulatory Lead for the Phase II Ongoing Trials until the IND Transfer Date. Within [\*\*\*] after the Phase II Ongoing Trials Data Read-Out for both of the Phase II Ongoing Trials, Takeda will transfer and assign to Neurocrine all rights, title, sponsorship, and interests in and to the Phase II Ongoing Trials Regulatory Submissions and assist Neurocrine with such transfer and assignment. The date of such transfer will be the "IND Transfer Date." Neurocrine will take over as Regulatory Lead for the Phase II Asset on the IND Transfer Date. Prior to or on the IND Transfer Date, Takeda will submit written notification to the FDA informing it of the transfer of the Phase II Ongoing Trials Regulatory Submissions from Takeda to Neurocrine. Takeda will provide reasonable assistance from Takeda's FTEs at no cost to Neurocrine as set forth in Section 2.8 (Knowledge and Technology Transfer), and Neurocrine will thereafter be responsible and reimburse Takeda for all documented FTE Costs at the FTE Rate and expenses associated with such assistance, to the extent consistent with a detailed budget agreed by the Parties in advance of Takeda's commencing any particular assistance, and accordingly, Takeda may invoice Neurocrine for the FTE Costs and expenses, in each case, incurred in accordance with such budget in connection with providing such assistance, and Neurocrine will pay the undisputed invoiced amounts within [\*\*\*] after the date of such invoice. Notwithstanding any provision to the contrary set forth in this Agreement, after the initial [\*\*\*] FTE hours, Takeda will not be obligated to provide any additional assistance under this Section 5.2.1(a) (Clinical Trial Regulatory Submissions) or Section 2.8 (Knowledge and Technology Transfer) beyond that which can be provided in accordance with the amounts included in the budget agreed by the Parties (as such budget may be updated from time to time by agreement of the Parties).
- b. **Other Assigned Regulatory Submissions**. Promptly after the IND Transfer Date, Takeda will transfer or otherwise make available to Neurocrine copies (in electronic or other format) of other Regulatory Approvals or Regulatory Submissions in the Territory Controlled by Takeda or its Affiliates as of the IND Transfer Date and not transferred to Neurocrine prior to the IND Transfer Date pursuant to Section 5.2.1(a) (Clinical Trial Regulatory Submissions), to the extent such materials specifically relate to the Phase II Asset. No later than [\*\*\*] after the completion of all transition activities set forth in this Section 5.2.1(b) (Other Assigned Regulatory Submissions), Takeda will send a letter to each applicable Regulatory Authority to record and notify such Regulatory Authority of the transfer to Neurocrine of all Regulatory Approvals and Regulatory Submissions for the Phase II Asset.

- c. **Clinical Trial Data**. In connection with the transfer of Regulatory Submissions provided for in this Section 5.2.1 (Phase II Asset Clinical Trial Regulatory Submissions), Takeda will provide to Neurocrine separate copies (in electronic or other format) of the study reports Controlled by Takeda or its Affiliates and underlying data (to the extent not previously provided to Neurocrine) from the Phase II Ongoing Activities.
- **5.2.2. Other Regulatory Submissions**. For each Phase I Asset, (a) within [\*\*\*] after the Effective Date, Takeda will transfer and assign to Neurocrine all of Takeda's rights, title, and interests in and to all INDs, MAAs, and other Regulatory Approvals or Regulatory Submissions in the Territory for such Phase I Asset Controlled by Takeda or its Affiliates; (b) the Parties will complete all other transition activities of such transition to Neurocrine of the Regulatory Lead within [\*\*\*] after the Effective Date; and (c) no later than [\*\*\*] after the completion of all transition activities set forth in the foregoing clause (b), Takeda will send a letter to each Regulatory Authority as applicable to a specific country or jurisdiction to record and notify such Regulatory Authority of the transfer to Neurocrine of all Regulatory Approvals and Regulatory Submissions for such Phase I Asset in such country or jurisdiction. [\*\*\*].
- **5.2.3. Cooperation**. Subject to the terms and conditions of this Agreement, within a reasonable time following Neurocrine's request, Takeda will execute and deliver, or will cause to be executed and delivered, to Neurocrine such endorsements, assignments, and other documents as may be reasonably necessary to assign, convey, transfer, and deliver to Neurocrine all of Takeda's rights, title, and interests in and to the Assigned Regulatory Submissions. Schedule 5.2.3 (Regulatory Submissions Dates) sets forth upcoming dates of Regulatory Submission for each of the Licensed Assets as of the Execution Date.

## 5.3. Regulatory Submissions, Study Reports and Data not Controlled by Takeda. [\*\*\*].

- 5.4. Neurocrine Obligations. Neurocrine will provide Takeda, through the JSC at least once every [\*\*\*] Calendar Quarters, with written notice of each of the following events with regard to each Licensed Product for which Neurocrine is the Regulatory Lead: (a) to the extent notice was not previously provided, the submission of any filings or applications for Regulatory Approval of such Licensed Products in the Territory to any Regulatory Authority; and (b) (i) all Regulatory Submissions (as well as orphan drug applications and designations) that were filed for any Licensed Products during such preceding Calendar Quarter and (ii) a summary of all Regulatory Submissions anticipated to be filed for any Licensed Products within the upcoming [\*\*\*] Calendar Quarters, in each case ((i) and (ii)), which will be provided electronically; *provided, however*, that Neurocrine will inform Takeda of such event under (a) or (b) prior to public disclosure of such event by Neurocrine.
- **5.5. Costs of Regulatory Affairs.** Except as otherwise expressly provided in this Article 5 (Regulatory Matters), (a) during the period of a PSP P&L Share for a Profit-Share Product, the Parties will share the applicable Eligible Development Expenses associated with obtaining and maintaining Regulatory Approval in the Territory, and related regulatory affairs activities as set forth in this Article 5 (Regulatory Matters) for such Profit-Share Product in accordance with Section 9.2.1 (Profit and Loss Share) and (b) outside the period of a PSP P&L Share, for a Royalty-Bearing Product, Neurocrine will bear all such costs and expenses for such Royalty-Bearing Product, except as otherwise expressly set forth in this Agreement.
  - 33

#### 6. COMMERCIALIZATION

#### 6.1. Commercialization of the Licensed Products.

- Co-Funded Commercialization Plan. No later than [\*\*\*] after the Initiation of the first Phase III Clinical Trial for each 6.1.1. Profit-Share Product, Neurocrine will prepare a reasonably detailed plan for Commercialization of Profit-Share Products in the Territory (as may be updated from time to time, a "Co-Funded Commercialization Plan," and the Commercialization activities described in the Co-Funded Commercialization Plan, the "Co-Funded Commercialization Activities") and submit such plan to the JSC to review, discuss, and determine whether to approve such plan. The Co-Funded Commercialization Plan will include: (a) [\*\*\*] (b) [\*\*\*] (c) a detailed written budget, on an activity-by-activity basis, of the expected FTE Costs, Out-of-Pocket Costs, and other costs and expenses within Eligible Shared Expenses for the Commercialization activities under the Co-Funded Commercialization Plan on a Calendar Year-by-Calendar Year basis in the subsequent [\*\*\*] Calendar Years, including a Calendar Quarter forecast for the first [\*\*\*] Calendar Quarters and an aggregate forecast for the final [\*\*\*] Calendar Quarters, which will include [\*\*\*] (as may be updated by the Parties from time to time, the "Co-Funded Commercialization Budget"). The Co-Funded Commercialization Budget must also include, [\*\*\*] Neurocrine, through the JSC, will propose updates to the Co-Funded Commercialization Plan on an annual basis, and will prepare (i) a proposed Co-Funded Commercialization Budget for the subsequent [\*\*\*] Calendar Years no later than December of the then-current Calendar Year and (ii) no later than June of the following Calendar Year, an updated proposed Co-Funded Development Budget for the same [\*\*\*]-Calendar Year period. In addition, Neurocrine may update the Co-Funded Development Plan as necessary. The JSC will review, discuss, and determine whether to approve the Co-Funded Commercialization Plan, including the [\*\*\*] Calendar Year of the Co-Funded Commercialization Budget, and each annual update and any other such update that is material.
- **6.1.2. Preliminary Co-Funded Commercialization Plan**. Notwithstanding Section 6.1.1 (Co-Funded Commercialization Plan), at any time prior to Neurocrine's preparation of a reasonably detailed Co-Funded Commercialization Plan for a Profit-Share Product pursuant to Section 6.1.1 (Co-Funded Commercialization Plan), Neurocrine may prepare a preliminary Co-Funded Commercialization Plan, describing [\*\*\*]. Such plan and budget will otherwise be subject to Section 6.1.1 (Co-Funded Commercialization Plan) and all other terms of this Agreement applicable to the Co-Funded Commercialization Plan and Co-Funded Commercialization Budget, and will be updated by Neurocrine to a more detailed plan and budget at an appropriate time in accordance with Section 6.1.1 (Co-Funded Commercialization Plan).
- **6.2. Commercialization Diligence Obligations**. Neurocrine will use Commercially Reasonable Efforts to perform the Co-Funded Commercialization Activities under the Co-Funded Commercialization Plan and to otherwise Commercialize each Licensed Product in each jurisdiction in which such Licensed Product receives Regulatory Approval and, if applicable, Pricing Approval.
- **6.3.** Licensed Products Commercialization Reporting. Commencing upon the First Commercial Sale of the first Licensed Product in the Territory and for so long as Neurocrine continues to

Commercialize any Licensed Product, Neurocrine will keep the JSC informed regarding the progress and results of Commercialization activities for all Licensed Products. Accordingly, Neurocrine will provide to the JSC, at least once per Calendar Year, a report (by means of a slide presentation or otherwise) summarizing results and key Commercialization activities undertaken and planned to be undertaken for the Licensed Products in each Major Market (including, for example, updates regarding regulatory matters and Commercialization activities for the next Calendar Quarter), and updates regarding intellectual property issues (each such report, a "LP Commercialization Report"). Neurocrine will promptly share with Takeda all other material developments and information that it comes to possess relating to the Commercialization of the Licensed Products reasonably requested by Takeda through the JSC from time to time to the extent and in the form readily available to Neurocrine and able to be disclosed to Takeda.

## 6.4. Licensed Products Commercialization Expenses.

- **6.4.1. Profit-Share Products**. The Parties will share the Eligible Commercialization Expenses for all Profit-Share Products as set forth in Section 9.2.1 (Profit and Loss Share).
- **6.4.2. Royalty-Bearing Products**. Neurocrine will be solely responsible for all costs and expenses relating to the Commercialization of all Royalty-Bearing Products.
- **6.5. Recalls, Market Withdrawals, or Corrective Actions**. Neurocrine will have the sole right to decide whether to conduct any recall or other similar market withdrawal or other action for any Licensed Product, and the manner in which any such recall will be conducted (including any such recall requested by a Regulatory Authority). During the period of a PSP P&L Share for a Profit-Share Product, the Parties will share the applicable expenses incurred pursuant to this Section 6.5 (Recalls, Market Withdrawals, or Corrective Actions) for such Profit-Share Product in accordance with Section 9.2.1 (Profit and Loss Share) and outside the period of a PSP P&L Share, for a Royalty-Bearing Product, Neurocrine will bear all such costs and expenses for such Royalty-Bearing Product, subject to Article 12 (Indemnification; Limitation of Liability; Insurance).

## 7. MEDICAL AFFAIRS

7.1. Co-Funded Medical Affairs Plan. No later than [\*\*\*] after the Initiation of the first Phase III Clinical Trial for each Profit-Share Product, Neurocrine will prepare a reasonably detailed plan for the Medical Affairs for Profit-Share Products in the Territory (as may be updated from time to time, the "Co-Funded Medical Affairs Plan," and all activities set forth under the Co-Funded Medical Affairs Plan, the "Co-Funded Medical Affairs Activities"), consider Takeda's reasonable comments with respect to such Co-Funded Medical Affairs Plan for a Profit-Share Product will contain (a) [\*\*\*] (b) [\*\*\*] (c) a written budget, on an activity-by-activity basis, of the expected FTE Costs and Out-of-Pocket Costs for all activities under the Co-Funded Medical Affairs Plan on a Calendar Year-by-Calendar Year basis for the subsequent [\*\*\*] Calendar Years, including a Calendar Quarter forecast for the first [\*\*\*] Calendar Quarters and an aggregate forecast for the final [\*\*\*] Calendar Quarters, which will include [\*\*\*] (as may be updated by the Parties from time to time, the "Co-Funded Medical Affairs Budget"). The Co-Funded Medical Affairs Budget must also include, [\*\*\*]. The JSC will have the right to comment on each such Co-Funded Medical Affairs Plan and each material update thereto, including annual updates, and Neurocrine will consider such comments in good faith and

incorporate such comments when appropriate prior to finalizing each such Co-Funded Medical Affairs Plan (or any update thereto). The JSC will review, discuss, and determine whether to approve the Co-Funded Medical Affairs Plan and the [\*\*\*] Calendar Year of Co-Funded Medical Affairs Budget and each update thereto that is material. Notwithstanding the foregoing, Neurocrine may, at any time prior to Neurocrine's preparation of a reasonably detailed Co-Funded Medical Affairs Plan for a Profit-Share Product, prepare a preliminary Co-Funded Medical Affairs Plan, describing only activities to be conducted prior to Initiation of a Phase III Clinical Trial for such Profit-Share Product, and a Co-Funded Medical Affairs Budget for such activities. Such plan and budget will otherwise be subject to the foregoing in this Section 7.1 (Co-Funded Medical Affairs Plan) and all other terms of this Agreement applicable to the Co-Funded Medical Affairs Plan and Co-Funded Medical Affairs Budget, and will be updated by Neurocrine to a more detailed plan and budget at an appropriate time in accordance with this Section 7.1 (Co-Funded Medical Affairs Plan).

**7.2. Medical Affairs Reports.** Within [\*\*\*] following the end of each Calendar Year after the first Regulatory Approval for a Profit-Share Product in the Territory, Neurocrine will provide to the JSC a report (by means of a slide presentation or otherwise) summarizing the Co-Funded Medical Affairs Activities since the prior report provided to the JSC. Such reports will be the Confidential Information of Neurocrine, and subject to the terms of Article 10 (Confidentiality and Publication).

### 7.3. Profit-Share Products Medical Affairs Expenses.

- **7.3.1. Profit-Share Products**. The Parties will share the Eligible Medical Affairs Expenses for all Profit-Share Products as set forth in Section 9.2.1 (Profit and Loss Share).
- **7.3.2. Royalty-Bearing Products**. Neurocrine will be solely responsible for all costs and expenses relating to the Medical Affairs activities of all Royalty-Bearing Products.

### 8. GOVERNANCE

- 8.1. Alliance Manager. Promptly following the Effective Date each Party will designate an individual to facilitate communication and coordination of the Parties' activities under this Agreement relating to the Licensed Products and to provide support and guidance to the JSC, including preparing agendas, meeting materials, and meeting minutes for JSC meetings (each, an "Alliance Manager"). Each Alliance Manager may, but is not required to, serve as a representative of its respective Party on the JSC, but the Alliance Managers or suitable designees will attend all meetings of the JSC. The Alliance Managers may bring to the attention of the JSC any matters or issues either of them reasonably believes should be discussed by the JSC. Each Party may replace its Alliance Manager at any time by written notice to the other Party. The Alliance Managers will be responsible for creating and maintaining a constructive work environment between the Parties. Without limiting the generality of the foregoing, the Alliance Managers will: (a) identify and timely bring to the attention of the JSC occur as set forth in this Agreement, that procedures are followed with respect to such meetings (including the giving of proper notice and the preparation and approval of minutes) and that relevant action items resulting from such
  - 36

meetings are appropriately carried out or otherwise addressed; and (d) undertake such other responsibilities as the Parties may mutually agree in writing.

# 8.2. Joint Steering Committee.

- **8.2.1. Purpose; Formation**. Within [\*\*\*] after the Effective Date, the Parties will establish a joint steering committee (the "JSC") that will monitor and provide strategic oversight of the activities under this Agreement and facilitate communication between the Parties, in each case, with respect to the Development of all Licensed Products and Commercialization of the Profit-Share Products, all in accordance with the terms of this Agreement. The JSC will disband upon the later of (a) [\*\*\*] (b) [\*\*\*]; *provided* that if, following the disbandment of the JSC pursuant to this Section 8.2.1 (Purpose; Formation), Neurocrine thereafter commences any additional Exploitation of any Licensed Product, then the JSC will be reinstated.
- **8.2.2. Composition**. Each Party will initially appoint [\*\*\*] representatives to the JSC, with each representative having knowledge and expertise in the Exploitation of assets and products similar to the Licensed Products, and having sufficient seniority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JSC's responsibilities. The JSC may change its size from time to time by unanimous consent of the Parties, *provided* that, unless otherwise agreed by the Parties in writing, the JSC will consist at all times of an equal number of representatives of each Party. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members to participate in the discussions and meetings of the JSC, but such participants will have no voting authority at the JSC and must be bound under written obligations of confidentiality no less protective of the Parties' Confidential Information than those set forth in this Agreement. The Alliance Managers will prepare and circulate agendas and ensure the preparation and approval of minutes.
- **8.2.3. Responsibilities of JSC**. In addition to its overall responsibility for monitoring and providing strategic oversight with respect to the Parties' activities with respect to the Development of all Licensed Products and Commercialization of the Profit-Share Products under this Agreement, the JSC will have the following responsibilities:
  - a. Review, discuss, and determine whether to approve the Co-Funded Development Plan (including the first Calendar Year of the Co-Funded Development Budget), the Co-Funded Commercialization Plan (including the first Calendar Year of the Co-Funded Commercialization Budget), and the Co-Funded Medical Affairs Plan (including the first Calendar Year of the Co-Funded Medical Affairs Budget), and review, discuss and approve [\*\*\*];
  - b. [\*\*\*];
  - C. [\*\*\*];
  - d. review, discuss, and determine whether to approve any proposed material amendments to the Co-Funded Development Plan (including annual updates to the Co-Funded Development Budget), as described in Section 4.1.1 (Co-Funded Development Plan);
    - 37

- e. review, discuss, and determine whether to approve any Potential PSP In-License Term Sheet, as described in Section 2.6.2 (Potential PSP In-Licenses by Neurocrine for Profit-Share Products);
- f. review, discuss, and determine the outcomes of the Phase II Ongoing Trials, as described in Section 4.1.2 (Phase II Asset Development);
- g. review, discuss, and determine whether to approve the parameters relating to [\*\*\*];
- h. review, discuss, and determine whether to approve [\*\*\*];
- i. review, discuss, and determine the appropriate course of action in the event of a safety signal with respect to a Profit Share Product or a recall decision by any Regulatory Authority with respect to a Profit Share Product;
- j. review, discuss, and determine whether to approve any proposed material amendments to the Co-Funded Commercialization Plan (including annual updates to the Co-Funded Commercialization Budget), as described in Section 6.1.1 (Co-Funded Commercialization Plan);
- k. discuss the exchange rate that Neurocrine intends to use in its financial reporting in accordance with Neurocrine's Accounting Standards, as described in Section 9.4.4 (Currency Exchange);
- 1. determine whether to approve any sublicense agreement in which the potential Sublicensee does not agree to assign or grant a sublicensable license to Neurocrine upon termination of such agreement or with respect to any territory that is not within the scope of the sublicense of all Know-How generated by the Sublicensee and all Patent Rights owned or controlled by such Sublicensee Covering any such Know-How, in each case, that are necessary to Exploit any Licensed Product subject to such agreement, as described in Section 2.2.2 (Sublicensing Agreements);
- m. determine whether to approve the engagement of any potential subcontractor that does not agree to assign or grant a sublicensable license (or in the case of a subcontractor that is an academic or nonprofit institution, a right to negotiate a license) to Neurocrine to all Know-How generated by the subcontractor and all Patent Rights owned or controlled by the subcontractor Covering any such Know-How, in each case, that are necessary to Exploit any Licensed Product (subject to the exclusion set forth in Section 2.3 (Subcontractors)), as described in Section 2.3 (Subcontractors);
- n. review and discuss any proposed publication by either Party, as described in Section 10.2 (Publication and Publicity);
- o. review, discuss, and determine, if requested by either Party, an alternate timeframe for Neurocrine's negotiation of an agreement with a qualified vendor for purposes of the transfer and storage of inventory of Licensed Product or for
  - 38

Takeda's transfer to Neurocrine of inventory of one or more Licensed Assets, as described on Schedule 2.7 (Transferred Inventory);

- p. serve as a forum for exchange of information for the Parties in relation to the Licensed Products, or any activities undertaken by or on behalf of either Party under this Agreement, including updates regarding activities performed by subcontractors as described in Section 2.3 (Subcontractors), LP Development Reports, as described in Section 4.2.4 (Licensed Products Development Reports), LP Commercialization Reports, as described in Section 6.3 (Licensed Products Commercialization Reporting), reports regarding Co-Funded Medical Affairs Activities, as described in Section 5.4 (Neurocrine Obligations);
- q. review and discuss any Third Parties engaged by Neurocrine for the Manufacture or performance of Clinical Trials of Profit-Share Products, as described in Section 2.3 (Subcontractors);
- r. review and discuss an appropriate allocation of or adjustment to Patent Costs for any Profit-Share Product, including convening emergency meetings of the JSC in the event that a Party anticipates the need to incur extraordinary Patent Costs relating to the Takeda Patent Rights or Program Patent Rights, in each case, with respect to any Profit-Share Product;
- s. attempt to resolve any disputes on matters within the JSC's authority on an informal basis and in good faith prior to the institution of escalation or other formal dispute resolution mechanisms hereunder; and
- t. perform such other functions expressly allocated to the JSC in this Agreement or by the written agreement of the Parties.
- **8.2.4.** JSC Meetings. The JSC will meet at least semi-annually unless the Parties mutually agree in writing to a different frequency. No later than [\*\*\*] prior to any meeting of the JSC (or such shorter time period as the Parties may agree), the Alliance Managers will prepare and circulate an agenda for such meeting; *provided*, *however*, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. Either Party may also call a special meeting of the JSC (by videoconference, teleconference, or in person) by providing at least [\*\*\*] prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the Alliance Managers to provide the members of the JSC, no later than [\*\*\*] prior to the special meeting, with an agenda for the meeting and materials reasonably adequate to enable an informed decision on the matters to be considered. In addition to any items set forth on the agenda for a meeting of the JSC, at each meeting of the JSC, Neurocrine will provide an update on all activities performed by or on behalf of Neurocrine in connection with the Exploitation of the Licensed Products since the last meeting of the JSC, and evaluate the activities performed against all relevant plans. The JSC may meet in person, by videoconference or by teleconference. Notwithstanding the foregoing, at least one meeting per Calendar Year will be in person unless the Parties agree in writing to waive such requirement. Inperson JSC meetings will be held at locations alternately
  - 39

selected by each Party. Each Party will bear the expense of its respective JSC members' participation in JSC meetings. Meetings of the JSC will be effective only if at least one representative of each Party (which representative is not such Party's Alliance Manager) is present or participating in such meeting. The Alliance Managers will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect material decisions made and action items identified at such meetings. The Alliance Managers will send draft meeting minutes to each member of the JSC for review and approval within [\*\*\*] after each JSC meeting. Such minutes will be deemed approved unless one or more members of the JSC object to the accuracy of such minutes within [\*\*\*] of receipt.

**8.3. Decisions of the JSC**. The JSC has the authority (a) for matters specifically delegated to it or expressly specified in this Agreement and (b) with respect to any other matter agreed to by the Parties in writing. For clarity, the JSC will not have any power to amend, modify, or waive compliance with this Agreement. The JSC has no other authority under this Agreement than what is expressly granted under this Agreement. The JSC will use good faith, commercially reasonable efforts in compliance with this Section 8.3 (Decisions of the JSC) to promptly resolve any such matter for which it has authority. If the JSC is unable to reach consensus with respect to any such matter for which it is responsible within [\*\*\*] after a Party affirmatively states to the other Party that a decision needs to be made, then such matter will be subject to Section 8.4 (Resolution of JSC Disputes).

# 8.4. Resolution of JSC Disputes.

- **8.4.1.** Referral to Executive Officers. Either Party may make an election under Section 8.3 (Decisions of the JSC) to refer a matter as to which the JSC cannot reach a consensus decision to the Executive Officers, following which the JSC will promptly submit in writing the respective positions of the Parties to their respective Executive Officers. Such Executive Officers will use good faith efforts, in compliance with this Section 8.4.1 (Referral to Executive Officers), to resolve promptly such matter within [\*\*\*] after the JSC's submission of such matter to such Executive Officers, which good faith efforts will include at least one in-person or telephonic meeting between such Executive Officers within such [\*\*\*] period. If the Executive Officers are unable to reach agreement on any such matter that relates to the approval of a budget within such [\*\*\*], then the Parties will refer such matter to the Chief Financial Officer for Neurocrine and the President, Research & Development for Takeda (together, the "Budget Dispute Officers"). Such Budget Dispute Officers will use good faith efforts will use good faith efforts within [\*\*\*] after the referral to them of such matter, which good faith efforts will include at least [\*\*\*].
- **8.4.2. Final Decision-Making Authority**. If the Executive Officers and, if applicable, the Budget Dispute Officers are unable to reach agreement on any such matter referred to them under Section 8.4.1 (Referral to Executive Officers) within the applicable [\*\*\*] period, then:
  - a. **No Decision**. Neither Party will have final decision-making authority on the approval of [\*\*\*].
  - b. **No Decision; Neurocrine Right to Proceed.** Neither Party will have final decision-making authority on the following matters if the Executive Officers and,

if applicable, Budget Dispute Officers are unable to reach unanimous agreement on any such matter, and no changes will be adopted with respect to any of the following matters, unless and until the Parties agree, *provided* that Neurocrine will have certain rights to proceed to the extent described below:

- [\*\*\*].
- c. **Neurocrine Final Decision-Making Authority**. Neurocrine will have final decision-making authority with respect to all other matters not specified in Section 8.4.2(a) (No Decision) or 8.4.2(b) (No Decision; Neurocrine Right to Proceed), including with respect to (a) [\*\*\*], and (b) [\*\*\*].
- **8.4.3.** Limitations on Decisions. Notwithstanding any provision to the contrary set forth in this Agreement, without the other Party's prior written consent, no exercise of a Party's decision-making authority on any such matters may, without the other Party's prior written consent, (a) result in an increase in the other Party's or its Affiliates' obligations (other than payment obligations to the extent provided in this Section 8.4 (Resolution of JSC Disputes)) under this Agreement or the Co-Funded Development Plan, Co-Funded Commercialization Plan, or Co-Funded Medical Affairs Plan, (b) impose any requirements that the other Party take or decline to take any action that would result in a violation of any Law, ethical requirement, or any agreement with any Third Party (including any In-License) or the infringement of intellectual property rights of any Third Party, or (c) otherwise conflict with, or constitute a modification of or waiver under, this Agreement.
- **8.4.4. Good Faith**. In conducting themselves on committees, and in exercising their rights under this Section 8.4 (Resolution of JSC Disputes), all representatives of both Parties will consider diligently, reasonably, and in good faith all input received from the other Party, and will use reasonable efforts to reach consensus on all matters before them. In exercising any decision-making authority granted to it under this Section 8.4 (Resolution of JSC Disputes), each Party will act based on its reasonable and good faith judgment taking into consideration Neurocrine's obligations to use Commercially Reasonable Efforts with respect to Exploitation of the Licensed Products as set forth in this Agreement.
- **8.5. JSC Termination**. Notwithstanding any Section in this Article 8 (Governance) governing the disbandment of the JSC, at any time following the Execution Date, Takeda will have the right, upon written notice to Neurocrine, to disband and no longer participate in the JSC. After the termination of the JSC under this Article 8 (Governance), the JSC will have no further obligations under this Agreement, and thereafter each Party will designate a contact person for the exchange of information under this Agreement or such exchange of information will be made through the Alliance Managers, and decisions of the disbanded JSC will be decisions as between the Parties, subject to the other terms and conditions of this Agreement.

## 9. PAYMENTS

- **9.1. Upfront Payment**. Within 5 Business Days after the Effective Date, in consideration of the licenses granted to Neurocrine hereunder, Neurocrine will pay to Takeda a non-refundable, non-creditable upfront payment in the amount of \$120,000,000 (*minus* the \$[\*\*\*] Earnest Money
  - 41

Deposit already paid by Neurocrine to Takeda[\*\*\*]) via wire transfer of immediately available funds in accordance with the instructions attached hereto as Schedule 9.4.1 (Wire Instructions).

## 9.2. Payments for the Licensed Assets and Licensed Products.

### 9.2.1. Profit and Loss Share.

- a. **Profit and Loss Share before Takeda's Phase I Opt-Out**. Unless and until Takeda exercises the Phase I Opt-Out Right with respect to a Phase I Asset in accordance with Section 3.1 (Takeda's Phase I Asset Opt-Out Right), on a Phase I Profit-Share Product-by-Phase I Profit-Share Product basis, Takeda and Neurocrine will share the Operating Profits or Losses for each Phase I Profit-Share Product as follows: Neurocrine will bear (and be entitled to) 50%, and Takeda will bear (and be entitled to) 50%, of such Operating Profits or Losses. Schedule 9.2.1 (Profit and Loss Share) sets forth the procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters.
- b. **Expenses after Takeda's Phase I Opt-Out**. If Takeda exercises the Phase I Opt-Out Right with respect to a Phase I Asset in accordance with Section 3.1 (Takeda's Phase I Asset Opt-Out Right), then, starting from the applicable Phase I Opt-Out Date, except for the [\*\*\*] Neurocrine will bear all costs and expenses incurred by or on behalf of Neurocrine and its Affiliates in connection with the Exploitation of such Phase I Royalty Product.
- c. **Expenses before Takeda's Phase II Asset Opt-In**. Prior to the Phase II Opt-In Date, Neurocrine will bear all costs and expenses incurred by or on behalf of Neurocrine and its Affiliates in connection with the Exploitation of such Phase II Royalty Product (including all costs and expenses incurred by or on behalf of Takeda and its Affiliates in connection with the Development and Manufacture of such Phase II Royalty Product that are required to be reimbursed by Neurocrine in accordance with Section 4.2.3(d) (Reimbursement for Phase II Ongoing Trials)), other than [\*\*\*]; *provided* that if Takeda exercises the Phase II Opt-In Right, then [\*\*\*].
- d. **Profit and Loss Share after Takeda's Phase II Opt-In**. If Takeda exercises the Phase II Opt-In Right in accordance with Section 3.2 (Takeda's Phase II Asset Opt-In Right), then, (a) [\*\*\*] (b) starting from the Phase II Opt-In Date, Takeda and Neurocrine will share the Operating Profits or Losses for the Phase II Profit-Share Product as follows: Neurocrine will bear (and be entitled to) 50% and Takeda will bear (and be entitled to) 50% of the Operating Profits or Losses for the Phase II Profit-Share Product.
- e. **Disagreements Regarding Costs and Expenses due to Breach**. The Parties will discuss in good faith any disagreement regarding whether or not any FTE Costs or Out-of-Pocket Costs shared by the Parties pursuant to this Section 9.2.1 (Profit and Loss Share) were caused by a performing Party's or its Affiliates' breach under this Agreement. If a Party believes that any such costs were incurred by

the performing Party as a result of a breach of this Agreement by such Party, then [\*\*\*].

#### 9.2.2. Royalty-Bearing Product Milestone Payments.

a. **Royalty-Bearing Product Development Milestones.** Subject to this Section 9.2.2(a) (Royalty-Bearing Product Development Milestones), Neurocrine will make [\*\*\*] milestone payments (each, an "**RBP Development Milestone Payment**") on a Royalty-Bearing Product-by-Royalty-Bearing Product basis to Takeda upon the first achievement by Neurocrine or its Affiliates or Sublicensees of each of the development milestone events set forth in Table 9.2.2(a) (Royalty-Bearing Product Development Milestones) below (each, an "**RBP Development Milestone Event**") for each Royalty-Bearing Product to achieve the applicable RBP Development Milestone Event. Neurocrine will notify Takeda in writing of the achievement of an RBP Development Milestone Event by Neurocrine or its Affiliates or Sublicensees no later than [\*\*\*] after the achievement thereof. Thereafter, Takeda will provide Neurocrine with an invoice for the corresponding RBP Development Milestone Payment, and Neurocrine will pay to Takeda such RBP Development Milestone Payment no later than [\*\*\*] after its receipt of an invoice for such RBP Development Milestone Payment.

Table 9.2.2(a) – Royalty-Bearing Product Development Milestones				
RBP Development Milestone Event	Phase II Royalty Product Milestone Payment	Phase I Royalty Product Milestone Payment	Phase Ib Product Milestone Payment	Nonclinical Asset Milestone Payment
(1) [***]	-	-	-	\$[***]
(2) [***]	-	-	-	\$[***]
(3) [***]	\$[***]	\$[***]	\$[***]	\$[***]
(4) [***]	\$[***]	\$[***]	\$[***]	\$[***]

For clarity, for a particular Royalty-Bearing Product, Milestone #1 will be deemed achieved and payable, if not already achieved, upon achievement of any of Milestone #2 or Milestone #3 for such Royalty-Bearing Product; Milestone #2 will be deemed achieved and payable, if not already achieved, upon achievement of Milestone #3 or Milestone #4; and Milestone #3 will be deemed achieved and payable, if not already achieved, upon achievement of Milestone #4 milestone #4. [\*\*\*].

b. **Royalty-Bearing Product Commercial Milestones**. Subject to this Section 9.2.2(b) (Royalty-Bearing Product Commercial Milestones), on a Licensed Asset-by-Licensed Asset basis, Neurocrine will make [\*\*\*] commercial milestone payments (each, an "**RBP Commercial Milestone Payment**" and together with the RBP Development Milestone Payments, the "**RBP Milestone Payments**") to Takeda upon the achievement by Neurocrine or its Affiliates or Sublicensees of each of the sales-based milestones events set forth in Table 9.2.2(b) (Royalty-Bearing Product Commercial Milestones) below (each, an "**RBP Commercial Milestone Event**" and together with the RBP Development Milestone Events, the "**RBP Milestone Events**") with respect to the worldwide aggregate RBP Annual Net Sales of all Royalty-Bearing Products that contain the same Licensed Asset, *provided* that Net Sales of any Royalty-Bearing Product in

any country will not be included after the Royalty Term for such Royalty-Bearing Product and country has ended. Neurocrine will notify Takeda in writing of the achievement of a RBP Commercial Milestone Event by Neurocrine or its Affiliates or Sublicensees no later than [\*\*\*] after the end of the Calendar Quarter in which such RBP Commercial Milestone Payment is payable pursuant to the preceding sentence. Thereafter, Takeda will provide Neurocrine with an invoice for the corresponding RBP Commercial Milestone Payment, and Neurocrine will pay to Takeda such RBP Commercial Milestone Payment no later than [\*\*\*] after receipt of the applicable invoice from Takeda. If, during any Calendar Quarter, Neurocrine or its Affiliates or Sublicensees achieves more than one RBP Commercial Milestone Events, then Neurocrine will make payment with respect to both such achieved RBP Commercial Milestone Events according to the foregoing payment timeline in such Calendar Quarter.

Table 9.2.2(b) – Royalty-Bearing Product Commercial Milestones				
RBP Commercial Milestone Event	<b>RBP</b> Commercial Milestone Payment			
First Calendar Year in which aggregate RBP Annual Net Sales in the Territory of all Royalty-Bearing Products that contain the same Licensed Asset exceed \$[***]	\$[***]			
First Calendar Year in which aggregate RBP Annual Net Sales in the Territory of each Royalty- Bearing Product that contain the same Licensed Asset exceed \$[***]	\$[***]			
First Calendar Year in which aggregate RBP Annual Net Sales in the Territory of each Royalty- Bearing Product that contain the same Licensed Asset exceed \$[***]	\$[***]			

**9.2.3. Royalty-Bearing Product Royalties**. Until the expiration of the Royalty Term for each Royalty-Bearing Product in each country in the Territory and subject to the provisions of Section 9.2.4 (Royalty Reductions), Neurocrine will pay to Takeda royalties in the amount of (a) the marginal Royalty Rates set forth in Table 9.2.3(a) (Royalty-Bearing Product Royalty Payments (US)) below, based on the aggregate Net Sales resulting from the sale of all Royalty-Bearing Products that contain the same Licensed Asset in the United States during each Calendar Year until the expiration of the applicable Royalty Term (for each Royalty-Bearing Product, the "**RBP Annual US Net Sales**," and such payments (Ex-US)) below, based on the aggregate Net Sales resulting from the sale of all Royalty Payments (Ex-US)) below, based on the aggregate Net Sales resulting from the sale of all Royalty-Bearing Product Royalty Term (for each Royalty Rates set forth in Table 9.2.3(b) (Royalty-Bearing Product Royalty Payments (Ex-US)) below, based on the aggregate Net Sales resulting from the sale of all Royalty-Bearing Products that contain the Same Licensed Asset in the United States during each Calendar Year until the expiration of the applicable Royalty Term (for each Royalty-Bearing Product, the "**RBP Annual Ex-US Net Sales**," and such payments, "**RBP Ex-US Royalties**").

TABLE 9.2.3(a) – Royalty-Bearing Products Royalty Payments (US)				
RBP Annual US Net Sales	Phase II Royalty Product Marginal Royalty Rate (% of RBP Annual US Net Sales)	Phase I Royalty Product or Phase Ib Product Marginal Royalty Rate (% of RBP Annual US Net Sales)	Nonclinical Asset Marginal Royalty Rate (% of RBP Annual US Net Sales)	
The portion of RBP Annual US Net Sales less than \$[***]	[***]%	[***]%	[***]%	
The portion of RBP Annual US Net Sales greater than or equal to \$[***] and less than \$[***]	[***]%	[***]%	[***]%	
[The portion of RBP Annual US Net Sales greater than or equal to \$[***] and less than \$[***]	[***]%	[***]%	[***]%	
[The portion of RBP Annual US Net Sales greater than or equal to \$[***]	[***]%	[***]%	[***]%	

TABLE 9.2.3(b) – Royalty-Bearing Products Royalty Payments (Ex-US)				
RBP Annual Ex-US Net Sales	Phase II Royalty Product Marginal Royalty Rate (% of RBP Annual Ex-US Net Sales)	Phase I Royalty Product or Phase Ib Product Marginal Royalty Rate (% of RBP Annual Ex-US Net Sales)	Nonclinical Asset Marginal Royalty Rate (% of RBP Annual Ex-US Net Sales)	
The portion of RBP Annual Ex-US Net Sales less than \$[***]	[***]%	[***]%	[***]%	
The portion of RBP Annual Ex-US Net Sales greater than or equal to \$[***] and less than \$[***]	[***]%	[***]%	[***]%	
The portion of RBP Annual Ex-US Net Sales greater than or equal to \$[***] and less than \$[***]	[***]%	[***]%	[***]%	
The portion of RBP Annual Ex-US Net Sales greater than or equal to \$[***]	[***]%	[***]%	[***]%	

# 9.2.4. [\*\*\*]

**9.3. Other Amounts Payable**. With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified in this Agreement, within [\*\*\*] after the end of each Calendar Quarter each Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed in respect of such Calendar Quarter. The owing Party will pay any undisputed amounts within [\*\*\*] after receipt of the invoice, and will pay any disputed amounts owed by such Party within [\*\*\*] of resolution of the Dispute.

# 9.4. Payment Terms.

**9.4.1. Manner of Payment**. All payments to be made between the Parties under this Agreement will be made in Dollars and may be paid by wire transfer in immediately

available funds in accordance with the instructions attached hereto as Schedule 9.4.1 (Wire Instructions).

- **9.4.2. Reports and Royalty Payments.** Commencing upon the First Commercial Sale of a Royalty-Bearing Product and continuing for as long as the RBP Royalties are due under Section 9.2.3 (Royalty-Bearing Product Royalties), Neurocrine will deliver to Takeda (a) within [\*\*\*] after the end of a Calendar Quarter, a written preliminary report setting forth [\*\*\*] (b) within [\*\*\*] after the end of each Calendar Quarter, a written report setting forth [\*\*\*] (each, a "**Royalty Report**"). Upon receipt of such Royalty Report, Takeda will issue an invoice to Neurocrine for the amount of the royalties set forth in such Royalty Report, which invoice will specify the amount of the RBP Royalties that should be made to Takeda. Neurocrine will pay all RBP Royalties for a Calendar Quarter set forth in any such invoice within [\*\*\*] after receipt of such invoice.
- 9.4.3. Records and Audits. Neurocrine will keep complete, true, and accurate books and records in accordance with the applicable Accounting Standards in relation to this Agreement, including in relation to all Operating Profits or Losses, Net Sales, Sublicense Revenue, and the RBP Royalties. Neurocrine will keep such books and records for three years following the Calendar Year to which they pertain. Takeda may, upon written request, cause an internationally-recognized independent accounting firm (the "Auditor") that is reasonably acceptable to Neurocrine to inspect the relevant records of Neurocrine and its Affiliates to verify the payments made by Neurocrine and the related reports, statements and books of accounts, as applicable. Before beginning its audit, the Auditor will execute an undertaking acceptable to Neurocrine by which the Auditor agrees to keep confidential all information reviewed during the audit. Neurocrine and its Affiliates will make their records available for inspection by the Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from Takeda. The Auditor will review the records solely to verify the accuracy of Neurocrine's Operating Profits or Losses, Net Sales, and the RBP Royalties, and compliance with the financial terms of this Agreement. Such inspection right will not be exercised more than once in any Calendar Year and not more frequently than once with respect to records covering any specific period of time. In addition, Takeda will only be entitled to audit the books and records of Neurocrine from the three Calendar Years prior to the Calendar Year in which the audit request is made. Takeda agrees to hold in strict confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any law, regulation or judicial order. The Auditor will provide its audit report and basis for any determination to Neurocrine at the time such report is provided to Takeda. In the event that the final result of the inspection reveals an undisputed underpayment or overpayment by Neurocrine, the underpaid or overpaid amount will be settled promptly. Takeda will pay for such inspections, as well as its expenses associated with enforcing its rights with respect to any payments hereunder; provided, however, that in the event of an underpayment of more than [\*\*\*]% of the total payments due hereunder for the audited period, then the fees and expenses charged by the Auditor will be paid Neurocrine.
- **9.4.4. Currency Exchange**. All amounts due to either Party hereunder will be expressed in Dollars. The rate of exchange to be used in computing the amount of currency equivalent in Dollars owed to a Party under this Agreement will be the exchange rate used by such
  - 46

Party in its financial reporting in accordance with its Accounting Standards, which exchange rate as used by Neurocrine will be discussed at the JSC.

## 9.4.5. Taxes.

- a. **Indirect Taxes**. Notwithstanding anything to the contrary in this Agreement, Takeda will be responsible for any value added, VAT or other similar tax that is imposed with respect to the transactions, payments or the related transfer of rights or other property pursuant to the terms of this Agreement. Neurocrine shall be entitled to offset any such taxes borne by it from amounts otherwise owed to Takeda under this Agreement.
- Withholding Taxes. The amounts payable pursuant to this Agreement ("Payments") will not be reduced on account b. of any Taxes unless required by applicable Law. Neurocrine will deduct and withhold from the Payments made to Takeda any Taxes that it is required by applicable Law to deduct or withhold, ("Withholding Taxes"), and any such amounts deducted or withheld by Neurocrine will be treated as having been paid to Takeda for purposes of this Agreement. Any such Withholding Taxes will be an expense of and borne by Takeda. If any such Withholding Tax is assessed against, or paid (but in each case not withheld) by Neurocrine, then Takeda will pay the relevant amount of such Withholding Tax to Neurocrine. In the event that a Governmental Authority retroactively determines that a payment made by Neurocrine to Takeda under this Agreement should have been subject to Withholding Taxes (or to additional Withholding Taxes), and Neurocrine remits such Withholding Taxes to the Governmental Authority, including any interest and penalties that may be imposed thereon, at the option of Neurocrine, then Takeda will pay the relevant amount of any Withholding Tax (including any interest and penalties thereon) to Neurocrine. Notwithstanding the foregoing, if Takeda is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable Withholding Tax, then it may deliver to Neurocrine or the appropriate Governmental Authority the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Neurocrine of its obligation to withhold tax. If Takeda timely delivers to Neurocrine a validly executed form establishing a reduced rate or exemption from withholding, Neurocrine shall apply the reduced rate of withholding, or not withhold, as the case may be, provided that Neurocrine is in receipt of evidence, in a form reasonably satisfactory to Neurocrine, for example Takeda's delivery of all applicable documentation at least two weeks prior to the time that the Payments are due. If, in accordance with the foregoing, Neurocrine withholds any amount, then it will pay to Takeda the balance when due, make timely payment (or cause its agent to make timely payment) to the proper taxing authority of the withheld amount, and send Takeda proof of such payment within [\*\*\*] following that payment. On or before the Effective Date, Takeda shall deliver to Neurocrine a properly completed Internal Revenue Service ("**IRS**") Form W-8BEN-E or other applicable IRS Form W-8.
- c. **Tax Cooperation**. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Law, of Withholding Taxes, VAT, or
  - 47

similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such Withholding Tax or VAT.

- d. **No Other Reductions**. Except as provided in this Section 9.4 (Payment Terms) and those deductions expressly included in the definition of Net Sales, the amounts payable hereunder will not be reduced on account of any Taxes, unless required by applicable Law.
- e. **Tax Exemptions and Credits**. The Parties will reasonably cooperate with each other in seeking any tax exemption or credits that may be available with respect to any Licensed Product, including the tax credit available under Section 45C of the Code by reason of a Party's research and Development expenditures contributing to the Licensed Product being granted orphan drug status by the FDA, or equivalent Law of any other country.
- f. **Withholding Reimbursement**. Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge and agree that if either Party redomiciles, or assigns or sublicenses its rights or obligations under this Agreement (including an assignment of this Agreement as permitted under Section 16.1 (Assignment) of this Agreement), and such action leads to the imposition of withholding Tax liability or VAT on the other Party that would not have been imposed in the absence of such action or in an increase in such liability above the liability that would have been imposed in the absence of such action, then such Party will increase such payment by the amount necessary to ensure that the other Party receives an amount equal to the amount it would have received had no such action occurred.
- **9.4.6. Blocked Payments**. In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed the other Party hereunder, such Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [\*\*\*], in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party.
- **9.4.7. Interest Due**. Each paying Party will pay the other Party interest on any undisputed payments that are not paid on or before the date such payments are due under this Agreement at the [\*\*\*].

# 10. CONFIDENTIALITY AND PUBLICATION

#### **10.1.** Nondisclosure and Non-Use Obligations.

**10.1.1. Confidential Information**. All Confidential Information disclosed by one Party to the other Party under this Agreement will, during the Term and for a period of [\*\*\*] thereafter, be maintained in confidence by the receiving Party and will not be disclosed to a Third Party or used for any purpose except to exercise its licenses and other rights, to perform its obligations, or as otherwise set forth herein, without the prior written consent of the disclosing Party. The existence and terms of this Agreement are the Confidential

Information of each Party, and each Party will be deemed a receiving Party with respect thereto. Unpublished patent applications or Know-How solely owned by a Party are such Party's Confidential Information, and Patent Rights and Know-How jointly owned by the Parties will be deemed both Parties' Confidential Information, in each case, regardless of which Party is the disclosing Party. All information exchanged between the Parties regarding the Prosecution and Maintenance, defense, and enforcement of the Patent Rights under Article 13 (Intellectual Property) will be the Confidential Information of the prosecuting Party. All data, results, and reports pertaining to any Licensed Product (a) generated by Neurocrine under this Agreement will be the Confidential Information of Neurocrine and (b) generated by Takeda under this Agreement will be the Confidential Information of Takeda; provided that Takeda will maintain such data, results, and reports described in the foregoing clause (b) in confidence and not disclose them to any Third Party for so long as they remain Confidential Information of Takeda, except as permitted under Section 10.1.2 (Permitted Disclosures), Section 10.2 (Publication and Publicity), or Section 13.2.1(b) (Takeda's Right). The Takeda Know-How will be the Confidential Information of Takeda. All information disclosed by a Party pursuant to that certain Confidentiality Agreement between the Parties dated January 31, 2020 is deemed the Confidential Information of such Party pursuant to this Agreement. During the Term, the receiving Party will use at least the same degree of care to protect the secrecy of the Confidential Information of the disclosing Party that it uses to prevent the disclosure of its own other confidential information of similar importance and in any event no less than a reasonable duty of care.

- **10.1.2. Permitted Disclosures**. Notwithstanding the obligations of confidentiality and non-use set forth above, a receiving Party may provide Confidential Information disclosed to it, and disclose the existence and terms of this Agreement to:
  - a. its Affiliates or, in the case of Neurocrine, actual or potential Sublicensees, and its and their respective employees, directors, agents, consultants, or advisors to the extent necessary for the potential or actual performance of its obligations or exercise of its licenses and other rights under this Agreement, in each case, who are under an obligation of confidentiality with respect to such information that is no less stringent than the terms of this Section 10.1.2 (Permitted Disclosures);
  - b. Governmental Authorities or other Regulatory Authorities (i) in connection with regulatory filings for Licensed Products as permitted hereunder and (ii) in order to obtain Patent Rights or otherwise perform its obligations or exploit its rights with respect to any Patent Right under this Agreement to the extent permitted;
  - c. the extent, based on the advice of outside counsel, required by Law or any Governmental Authorities, including by the rules or regulations of the United States Securities and Exchange Commission ("SEC") or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity; and
  - d. with respect to the terms of this Agreement and, in the case of Neurocrine, all Takeda Technology or, in the case of Takeda, information, data, and results related to any Licensed Product or, after termination of this Agreement with respect to any Terminated Product, the Grantback IP, any actual or *bona fide* 
    - 49

prospective acquirers, underwriters, investors, lenders, or other financing sources, in each case, who are under obligations of confidentiality and non-use with respect to such information that is no less stringent than the terms of this Section 10.1.2 (Permitted Disclosures) (except that the term of such obligations may be shorter, but no less than [\*\*\*]).

#### 10.1.3. Confidential Treatment.

- a. Notwithstanding any provision to the contrary set forth in this Agreement, if a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 10.1.2(c) (Permitted Disclosure), then it will, to the extent not prohibited by applicable Law or judicial or administrative process, give reasonable advance notice to the other Party of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosure of advised by its legal counsel. In any event, each Party agrees to take reasonable action to avoid any disclosure of Confidential Information of the other Party hereunder.
- b. In addition, the Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement (or portions of this Agreement or an abstract of the terms of this Agreement) with the SEC or other Governmental Authorities. Each Party will be entitled to make such a required filing, provided that it initially files a redacted copy of this Agreement (or portions of this Agreement or an abstract of the terms of this Agreement) reviewed by each Party ("Redacted Agreement") and requests confidential treatment of the terms redacted from this Agreement for a reasonable period of time, in each case, pursuant to the following procedure. In the event of any such filing, each Party will (i) permit the other Party to review and comment upon a Redacted Agreement at least [\*\*\*] in advance of its submission to the SEC or such other Governmental Authorities, (ii) cooperate in good faith with and reasonably consider and incorporate the other Party's reasonable comments thereon to seek confidential treatment of the terms and conditions of this Agreement that such other Party requests to be kept confidential or otherwise afforded confidential treatment, to the extent consistent with the then-current legal requirements governing redaction of information from material agreements (as determined based on the advice of such Party's outside counsel) that must be publicly filed in the applicable country, (iii) only disclose Confidential Information that counsel reasonably advises is legally required to be disclosed, (iv) promptly advise the other Party of any other substantive communications between it or its representatives with such Governmental Authority with respect to such confidential treatment request, (v) upon the written request of the other Party, request an appropriate extension of the term of the confidential treatment period upon the expiration thereof, where available, and (vi) if such Governmental Authority requests any changes to the redactions set forth in the Redacted Agreement, use Commercially Reasonable Efforts to reach a reasonable resolution in light of the redactions in the Redacted Agreement as originally filed and taking into account the then-current legal requirements governing redaction of information from material agreements that must be publicly filed, as determined based on the advice of such Party's outside

counsel, and, to the extent reasonably practicable, review with the other Party any changes to the redactions in the Redacted Agreement before making such changes; *provided, however*, that each Party will have the right to make any such filing or disclosure as it reasonably determines to make, based on the advice of outside counsel, under applicable Laws. Each Party will be responsible for its own legal and other external costs in connection with any such filing, registration, or notification.

## **10.2.** Publication and Publicity.

- 10.2.1. Publication. Except for disclosures permitted in accordance with Section 10.1.2 (Permitted Disclosures), either Party wishing to make a publication or public presentation that contains the Confidential Information of the other Party or any Takeda Know-How will deliver to the other Party and the JSC a copy of the proposed written publication or presentation at least [\*\*\*] prior to submission for publication or presentation. The reviewing Party, through the JSC, will have the right to (a) propose modifications to the publication or presentation for patent reasons or trade secret reasons or to remove Confidential Information of the reviewing Party or its Affiliates, and the publishing Party will remove all Confidential Information of the reviewing Party if requested by the reviewing Party and otherwise use good faith efforts to reflect such Party's reasonable comments, or (b) request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay to enable the reviewing Party to file patent applications as permitted under Article 13 (Intellectual Property) protecting such Party's right in such information, then the publishing Party will delay such submission or presentation for a period of [\*\*\*] (or such shorter period as may be agreed by the Parties). With respect to any proposed publications or disclosures by investigators or academic or non-profit collaborators, such materials will be subject to review under this Section 10.2 (Publication and Publicity) to the extent that Takeda or Neurocrine, as the case may be, has the right and ability to do so (after using Commercially Reasonable Efforts to obtain such right and ability). All publications relating to any Licensed Product will be prepared, presented, and published in accordance with pharmaceutical industry accepted guidelines including: (i) International Committee of Medical Journal Editors (ICMJE) guidelines, (ii) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, (iii) Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines, and (iv) Principles on Conduct of Clinical Trials.
- **10.2.2. Publicity**. Except as set forth in Section 10.1 (Nondisclosure and Non-Use Obligations), Section 10.2 (Publication and Publicity) or Section 10.2.3 (Press Release), the terms of this Agreement may not be disclosed by either Party. Neither Party will use the name, Trademark, trade name or logo of the other Party or its employees in any publicity, news release or disclosure relating to this Agreement, its subject matter, or the activities of the Parties hereunder, in each case, without the prior express written permission of the other Party, except (a) as may be required by applicable Law (as determined based on the advice of outside counsel), including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in any country other than the United States or of any stock exchange or listing entity, *provided* that the Party making such disclosure or use of the name, Trademark, trade name, or logo of the other Party or its employees gives the other Party reasonable prior written notice of such disclosure and otherwise complies with Section 10.1.2 (Permitted Disclosures), or (b) as expressly permitted by the terms hereof.

**10.2.3. Press Release**. The Parties have agreed on the contents of an initial joint press release, in substantially the form attached hereto as Schedule 10.2.3 (Joint Press Release) or as otherwise agreed by the Parties, and which will be issued by the Parties promptly after the Effective Date. Following such initial press release, except as provided in Section 10.2.1 (Publicity) or this Section 10.2.3 (Press Release), neither Party will issue any press release or public announcement relating to this Agreement without the prior written approval of the other Party (such approval not to be unreasonably withheld), except that a Party may (a) once a press release or other public statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other written statement without the further approval of the other Party (so long as such information remains true and correct), and (b) issue a press release or public announcement as required by applicable Law (including a press release corresponding to any securities disclosure, such as pursuant to a Form 8[K, or any earnings or financial press release), including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity, *provided* that the Party issuing such press release gives reasonable prior notice to the other Party of and the opportunity to comment on the press release or public announcement, and otherwise complies with this Article 10 (Confidentiality and Publication).

# 11. REPRESENTATIONS, WARRANTIES AND COVENANTS

- **11.1. Mutual Representations and Warranties as of the Execution Date.** Each Party represents and warrants to the other Party, as of the Execution Date, that:
  - **11.1.1.** such Party is a corporation duly organized, validly existing, and in good standing under the Laws of its jurisdiction of incorporation or formation;
  - **11.1.2.** such Party has all requisite corporate power and corporate authority to enter into this Agreement and to carry out its obligations under this Agreement;
  - **11.1.3.** all requisite corporate action on the part of such Party, its directors and stockholders required by applicable Law for the authorization, execution, and delivery by such Party of this Agreement, and the performance of all obligations of such Party under this Agreement, has been taken;
  - **11.1.4.** the execution, delivery, and performance of this Agreement, and compliance with the provisions of this Agreement, by such Party do not and will not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment, or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event that, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which such Party or any of its assets are bound, or (c) violate or conflict with any of the provisions of such Party's organizational documents (including any articles or memoranda of organization or association, charter, bylaws, or similar documents); and
  - **11.1.5.** no consent, approval, authorization, or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by such

Party in connection with the authorization, execution, and delivery by such Party of this Agreement, except as required pursuant to the HSR Act and any other applicable Antitrust Laws.

- **11.2. Representations and Warranties by Takeda**. Takeda represents and warrants to Neurocrine, as of the Execution Date that:
  - **11.2.1. Takeda Patent Rights**. Schedule 11.2.1 (Takeda Patent Rights) sets forth a complete and accurate list of all Takeda Patent Rights issued or pending as of the Execution Date.
  - **11.2.2. Takeda Technology**. Except as otherwise set forth on Schedule 11.2.2 (Takeda Technology), Takeda has (a) legal or beneficial title and sole ownership of all Takeda Technology, free and clear of all mortgages, pledges, liens, encumbrances or claims of any kind, including claims by any Governmental Authority or academic or non-profit institution; and (b) authority to grant to Neurocrine and its Affiliates the licenses set forth in this Agreement under the Takeda Technology. Takeda is not a party to any agreement with a Third Party under which Takeda has obligations to such Third Party with respect to (i) the grant of a license to Neurocrine under any Takeda Technology or (ii) Neurocrine's practice thereunder or Exploitation of Licensed Products.
  - **11.2.3. Control**. Takeda or its Affiliates Controls all Patent Rights and Know-How owned, invented or licensed by Takeda as of the Execution Date that are necessary or actually used as of the Execution Date to Exploit Licensed Products.
  - **11.2.4. Ownership of Takeda Technology**. With respect to any Takeda Technology owned or purported to be owned by Takeda, (a) to Takeda's Knowledge, Takeda and its Affiliates have obtained from all employees and independent contractors who participated in the invention or authorship thereof, assignments of all ownership rights of such employees and independent contractors in such Takeda Technology, either pursuant to written agreement or by operation of Law; (b) except as otherwise set forth on Schedule 11.2.4 (Ownership of Takeda Technology), all of its employees, officers, contractors, and consultants have executed agreements or have existing obligations under applicable Law requiring assignment to Takeda or its Affiliate, as applicable, of all rights, title, and interests in and to inventions made during the course of and as the result of this Agreement; and (c) to Takeda's Knowledge, no officer or employee of Takeda or its Affiliate is subject to any agreement with any other Third Party that requires such officer or employee to assign any interest in any Takeda Technology to any Third Party.
  - **11.2.5.** Validity and Enforceability. With respect to Takeda Patent Rights, there are no oppositions, nullity actions, interferences, *inter partes* reexaminations, *inter partes* reviews, post-grant reviews, derivation proceedings, or other proceedings pending or, to Takeda's Knowledge, threatened in writing (but excluding office actions or similar communications issued by the United States Patent and Trademark Office or any analogous foreign Governmental Authority (collectively, "Patent Offices") in the ordinary course of Prosecution and Maintenance of any patent application) that challenge the scope, validity, or enforceability of the Takeda Patent Rights owned or purported to be owned by Takeda. Takeda does not have Knowledge of any fact or circumstance that would cause Takeda to reasonably conclude that any of the Takeda Patent Rights is, or will be upon issuance, invalid or unenforceable.
    - 53

- **11.2.6. Inventorship.** To Takeda's Knowledge, inventorship of each Takeda Patent Right is properly identified on each patent and patent application. Takeda has no Knowledge of any disputes with respect to inventorship of any Takeda Patent Rights.
- **11.2.7. Good Standing**. All official fees, maintenance fees and annuities for any pending or issued Takeda Patent Rights have been paid when due, and all administrative procedures with Governmental Authorities have been completed for such Takeda Patent Rights such that such Patent Rights are subsisting and in good standing.
- **11.2.8. Duty of Disclosure**. To Takeda's Knowledge, all Takeda Patent Rights have been duly and properly filed and maintained and the inventors thereof and parties prosecuting such applications have complied in all material respects with their duty of candor and disclosure to the U.S. Patent and Trademark Office and other foreign patent offices in connection with such applications.
- **11.2.9. Disclosure to Neurocrine**. To Takeda's Knowledge, Takeda has disclosed to Neurocrine in writing (a) all information that is (i) known to any individual associated with the filing or prosecution (as defined in 37 C.F.R. § 1.56(c)) of the Takeda Patent Rights and (ii) material to patentability of the Takeda Patent Rights (as defined in 37 C.F.R. § 1.56(b)), or that would be considered material to patentability as defined in 37 C.F.R. § 1.56(b) but for an exception under 35 U.S.C. § 102(b), and (b) an indication to which Takeda Patent Rights each piece of such information relates.
- **11.2.10.Prior Art**. To Takeda's Knowledge, there is not any reference or prior art that would anticipate the issuance of any claim as pending as of the Execution Date in any Takeda Patent Rights.
- **11.2.11.Government Funding**. No government funding, facilities of a university, college, or other educational institution or research center was used in the development of any Takeda Patent Rights. No Person who was involved in, or who contributed to, the creation or development of any Takeda Patent Rights has performed services for the government, university, college, or other educational institution or research center in a manner that would affect Takeda's rights in the Takeda Patent Rights.
- **11.2.12.No Claims**. There are (a) no claims, judgments or settlements against or owed by Takeda or its Affiliates and (b) no pending or, to Takeda's Knowledge, threatened claims or litigation, in each case ((a) and (b)), related to the Takeda Technology or the Licensed Assets.
- **11.2.13.Notice of Infringement or Misappropriation**. Neither Takeda nor its Affiliates have received any written notice or, to Takeda's Knowledge, threat in writing from any Third Party asserting or alleging that any Development or Manufacture of the Licensed Assets by Takeda or its Affiliates prior to the Execution Date infringed or misappropriated any intellectual property rights of such Third Party.
- **11.2.14.No Conflicts**. Takeda has not entered into any agreement with any Third Party that is in conflict with the rights granted to Neurocrine under this Agreement, and has not taken any action that would prevent it from granting the rights granted to Neurocrine under this Agreement, or that would otherwise materially conflict with or adversely affect Neurocrine's rights under this Agreement.

- **11.2.15.Third Party Technology**. To Takeda's Knowledge (a) the Development, Manufacture and Commercialization of Licensed Assets and Licensed Products in the form such Licensed Assets and Licensed Products exist as of the Effective Date does not and will not infringe any issued patents of a Third Party, (b) Takeda has disclosed to Neurocrine any pending Third Party patent applications that, if issued with the published or currently pending claims, would be infringed by any such activities, and (c) except for those disclosed by Takeda as described in clause (b), there are no pending Third Party patent applications that, if issued with the published or currently pending claims, would be infringed by any such activities.
- **11.2.16.Third Party Infringement**. To Takeda's Knowledge, no Third Party is infringing or has infringed any Takeda Patent Rights or has misappropriated any Takeda Know-How.
- **11.2.17.Compliance with Laws**. Takeda and its Affiliates have conducted the Exploitation of the Licensed Assets in material compliance with all applicable Laws, including as applicable GLP, GCP, and cGMP and any applicable anti-corruption or anti-bribery laws or regulations of any Governmental Authority with jurisdiction over such Exploitation. Takeda and its Affiliates did not use in any capacity in connection with the Exploitation of any Licensed Asset any Person that had been debarred pursuant to Section 306 of the FD&C Act, as amended, or that was the subject of a conviction described in such section.
- **11.2.18.Regulatory Submissions and Study Reports**. Takeda or its Affiliates Control all Regulatory Submissions in the Territory related to the Licensed Assets, and to Takeda's Knowledge, Takeda or its Affiliates Control all study reports and underlying data from the Phase II Ongoing Activities or any other Clinical Trials of any Licensed Asset conducted before the Effective Date.
- **11.2.19.No Fraudulent Statements**. Neither Takeda nor its Affiliates, nor, to Takeda's Knowledge, any of its or their respective directors, officers, employees or agents has (a) committed an act, (b) made a statement or (c) failed to act or make statement, in any case ((a), (b) or (c)), that (i) would be or create an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development and Manufacture of any Licensed Asset or Licensed Product or (y) could reasonably be expected to provide a basis for the FDA or any other Regulatory Authority to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies, with respect to the Development and Manufacture of any Licensed Asset or Licensed Product.
- **11.2.20.Disclosure**. Takeda has not withheld material information related to the Takeda Technology, Licensed Assets, or Licensed Products, in each case, that was requested by Neurocrine in writing.
- **11.3. Warranty Disclaimer**. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY PATENTS, KNOW-HOW, MATERIALS, COMPOUND, PRODUCT, LICENSED ASSET, LICENSED PRODUCT, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND HEREBY DISCLAIMS ALL

IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE OR NONINFRINGEMENT WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE EXPLOITATION OF ANY LICENSED ASSET OR LICENSED PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL.

### 11.4. Certain Covenants.

- **11.4.1. Compliance**. Neurocrine and its Affiliates or Sublicensees will conduct the Exploitation of the Licensed Products in a good scientific manner [\*\*\*] in accordance with all applicable Laws, including, as applicable, GLP, GCP, and cGMP or regulations of any Governmental Authority with jurisdiction over the activities performed by or on behalf of Neurocrine or its Affiliates or Sublicensees in furtherance of such obligations. In addition, if Neurocrine is or becomes subject to a legal obligation to a Governmental Authority (such as a corporate integrity agreement or settlement agreement with a Governmental Authority), then Takeda will perform such activities as may be reasonably requested by Neurocrine to enable Neurocrine to comply with its legal obligation to such Governmental Authority with respect to the Licensed Products. Before entering into a sublicense agreement with any potential Sublicensee, Neurocrine will conduct appropriate due diligence regarding such potential Sublicensee's compliance programs to assess the Sublicensee's ability to comply with the requirements of this provision and will not grant rights to any potential Sublicensee's compliance with this provision.
- **11.4.2.** No Debarment. Neurocrine will not use and will not permit its Affiliates or Sublicensees to use, in any capacity in connection with the performance of its obligations under this Agreement, any Person that has been debarred pursuant to Section 306 of the FD&C Act, as amended, or that is the subject of a conviction described in such section. Neurocrine agrees to inform Takeda in writing immediately if it or any Person that is performing activities under this Agreement is debarred or is subject to debarment or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation, or legal or administrative proceeding (a) has been filed and is pending or (b) is threatened in writing relating to the debarment or conviction of Neurocrine or, to Neurocrine's knowledge, any Person or entity used in any capacity by Neurocrine or any of its Affiliates with respect to this Agreement or the performance of its other obligations under this Agreement. Neurocrine will use commercially reasonable efforts to include in any agreement with any Person or entity used in any capacity by Neurocrine or any of its Affiliates with respect to this Agreement or the performance of its other obligations under this Agreement an obligation to provide notice to Neurocrine of the matters described in this Section 11.4.2 (No Debarment).
- **11.4.3. Control**. Takeda or its Affiliates will retain Control during the Term of all Patent Rights and Know-How owned by Takeda or its Affiliates as of the Effective Date that are (a) necessary to Exploit any Licensed Products (excluding any active pharmaceutical ingredient therein that is not a Licensed Asset) in the Field in the Territory or (b) reasonably useful to Exploit one or more Licensed Products in the Field in the Territory, but, in the case of this clause (b), excluding any Patent Rights or Know-How that were not practiced or used by Takeda or its Affiliates in connection with the Exploitation of the
  - 56

applicable Licensed Products as of the Effective Date and (i) that Covers (in the case of Patent Rights) or relates to (in the case of Know-How) manufacturing, formulation or other technology that is generally applicable to other products, as well as one or more Licensed Products, or (ii) to the extent related to any active pharmaceutical ingredient Controlled by Takeda or any of its Affiliates that is not a Licensed Asset.

- **11.4.4. Domain Names**. Within [\*\*\*] after the Effective Date, Takeda will provide to Neurocrine all login and password information necessary to access and maintain the domain names related to the Phase II Asset as set forth on Schedule 11.4.4 (Domain Names).
- **11.4.5.** No Conflicts. Takeda will not enter into any agreement with any Third Party that is in conflict with the rights granted to Neurocrine under this Agreement and will not take any action that would prevent it from granting the rights granted to Neurocrine under this Agreement or that would otherwise materially conflict with or adversely affect the rights granted to Neurocrine under this Agreement.
- **11.4.6. Assignment**. Upon Neurocrine's request, Takeda or its Affiliates will obtain, unless impracticable, from each employee and independent contractor who participated in the invention or authorship of any Takeda Technology, assignments of all ownership rights of such employees and independent contractors in such Takeda Technology pursuant to written agreement.

# 12. INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

- 12.1. Indemnification by Takeda. Takeda will indemnify, hold harmless, and defend Neurocrine, its Affiliates, and their respective directors, officers, employees, and agents ("Neurocrine Indemnitees") from and against any and all losses, liabilities, damages, costs, taxes (including penalties and interest) fees, and expenses (including reasonable attorneys' fees and litigation expenses) (collectively, "Losses") resulting from any claims, suits, proceedings or causes of action brought by a Third Party (collectively, "Claims") against such Neurocrine Indemnitees to the extent arising out of or resulting from:
  - **12.1.1.** any breach of, or inaccuracy in, any representation or warranty made by Takeda in this Agreement, or any breach or violation of any covenant or agreement of Takeda in this Agreement,
  - **12.1.2.** the negligence or willful misconduct by or of Takeda or any of its Affiliates, or any of their respective directors, officers, employees, or agents in the performance of Takeda's obligations or exercise of its rights under this Agreement, or
  - **12.1.3.** the Exploitation of any Licensed Product prior to the Effective Date or of any Terminated Product, in each case, by or on behalf of Takeda or any of its Affiliates, or the conduct of the Phase II Ongoing Activities.

Notwithstanding the foregoing, Takeda will have no obligation to indemnify the Neurocrine Indemnitees to the extent that the Losses arise out of or result from matters described under Section 12.2.1 or 12.2.2 (Indemnification by Neurocrine).

- **12.2. Indemnification by Neurocrine**. Neurocrine will indemnify, hold harmless, and defend Takeda, its Affiliates and licensees and their respective directors, officers, employees, and agents ("**Takeda Indemnitees**") from and against any and all Losses resulting from any Claims against such Takeda Indemnitees to the extent arising out of or resulting from:
  - **12.2.1.** any breach of, or inaccuracy in, any representation or warranty made by Neurocrine in this Agreement, or any breach or violation of any covenant or agreement of Neurocrine in this Agreement,
  - **12.2.2.** the negligence or willful misconduct by or of Neurocrine or any of its Affiliates or Sublicensees, or any of their respective directors, officers, employees, or agents in the performance of Neurocrine's obligations or exercise of its rights under this Agreement,
  - **12.2.3.** the Exploitation of any Royalty-Bearing Product by or on behalf of Neurocrine or any of its Affiliates or Sublicensees, including the infringement of any Third Party Patent Right in the course of such Exploitation, and
  - 12.2.4. any action or failure to act [\*\*\*] (a "Safety or Recall Response Event").

Notwithstanding the foregoing, Neurocrine will have no obligation to indemnify the Takeda Indemnitees to the extent that the Losses arise out of or result from matters described under Section 12.1.1 or 12.1.2 (Indemnification by Takeda).

**12.3.** Third Party Losses for Profit-Share Products. Any Losses arising out of Claims arising from the Exploitation of any Profit-Share Product will initially be borne by Neurocrine, other than Losses arising out of (a) any breach of, or inaccuracy in, any representation or warranty made by a Party in this Agreement, or any breach or violation of any covenant or agreement of a Party in this Agreement, (b) the negligence or willful misconduct by or of a Party or any of its respective Affiliates or (in the case of Neurocrine) Sublicensees, or any of their respective directors, officers, employees, or agents in the performance of such Party's obligations or exercise of its rights under this Agreement, or (c) any Safety or Recall Response Event, and Takeda will reimburse its 50% share of such Losses within [\*\*\*] after receipt of invoice therefor from Neurocrine. Each Party will notify the other Party in writing promptly upon being notified of or having knowledge of any claim by a Third Party arising from the Exploitation of any Profit-Share Products) pursuant to Section 12.4 (Indemnification Procedure). Notwithstanding the foregoing, if either Party believes that any Losses arising out of Claims arising from the Exploitation of any Profit-Share Products) by the Parties because they are Losses described in the parenthetical of the first sentence of this Section 12.3 (Third Party Losses for Profit-Share Products), then [\*\*\*].

#### 12.4. Indemnification Procedure.

12.4.1. Notice. The Party entitled to indemnification under this Article 12 (Indemnification; Limitation of Liability; Insurance) (an "Indemnified Party") will notify the Party responsible for such indemnification (the "Indemnifying Party") in writing promptly upon being notified of or having knowledge of any claim or claims asserted or threatened against the Indemnified Party that could give rise to a right of indemnification under this Agreement; *provided* that the failure to give such notice will not relieve the Indemnifying

Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices the Indemnifying Party.

- **12.4.2. Indemnifying Party's Right to Defend**. The Indemnifying Party will have the right to defend, at its sole cost and expense, any such claim by all appropriate proceedings; *provided* that the Indemnifying Party may not enter into any compromise or settlement unless (a) such compromise or settlement imposes only a monetary obligation on the Indemnifying Party and which includes as an unconditional term thereof the giving by each claimant or plaintiff of the Indemnified Party a release from all liability in respect of such claim; or (b) the Indemnified Party consents to such compromise or settlement, which consent will not be unreasonably withheld unless such compromise or settlement involves (i) any admission of legal wrongdoing by the Indemnified Party, (ii) any payment by the Indemnified Party that is not indemnified under this Agreement, or (iii) the imposition of any equitable relief against the Indemnified Party (in which case, (i) through (iii), the Indemnified Party may withhold its consent to such settlement in its sole discretion).
- **12.4.3. Indemnified Party's Right to Defend**. If the Indemnifying Party does not elect to assume control of the defense of a claim, then the Indemnified Party will have the right, at the expense of the Indemnifying Party, upon at least [\*\*\*]' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party); *provided* that the Indemnified Party will keep the Indemnifying Party apprised of all material developments with respect to such claim. The Indemnified Party may not enter into any compromise or settlement without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld.
- **12.4.4. Cooperation**. The Indemnified Party will cooperate with the Indemnifying Party and may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 12.4 (Indemnification Procedure) and will bear its own costs and expenses with respect to such participation; *provided* that the Indemnifying Party will bear such costs and expenses if counsel for the Indemnifying Party reasonably determines that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party.
- **12.5. Limitation of Liability**. NEITHER PARTY WILL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT, OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, OR ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, INCLUDING LOST PROFITS (OTHER THAN, TO THE EXTENT THAT THE PARTIES ARE SHARING PROFITS, IN THE FORM OF DIRECT DAMAGES), REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES, EXCEPT FOR DAMAGES THAT ARISE AS A RESULT OF (A) A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, (B) A BREACH OF ARTICLE 10 (CONFIDENTIALITY AND PUBLICATION), OR (C) INFRINGEMENT, MISAPPROPRIATION, OR OTHER VIOLATION OF ANY TAKEDA TECHNOLOGY OR GRANTBACK IP (AS APPLICABLE). NOTHING IN THIS SECTION 12.5 (LIMITATION OF LIABILITY) IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT.
  - 59

12.6. **Insurance**. Neurocrine will obtain and maintain insurance during the Term and for a period of at least [\*\*\*] after the last commercial sale of any Licensed Product for any claims made policies, in an amount appropriate for its business and products of the type that are the subject of this Agreement and for its obligations under this Agreement. Specifically, Neurocrine will maintain (a) worker's compensation insurance with statutory limits in compliance with the worker's compensation laws of the state or states in which Neurocrine has employees in the United States (excluding Puerto Rico), (b) employer's liability coverage with a minimum limit of \$[\*\*\*] per occurrence; provided that Neurocrine has employees in the United States (excluding Puerto Rico), (c) [\*\*\*] with a minimum limit of \$[\*\*\*], and (d) [\*\*\*] with a minimum limit of [\*\*\*]. Beginning at least [\*\*\*] prior to the Initiation of a Clinical Trial, Neurocrine will obtain and maintain clinical trial insurance (either separately or as part of the general or product liability insurance). Beginning at least [\*\*\*] prior to the First Commercial Sale of Licensed Product, Neurocrine will obtain and maintain product liability insurance of \$[\*\*\*]. Upon request, Neurocrine will provide Takeda with evidence of the existence and maintenance of such insurance coverage. Neurocrine will notify Takeda [\*\*\*] in advance of cancelation of any such insurance. All such insurances under this Section 12.6 (Insurance) will be provided by a company or companies licensed to do business in United States having a financial rating of not less than A- Viii in the most current edition of Best's Key Rating Guide. Takeda will maintain, during the Term and for [\*\*\*] thereafter, at its own expense, insurance or self-insurance, as reasonably necessary to cover its own product liability and its obligations under this Agreement.

# 13. INTELLECTUAL PROPERTY

#### 13.1. Inventions.

- **13.1.1. Inventorship**. Ownership of Program Know-How and Program Patent Rights will be determined in accordance with United States patent Laws for determining inventorship. The Parties will jointly own any and all Joint Program Technology. Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party will be entitled to practice, license, assign, and otherwise practice under the Joint Program Technology without the duty of accounting or seeking consent from the other Party, and where consent is required, such consent is hereby given.
- **13.1.2. Disclosure**. Each Party will promptly disclose to the other Party all invention disclosures or other similar documents relating to Program Know-How made by or on behalf of such Party hereunder during the Term, in the case of Neurocrine as the disclosing Party, only for Program Know-How that Takeda requires to practice the license granted pursuant to Section 2.9 (License to Takeda), and all invention disclosures or other similar documents submitted to such Party by its or its Affiliates' employees, agents or independent contractors relating to such Program Know-How, and shall also respond promptly to reasonable requests from the other Party for additional information relating to such disclosures, documents or applications.
- **13.1.3. Personnel Obligations**. Each employee, agent, or independent contractor of a Party or its respective Affiliates performing work under this Agreement will, prior to commencing such work, be bound by written invention assignment obligations, including: (a) promptly reporting any invention, discovery, or other intellectual property right; (b) presently assigning to the applicable Party or Affiliate all of his or her right, title, and interest in and to any invention, discovery, or other intellectual property; (c) cooperating in the

preparation, filing, prosecution, maintenance and enforcement of any patent and patent application; and (d) performing all acts and signing, executing, acknowledging, and delivering any and all documents required for effecting the obligations and purposes of this Agreement. It is understood and agreed that such invention assignment agreement need not reference or be specific to this Agreement. Each Party will be solely responsible for any payments to inventors with an obligation to assign, or who do assign, their rights, title, and interests in and to any Program Know-How and Program Patent Rights to such Party. Takeda will be solely responsible for any other Takeda Patent Rights.

- **13.1.4.** Joint Research Agreement. This Agreement is a joint research agreement within the meaning of pre-AIA 35 U.S.C. § 103(c) and AIA 35 U.S.C. § 102(c).
- **13.2. Prosecution and Maintenance of Patent Rights**. The Parties will conduct the Prosecution and Maintenance of the applicable Patent Rights in accordance with this Section 13.2 (Prosecution and Maintenance of Patent Rights).

#### 13.2.1. Right to Prosecute Patent Rights.

a. Neurocrine's Right. Beginning on the Effective Date, as between the Parties, Neurocrine will have the first right (but not the obligation) to Prosecute and Maintain all (i) Takeda Patent Rights, (ii) Defensive Patent Rights, and (iii) Joint Program Patent Rights in the Territory and the sole right (but not the obligation) to Prosecute and Maintain (iv) the Neurocrine Sole Program Patent Rights (such Patent Rights in clauses (i), (ii), (iii), and (iv), collectively, the "Neurocrine Prosecuted Patent Rights"), in each case (clauses (i), (ii), (iii), and (iv)), using outside patent counsel agreed to by Takeda (such agreement not to be unreasonably withheld). During the period of a PSP P&L Share for a Profit-Share Product, the Parties will share the applicable Patent Costs incurred by Neurocrine for the Prosecution and Maintenance of the Neurocrine Prosecuted Patent Rights Covering any Profit-Share Product in accordance with Section 9.2.1 (Profit and Loss Share), and for any such Patent Rights that Cover any Royalty-Bearing Product, Neurocrine will bear all such Patent Costs. Neurocrine will bear the costs and expenses of all annuities and maintenance fees for Takeda Patent Rights and Defensive Patent Rights from and after the Effective Date, including the near-term annuities and maintenance fees set forth on Schedule 13.2.1(a) (Annuities and Maintenance Fees). Neurocrine will provide Takeda a reasonable opportunity to review and comment on material communications from any patent authority in the Territory regarding the Neurocrine Prosecuted Patent Rights, as well as drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Neurocrine will consider Takeda's comments regarding such communications and drafts in good faith. In addition, Neurocrine will provide Takeda with (A) copies of all final material filings and responses made to any Patent Office with respect to the Neurocrine Prosecuted Patent Rights in a timely manner following submission thereof, and (B) a report each Calendar Year detailing the status of all Neurocrine Prosecuted Patent Rights. Takeda will (1) promptly after the Effective Date provide to Neurocrine or counsel designated by Neurocrine the file histories for, and correspondence with foreign patent counsel related to, the Takeda Patent

Rights and Defensive Patent Rights, (2) provide to Neurocrine promptly after the Effective Date a report detailing the status of the Takeda Patent Rights and Defensive Patent Rights, and (3) provide all assistance reasonably requested by Neurocrine in Neurocrine's Prosecution and Maintenance of the Takeda Patent Rights, Defensive Patent Rights, and Program Patent Rights (including by executing all requested documents and providing additional information with respect to the applicable Patent Rights), *provided* that Neurocrine will be responsible for any reasonable costs and expenses paid to a Third Party relating to such assistance and transition of the Prosecution and Maintenance to Neurocrine of the Takeda Patent Rights and Defensive Patent Rights, and accordingly, Takeda will submit a reasonably detailed invoice to Neurocrine for any such costs and expenses incurred by Takeda in connection with such transition, along with reasonable documentation therefor, which undisputed invoiced amounts Neurocrine will pay no later than [\*\*\*] after its receipt of such invoice.

- b. Takeda's Right. If Neurocrine determines in its sole discretion to abandon, not to Maintain, or not to pursue the Prosecution of any Takeda Patent Right, Defensive Patent Right, or Joint Program Patent Right, then (i) Neurocrine will provide Takeda with written notice promptly after such determination to allow Takeda a reasonable period of time to determine, on a country-by-country basis, in its sole discretion, its interest in Prosecuting or Maintaining such Patent Rights in the Territory (which notice by Neurocrine will be given no later than [\*\*\*] prior to the final deadline for any pending action or response that may be due with respect to such Patent Right with the applicable Patent Office), and (ii) only in the event that such abandonment or decision not to Maintain or pursue the Prosecution of such Patent Rights (A) is not done for strategic reasons to improve the exclusivity position for, or revenue from, a Licensed Product and (B) applies with respect to all applications within a particular patent family in a particular country or jurisdiction, then such Patent Rights will no longer be included in the Takeda Technology subject to the licenses granted by Takeda to Neurocrine in Section 2.1 (License Grant to Neurocrine) in such country or jurisdiction. If Takeda provides written notice to Neurocrine expressing its interest in Maintaining such Patent Right, then, with respect to such Patent Right in such country in the Territory, (A) Takeda may, in its sole discretion and at Takeda's cost and expense, Prosecute and Maintain or abandon such Patent Right, and (B) Neurocrine will promptly: (1) provide to Takeda or counsel designated by Takeda the file histories for, and correspondence with foreign patent counsel related to, such Patent Right, (2) provide to Takeda a report detailing the status of such Patent Right as of the applicable date of such notice by Neurocrine, and (3) provide all assistance reasonably requested by Takeda in Takeda's Prosecution and Maintenance of the applicable Patent Rights (including by executing all requested documents and providing additional information with respect to the applicable Patent Rights).
- **13.3. Third Party Infringement and Defense**. The Parties will conduct the enforcement and defense of the applicable Patent Rights in accordance with this Section 13.3 (Third Party Infringement and Defense).

**13.3.1. Notices**. Each Party will promptly report in writing to the other Party any Competitive Infringement of which such Party (or any of its Affiliates or Sublicensees) becomes aware, and will provide the other Party with all available evidence of such Competitive Infringement in such Party's control.

## 13.3.2. Infringement Actions.

- a. **Neurocrine's Right**. As between the Parties, Neurocrine will have (i) the first right, but not the obligation, to bring an appropriate suit or other action to abate any existing, alleged, or threatened Competitive Infringement involving the Takeda Patent Rights, Defensive Patent Rights, or Joint Program Patent Rights, and (ii) the sole right, but not the obligation, to bring an appropriate suit or other action to abate any existing, alleged, or threatened Competitive Infringement involving the Neurocrine Sole Program Patent Rights.
- b. **Takeda's Right**. Neurocrine will notify Takeda of its decision as to whether to take any action in accordance with Section 13.3.2(a) (Neurocrine's Right) at least [\*\*\*] before any time limit set forth in an applicable Law or regulation, or within [\*\*\*] after being notified of such Competitive Infringement, whichever is shorter. If Neurocrine decides not to take such action with respect to any Takeda Patent Right, Defensive Patent Right, or Joint Program Patent Right, then Neurocrine will so notify Takeda in writing, and following discussion with Neurocrine and consideration in good faith of any rationale provided by Neurocrine as to why Neurocrine elected not to take such action, and Neurocrine's written consent (not to be unreasonably withheld) following consideration in good faith of any rationale provided by Takeda, Takeda will have the right, but not the obligation, to commence a suit or take action to enforce the applicable Takeda Patent Right, Defensive Patent Right, or Joint Program Patent Right to abate such Competitive Infringement in the Territory, by counsel of its own choice and at its own expense.
- c. Hatch-Waxman. Notwithstanding any provision to the contrary in this Agreement, should a Party receive a certification for a Licensed Product pursuant to the Hatch-Waxman Act, or its equivalent in a country other than the U.S., with respect to any activities under this Agreement in the Field, then such Party will immediately provide the other Party with a copy of such certification. For each Licensed Product, Neurocrine will have [\*\*\*] from the date on which it receives or provides a copy of such certification to provide written notice to Takeda ("H-W Suit Notice") whether Neurocrine will bring suit, at its expense, within a [\*\*\*] period from the date of such certification. Should such [\*\*\*] period expire without Neurocrine bringing suit or providing such H-W Suit Notice, then Takeda will be free to bring suit in its name (i) if such certification is with respect to U.S. patents or (ii) upon Neurocrine's written consent, not to be unreasonably withheld, if such certification is with respect to patents for any country other than the U.S. and there is at such time an ongoing suit or there may be in the future a suit regarding a certification for a Licensed Product pursuant to the Hatch-Waxman Act in the U.S..

- d. **Cooperation**. Each Party will provide to the Party enforcing any such rights under this Section 13.3.2 (Infringement Actions) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by applicable Law to pursue such action or providing the enforcing Party any reasonably requested documentation or other materials. The enforcing Party will keep the other Party regularly informed of the status and progress of such enforcement efforts, including providing the other Party a reasonable opportunity to comment on the enforcing Party's determination of litigation strategy and the filing of important papers to the competent court and the enforcing Party will consider such comments in good faith. If one Party elects to bring suit or take action against the Competitive Infringement, then the other Party will have the right, during or prior to commencement of the trial, suit, or action, to join any such suit or action at such other Party's own expense by counsel of its own choice, but such other Party will at all times reasonably cooperate with the Party bringing such action.
- e. **Expenses**. Subject to this Section 13.3.2(e) (Expenses) and Section 13.3.2(g) (Allocation of Proceeds), the enforcing Party will be responsible for all expenses arising from a suit or action against a Competitive Infringement. During the period of a PSP P&L Share for a Profit-Share Product, the Parties will share the applicable Patent Costs incurred by Neurocrine arising from a suit or action initiated by Neurocrine as the enforcing Party against a Competitive Infringement with respect to such Profit-Share Product in accordance with Section 9.2.1 (Profit and Loss Share) and with respect to any Royalty-Bearing Product, Neurocrine will bear all such Patent Costs. For the avoidance of doubt, the enforcing Party will not be responsible for the other Party's internal expenses (*e.g.*, FTEs) incurred as a result of the other Party's cooperation with the enforcement action as provided in this Section 13.3.2 (Infringement Actions).
- f. **Settlement**. Neither Party will settle any claim, suit, or action that it brought under this Section 13.3.2 (Infringement Actions) in a manner that could reasonably be expected to affect the other Party's rights or interests without the prior written consent of the other Party, which consent will not be unreasonably withheld.
- g. Allocation of Proceeds. If either Party recovers monetary damages from any Third Party in a suit in the Territory pursuant to this Section 13.3.2 (Infringement Actions) or any royalties from a license agreement with a Third Party related to any alleged Competitive Infringement, whether or not such damages or royalties result from the infringement of Neurocrine Prosecuted Patent Rights, such recovery will be allocated first to the reimbursement of any expenses incurred by each Party in such litigation, action, or license, and any remaining amounts will be split as follows: (i) with respect to Royalty-Bearing Products, (A) if Neurocrine brings the action, then [\*\*\*], and (B) if Takeda brings the action, [\*\*\*], and (ii) with respect to Profit-Share Products, all recoveries, net of any expenses that were not shared equally by the Parties, will be split 50% to Takeda and 50% to Neurocrine.

- **13.3.3. Defense**. As between the Parties, the Party controlling the Prosecution and Maintenance of any Patent Right under Section 13.2 (Prosecution and Maintenance of Patent Rights), will have the right (but not the obligation), at its sole discretion, to defend against a declaratory judgment action, *inter partes* review, opposition proceeding, interference, or other legal or administration action challenging any such Patent Right. If the Party controlling such Prosecution and Maintenance of Takeda Patent Rights, Defensive Patent Rights, or Joint Program Patent Rights under Section 13.2 (Prosecution and Maintenance of Patent Rights) does not defend such Patent Right under this Section 13.3.3 (Defense) within [\*\*\*], or elects not to continue any such defense (in which case it will promptly provide notice thereof to the other Party), then the other Party will have the right (but not the obligation), at its sole discretion, to defend any such Patent Right. Any awards or amounts received in defending any such action will be allocated between the Parties as provided in 13.3.2(g) (Allocation of Proceeds).
- **13.4. Patent Right Extensions**. Neurocrine will have the right to elect and file for patent term restoration or extension, supplemental protection certificate, or any of their equivalents with respect to Neurocrine Prosecuted Patent Rights in the Territory. Neurocrine will inform Takeda of any such decision. Neurocrine will be responsible for applying for any patent term extension. Upon the request by Neurocrine, Takeda will reasonably cooperate in the implementation of Neurocrine's decisions made pursuant to this Section 13.4 (Patent Right Extensions). During the period of a PSP P&L Share for a Profit-Share Product, the Parties will share the applicable Patent Costs incurred by Neurocrine in furtherance of such filing for such Profit-Share Product in accordance with Section 9.2.1 (Profit and Loss Share) and for any Royalty-Bearing Product, Neurocrine will bear all such Patent Costs.
- **13.5. Third Party Rights**. Notwithstanding anything in this Article 13 (Intellectual Property) to the contrary, the Parties' rights and obligations with respect to any Patent Right Controlled pursuant to a PSP In[License under this Article 13 (Intellectual Property) will be subject to the Third Party rights and obligations under any such applicable PSP In[License.
- **13.6. Orange Book Listing**. Neurocrine and Takeda will discuss in good faith the Takeda Patent Rights, Defensive Patent Rights, or Program Patent Rights that will be included in the Orange Book maintained by the FDA or similar or equivalent patent listing source, if any, in other countries in the Territory for Licensed Products, and, after considering Takeda's comments in good faith, Neurocrine will have the sole right to determine which Patent Rights will be included. Takeda will provide such assistance as may be reasonably requested by Neurocrine in connection with such listing.
- **13.7. Trademarks**. Neurocrine will have the right to brand Licensed Products using Neurocrine-related Trademarks and any other Trademarks it determines appropriate, which may vary by country or within a country. Neurocrine will own all rights in such Trademarks and shall have the sole right to register and maintain such Trademarks in the countries and regions that it determines, at Neurocrine's cost and expense.
- **13.8. Common Interest.** All information exchanged between the Parties regarding the Prosecution and Maintenance, defense, and enforcement, of the Patent Rights under this Article 13 (Intellectual Property) will be deemed Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such Prosecution and Maintenance, defense, and enforcement of the Patent Rights under this Article 13 (Intellectual
  - 65

Property), the interests of the Parties as licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights under this Article 13 (Intellectual Property), including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding any provision to the contrary contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Article 13 (Intellectual Property) is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

# 14. TERM AND TERMINATION

**14.1. Term**. This Agreement will be effective as of the Effective Date and, unless terminated earlier, will continue on a Licensed Productby-Licensed Product and country-by-country basis until the date on which, (a) for any Royalty-Bearing Product, the Royalty Term has expired in such country in the Territory; and (b) for any Profit-Share Product, for so long as Neurocrine continues to Exploit such Licensed Product (collectively, the "**Term**"). Upon expiration of the Royalty Term for a Licensed Product in any country in the Territory, the licenses granted from Takeda to Neurocrine in Section 2.1 (License Grant to Neurocrine) with respect to such Licensed Product, in such country will become fully paid, irrevocable, and perpetual.

## 14.2. Termination for Convenience.

- **14.2.1. Prior to First Commercial Sale**. Neurocrine may terminate this Agreement for convenience in its entirety or in one or more (but not all) of the Major Markets, *provided* that for purposes of this Section 14.2 (Termination for Convenience), [\*\*\*], on six months' written notice to Takeda (a) with respect to all Licensed Products prior to the First Commercial Sale of the first Licensed Product for which First Commercial Sale occurs in the Territory or the applicable Major Market(s), or (b) with respect to all Licensed Products in one or more given Target Classes prior to the First Commercial Sale of the first Licensed Product in such Target Class(es) for which First Commercial Sale occurs in the Territory or the applicable Major Market(s).
- **14.2.2.** After First Commercial Sale. Neurocrine may terminate this Agreement for convenience in its entirety or in one or more (but not all) of the Major Markets on 12 months' written notice to Takeda (a) with respect to all Licensed Products following the First Commercial Sale of the first Licensed Product for which First Commercial Sale occurs in the Territory or the applicable Major Market(s), or (b) with respect to all Licensed Products in one or more given Target Classes following the First Commercial Sale of the first Licensed Product in such Target Class(es) for which First Commercial Sale occurs in the Territory or the applicable Major Market(s):

# 14.3. Termination for Cause.

# **14.3.1.** Termination by Takeda.

- a. **Termination for Material Breach**. Takeda will have the right to terminate this Agreement upon delivery of written notice to Neurocrine in the event of any material breach of this Agreement by Neurocrine, solely with respect to the Target Class of a Licensed Product to which such material breach relates, or in its entirety in the event of any material breach of this Agreement by Neurocrine that relates to all Licensed Products, *provided* that such termination will not be effective if such breach has been cured within [\*\*\*] after written notice thereof is given by Takeda to Neurocrine specifying the nature of the alleged breach; *provided*, *however*, that (i) to the extent such material breach involves the failure to make a payment when due, such breach must be cured within [\*\*\*] after written notice thereof is given by Takeda to Neurocrine, and (ii) if such breach (other than a failure to make a payment when due) is capable of cure but is not reasonably capable of cure within such [\*\*\*] period, then Neurocrine may submit a reasonable cure plan prior to the end of such time period, in which case Takeda will not have the right to terminate this Agreement for so long as Neurocrine is using reasonable efforts to implement such cure, for a period not to exceed an additional [\*\*\*] from the end of the initial [\*\*\*] cure period.
- b. **Termination for Patent Challenge**. If Neurocrine or any of its Affiliates files, assists a Third Party in filing, or joins a Third Party in filing or maintaining, a Patent Challenge of any Patent Right Controlled by Takeda that Covers any Licensed Product, then Takeda may terminate this Agreement with respect to the Target Classes for all Licensed Products Covered by such Patent Right by providing written notice of such termination to Neurocrine. This Section 14.3.1(b) (Termination for Patent Challenge) will not apply to any such Patent Challenge that is first made by Neurocrine or any of its Affiliates in defense of a claim of patent infringement brought by Takeda under the applicable Patent Right, and with respect to any Sublicensee, Takeda will not have the right to terminate this Agreement under this Section 14.3.1(b) (Termination for Patent Challenge to be terminated or dismissed (or in the case of *ex parte* proceedings, multi-party proceedings, or other Patent Challenges in which Neurocrine does not have the power to unilaterally cause the Patent Challenge to be withdrawn, causes such Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge) or (ii) terminates such Sublicensee's sublicense to the Patent Rights being challenged by the Sublicensee, in each case, within [\*\*\*] of Takeda's notice to Neurocrine under this Section 14.3.1(b) (Termination for Patent Challenge).
- c. **Termination for Cessation of Development or Commercialization**. On a Target Class-by-Target Class basis, Takeda may, at its election, terminate this Agreement with respect to a Target Class upon [\*\*\*] prior written notice to Neurocrine in the event that Neurocrine, itself or together with or through any of its Affiliates or Sublicensees, does not conduct any Development or Commercialization activities with respect to any Licensed Product within such Target Class for a continuous period of more than [\*\*\*]. Notwithstanding any provision to the contrary set forth in this Section 14.3.1(c) (Termination for Cessation of Development or Commercialization), [\*\*\*].

- **14.3.2. Termination by Neurocrine**. Neurocrine will have the right to terminate this Agreement upon delivery of written notice to Takeda in the event of any material breach of this Agreement by Takeda solely with respect to the Target Class of a Licensed Product to which such material breach relates, or in its entirety in the event of any material breach of this Agreement by Takeda that relates to all Licensed Products, *provided* that such termination will not be effective if such breach has been cured within [\*\*\*] after written notice thereof is given by Neurocrine to Takeda specifying the nature of the alleged breach; *provided*, *however*, that (i) to the extent such material breach involves the failure to make a payment when due, such breach must be cured within [\*\*\*] after written notice thereof is given by Neurocrine to Takeda, and (ii) if such breach (other than a failure to make a payment when due) is capable of cure but is not reasonably capable of cure within such [\*\*\*] period, then Takeda may submit a reasonable cure plan prior to the end of such time period, in which case Neurocrine will not have the right to terminate this Agreement for so long as Takeda is using reasonable efforts to implement such cure, for a period not to exceed an additional [\*\*\*] from the end of the initial [\*\*\*] cure period.
- **14.3.3. Disputed Breach**. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 14.3.1(a) (Termination for Material Breach), Section 14.3.2 (Termination by Neurocrine), or Section 14.3.1(c) (Termination for Cessation of Development or Commercialization) and such alleged breaching Party provides the other Party notice of such Dispute within such applicable period, then the cure periods set forth in Section 14.3.1(a) (Termination for Material Breach), Section 14.3.2 (Termination by Neurocrine), or Section 14.3.1(c) (Termination for Cessation of Development or Commercialization), as applicable, will be tolled during the pendency of the dispute resolution process as set forth in Section 14.3.1(a) (Termination for Material Breach), Section 14.3.2 (Termination Breach), Section 14.3.2 (Termination by Neurocrine), or Section 14.3.1(c) (Terminate this Agreement under Section 14.3.1(a) (Termination for Material Breach), Section 14.3.2 (Termination by Neurocrine), or Section 14.3.1(c) (Termination for Cessation of Development or Commercialization) and the non-breaching Party will not have the right to terminate this Agreement under Section 14.3.1(a) (Termination for Material Breach), Section 14.3.2 (Termination by Neurocrine), or Section 14.3.1(c) (Termination for Cessation of Development or Commercialization), as applicable, unless and until such dispute resolution process has been completed (including the tolling and cure period set forth therein) and such process results in a determination that the alleged breaching Party has materially breached this Agreement and failed to cure such breach within the applicable time periods. During the pendency of such dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.
- **14.4.** Effects of Termination. Upon termination (but not expiration) of this Agreement in its entirety or on a Terminated Target Class-by-Terminated Target Class basis, as applicable, in each case, in accordance with Section 14.2 (Termination for Convenience) or Section 14.3 (Termination for Cause), all rights in the Licensed Products that are Terminated Products in the Terminated Territory will revert to Takeda, and the following will apply with respect to the Terminated Products in the Terminated Territory:
  - **14.4.1. Termination of Licenses.** As of the effective date of termination of this Agreement, all licenses granted under Article 2 (License Grant) with respect to the Terminated Products in the Terminated Territory will terminate, and all sublicenses granted by Neurocrine or its Affiliates pursuant to Section 2.2 (Sublicensing Terms) with respect to the Terminated Products in the Terminated Territory will also terminate, unless the applicable Sublicensee is not then in breach of its sublicense agreement or the terms of this
    - 68

Agreement applicable to such Sublicensee and elects in writing prior to such termination to be granted a direct license from Takeda under the terms of Section 14.4.5 (New License Agreements).

**14.4.2. Return of Confidential Information**. As soon as reasonably practicable after the effective date of termination of this Agreement, each Party will promptly destroy (and certify such destruction in writing) or return to the other Party all of such other Party's Confidential Information that relates specifically to a Terminated Product or the Terminated Territory, except that such Party will have the right to retain a copy of tangible Confidential Information of such other Party for legal archival purposes.

## 14.4.3. Intellectual Property License to Takeda.

- a. Effective upon any termination of this Agreement other than as provided in the following Section 14.4.3(b) (Intellectual Property License to Takeda), upon Takeda's request, Neurocrine will grant, and hereby does grant (which license shall be exercisable only upon the date that such termination becomes effective), to Takeda an irrevocable, perpetual license in the Field in the Terminated Territory, with the right to grant sublicenses (through multiple tiers), under [\*\*\*] ("**Grantback IP**"), [\*\*\*]:
  - i. [\*\*\*].
  - ii. [\*\*\*].
- b. Effective upon termination of this Agreement by Neurocrine pursuant to Section 14.3.2 (Termination by Neurocrine), upon Takeda's request, Neurocrine will grant, and hereby does grant (which license shall be exercisable only upon the date that such termination becomes effective), to Takeda a [\*\*\*] license in the Field in the Terminated Territory, with the right to grant sublicenses (through multiple tiers) under the Grantback IP to Exploit the Terminated Product in the form such product exists as of the applicable effective date of termination, [\*\*\*].
- c. To the extent any such Grantback IP is in-licensed or acquired by Neurocrine from a Third Party, [\*\*\*].
- d. [\*\*\*].
- e. The terms of Article 9 (Payments) will apply to the payment and reporting of any royalties described in this Section 14.4.3 (Intellectual Property License to Takeda), *mutatis mutandis*.
- **14.4.4. Trademarks for Terminated Products**. Effective upon any termination of this Agreement in all countries of the Territory, if, as of the effective date of termination, the Terminated Product has received Regulatory Approval in any country in the Territory, Neurocrine will assign and transfer (and if unable to assign and transfer, exclusively license) to Takeda any trademarks owned or Controlled by Neurocrine that identify such Terminated Product for the purpose of Commercializing such Terminated Product. If this Agreement is terminated with respect to one or more, but not all, countries in the Territory, then Neurocrine will grant an exclusive license to Takeda under any

trademarks in the Terminated Territory owned or Controlled by Neurocrine or its Affiliates or terminated Sublicensees that identify such Terminated Product for the purpose of Commercializing such Terminated Product in the Terminated Territory.

- **14.4.5.** New License Agreements. Upon termination of this Agreement for any reason with respect to Terminated Product and the Terminated Territory, [\*\*\*] (each a "New License Agreement"). Under any such New License Agreement [\*\*\*].
- **14.4.6.** Assignment of Agreements. Upon any termination of this Agreement and upon Takeda's request, Neurocrine will [\*\*\*] assign to Takeda any Third Party agreements pursuant to which Neurocrine then Controls any Patent Rights that Cover, or Know-How that relates to, a Terminated Product in the Terminated Territory, [\*\*\*]. [\*\*\*] If such a sublicense or other right is granted to Takeda, then Takeda will pay to Neurocrine [\*\*\*]% of all payments due to the applicable Third Party under any such Third Party agreement in consideration of such sublicense or other rights. [\*\*\*].
- **14.4.7. Assignment and Disclosure**. Upon termination of this Agreement, to the extent requested by Takeda following the date that a Party provides notice of termination of this Agreement (and in any event, no later than [\*\*\*] after the effective date of termination), Neurocrine will use reasonable efforts promptly upon request of Takeda to:
  - a. assign and transfer to Takeda or its designee all of Neurocrine's rights, title, and interests in and to all (i) clinical trial agreements (subject to Section 14.4.9 (Ongoing Clinical Trials)), manufacturing and supply agreements, distribution agreements, and other agreements to which Neurocrine is a party that relates to the Terminated Product and (ii) data from any applicable Clinical Trials in Neurocrine's Control, in each case, solely to the extent assignable without consent of, or the provision of consideration (whether monetary or otherwise) to, any Third Party and not cancelled and solely to the extent the foregoing relate exclusively to the Terminated Products in the Terminated Territory and are necessary for the Exploitation of the Terminated Products in the Terminated Territory; and
  - b. to the extent any agreement or data set forth in the foregoing clause (a) is not assignable to Takeda or does not exclusively relate to the Terminated Products in the Terminated Territory, reasonably cooperate with Takeda to arrange to continue to provide such services for a reasonable time after termination of this Agreement (not to exceed [\*\*\*]) with respect to such Terminated Products in the Terminated Territory to facilitate the orderly transition of all Development, Commercialization, and other activities then being performed by or on behalf of Neurocrine or its Affiliates or Sublicensees for the Terminated Products in the Terminated Territory to Takeda or its designee. Neurocrine will provide up to an aggregate (including such assistance provided pursuant to this Section 14.4.7(b) (Assignment and Disclosure), Section 14.4.11 (Know-How Transfer Support), and Section 14.4.14 (Transition Assistance)) of [\*\*\*] FTE hours of transition assistance per Terminated Product from Neurocrine FTEs at no cost to Takeda, up to a maximum of [\*\*\*] FTE hours in the aggregate for all Terminated Products, *provided* that Takeda will thereafter be responsible and reimburse Neurocrine for all documented FTE Costs at the FTE Rate and expenses

associated with such assistance in accordance with an agreed budget, and accordingly, Neurocrine may invoice Takeda for such FTE Costs and expenses, in each case, incurred in connection with providing such assistance in accordance with such budget, and Takeda will pay the undisputed invoiced amounts within [\*\*\*] after the date of such invoice.

Neurocrine will be responsible for the costs and expenses it incurs associated with the assignments set forth in this Section 14.4.7 (Assignment and Disclosure).

14.4.8. Assignment of Regulatory Documentation; Data. Upon termination of this Agreement in its entirety or with respect to Terminated Products in the Terminated Territory and upon Takeda's request, (a) Neurocrine will and hereby does, and will cause its Affiliates and applicable terminated Sublicensees to, assign and transfer to Takeda or its designee, at no cost to Takeda, all of Neurocrine's rights, title, and interest in and to all Regulatory Submissions, Regulatory Approvals, and Pricing Approvals for the Terminated Products in the Terminated Territory then Controlled by Neurocrine or any of its Affiliates or, as applicable, terminated Sublicensees, and (b) to the extent assignment pursuant to clause (a) is delayed or is not permitted by the applicable Regulatory Authority, permit Takeda to cross-reference and rely upon any Regulatory Submissions, Regulatory Approvals, and Pricing Approvals filed by Neurocrine with respect to such Terminated Products in the Terminated Territory. Upon Takeda's reasonable written request, Neurocrine will execute and deliver, or will cause to be executed and delivered, to Takeda or its designee such endorsements, assignments, commitments, acknowledgements, and other documents as may be necessary to assign, convey, transfer, and deliver to Takeda or its designee all of Neurocrine's or its applicable Affiliate's or designee's rights, title, and interests in and to all such assigned Regulatory Submissions, Regulatory Approvals, and Pricing Approvals, including submitting to each applicable Regulatory Authority or other Governmental Authority in the Terminated Territory a letter or other necessary documentation (with copy to Takeda) notifying such Regulatory Authority or other Governmental Authority of, or otherwise giving effect to, the transfer of ownership to Takeda of all such assigned Regulatory Submissions, Regulatory Approvals, and Pricing Approvals. In addition, upon Takeda's reasonable written request, Neurocrine will, (i) at its cost and expense, provide to Takeda copies of all material related documentation, including material non-clinical, preclinical, and clinical data related to the Terminated Products in the Terminated Territory that are then held by or reasonably available to Neurocrine or its Affiliates, provided that Neurocrine will have no obligation to provide copies of any such documentation to the extent previously received by Neurocrine from Takeda or provided from Neurocrine to Takeda or otherwise publicly available, and (ii) provide Takeda with reasonable assistance with any inquiries and correspondence with Regulatory Authorities regarding the Terminated Products. The Parties will discuss and establish appropriate arrangements with respect to safety data exchange.

# 14.4.9. Ongoing Clinical Trials.

a. **Transfer to Takeda**. Unless prohibited by any Regulatory Authority or applicable Law, at Takeda's written request, Neurocrine will transfer control of all Clinical Trials involving any Terminated Products being conducted only in the Terminated Territory by or on behalf of Neurocrine, its Affiliate, or applicable terminated Sublicensees as of the effective date of termination to Takeda or its

Affiliates or a Third Party that is designated in writing by Takeda. Neurocrine will continue to conduct such Clinical Trials, at Takeda's cost, to minimize interruption of any such Clinical Trials. Takeda will pay all external expenses incurred by either Party and all internal costs incurred by Neurocrine to complete such Clinical Trials if Takeda requests that such Clinical Trials be completed.

- b. **Neurocrine Wind-Down**. If Takeda does not elect to assume control of any such Clinical Trials, then Neurocrine will, in accordance with accepted pharmaceutical industry norms and ethical practices, wind-down any on-going Clinical Trials of Terminated Products in the Terminated Territory for which it has responsibility hereunder. Neurocrine will be responsible for any external expenses associated with such wind-down.
- **14.4.10.Appointment as Exclusive Distributor**. Upon any termination of this Agreement, if Neurocrine is Commercializing any Terminated Products in the Terminated Territory as of the applicable effective date of termination, then, upon Takeda's request (in its sole discretion) on a country-by-country basis and at Takeda's expense, until such time as all Regulatory Approvals with respect to such Terminated Products in such Terminated Territory have been assigned and transferred to Takeda, Neurocrine will appoint Takeda or its designee as its exclusive distributor of such Terminated Products in such Terminated Territory and grant Takeda or its designee the right to appoint sub-distributors, to the extent not prohibited by any written agreement between Neurocrine or any of its Affiliates and a Third Party.
- **14.4.11.Know-How Transfer Support**. Upon any termination of this Agreement, in furtherance of the license of Grantback IP pursuant to Section 14.4.3 (Intellectual Property License to Takeda), Neurocrine will, for a period of [\*\*\*] from the effective date of such termination, provide a reasonable amount of consultation or other assistance, as Takeda may reasonably request to assist Takeda in becoming familiar with such Grantback IP in order for Takeda to undertake further Exploitation of the Terminated Products in the Terminated Territory. Neurocrine will provide assistance and the Parties will bear costs of such assistance as set forth in Section 14.4.7(b) (Assignment and Disclosure).
- **14.4.12.Inventory**. Upon any termination of this Agreement with respect to the Terminated Products in the Terminated Territory, upon Takeda's request, Neurocrine will transfer to Takeda or its designee some or all inventory of the Terminated Products (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or Control of Neurocrine or its Affiliates or applicable terminated Sublicensees; *provided* that Takeda will pay Neurocrine [\*\*\*].
- **14.4.13.Wind-Down**. Upon termination of this Agreement, Neurocrine will either, as directed by Takeda, (a) wind-down any ongoing activities with respect to the Terminated Products for the Terminated Territory in an orderly fashion, or (b) transfer such activities to Takeda or its designee in accordance with this Section 14.4 (Effects of Termination) in an orderly fashion and in compliance with all applicable Laws.
- **14.4.14.Transition Assistance**. Upon any termination of this Agreement, upon Takeda's request, Neurocrine will use reasonable efforts to seek an orderly transition of the Development
  - 72

and Commercialization of the Terminated Products in the Terminated Territory to Takeda or its designee, for so long as is necessary to ensure patient safety, including ensuring continuity of supply to any patients, but in no event for longer than [\*\*\*] from the effective date of termination. Neurocrine will provide such assistance and the Parties will bear the costs of such assistance as set forth in Section 14.4.7(b) (Assignment and Disclosure).

**14.5. Survival**. In addition to the termination consequences set forth in Section 14.4 (Effects of Termination), the following provisions will survive the expiration or termination of this Agreement for any reason: all of Article 1 (Definitions), Section 2.8 (No Other Rights and Retained Rights), Section 4.4 (Scientific Records) (to the extent consistent with the applicable Party's record retention policies and applicable Law), Section 6.5 (Recalls, Market Withdrawals, or Corrective Actions), Article 9 (Payments) (solely with respect to amounts accrued prior to termination but not paid and the reporting and information sharing procedures associated therewith), Article 10 (Confidentiality and Publication), Article 12 (Indemnification; Limitation of Liability; Insurance), Section 13.1 (Inventions), Section 13.8 (Common Interest), Section 14.1 (Term) (solely in case of expiration), this Section 14.5 (Survival), and Article 16 (Miscellaneous). Expiration or termination of this Agreement for any reason will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity, with respect to any breach of this Agreement.

# **15. EFFECTIVENESS**

**15.1. Effective Date**. Except for the Parties' obligations under Article 10 (Confidentiality and Publication) and this Article 15 (Effectiveness), which will be effective as of the Execution Date, this Agreement will not become effective until the first Business Day after the Antitrust Clearance Date (the "**Effective Date**"); *provided* that the Effective Date will not occur if either Party exercises its termination right under Section 15.3 (Outside Date) prior to the Antitrust Clearance Date.

## 15.2. Filings.

**15.2.1.** Each Party will, within [\*\*\*] following the Execution Date, file the notification and report forms required under the HSR Act. The Parties will use reasonable efforts to cooperate with one another to the extent necessary in the preparation and execution of all such documents that are required to be filed pursuant to the HSR Act. Each Party will be responsible for its own costs and expenses associated with any such filing pursuant to the HSR Act. The Parties will each use reasonable efforts to ensure that any applicable waiting period under the HSR Act expires or is terminated as soon as practicable and to obtain any necessary approvals or consents under any applicable Antitrust Laws, at the earliest possible date after the date of filing. Notwithstanding any provision to the contrary set forth in this Agreement, nothing in this Agreement (including this Section 15.2 (Filings)) will require either Party or any of its Affiliates to (a) disclose to the other Party or any of its Affiliates any information that is subject to obligations of confidentiality or non-use owed to Third Parties (nor will either Party be required to conduct joint meetings with any Governmental Authority in which such information might be shared with the other Party) in connection with any Antitrust Filing, (b) commit to any consent decree or similar undertaking, or any divestiture, license (in whole or in

part), or any arrangement to hold separate (or any similar arrangement) with respect to any of its products or assets, or (c) litigate.

- **15.2.2.** In furtherance of the foregoing, each Party shall consult and cooperate with the other Party, including: (a) promptly notify the other of, and if in writing, furnish the other with copies of, any communications from or with any Governmental Authority with respect to this Agreement; (b) permit the other to review and discuss in advance, and consider in good faith the view of the other in connection with, any proposed substantive written or oral communication with any Governmental Authority; (c) not participate in any substantive meeting or have any substantive communication with any Governmental Authority unless it has given the other Party a reasonable opportunity to consult with it in advance and, to the extent permitted by such Governmental Authority, gives the other the opportunity to attend; (d) furnish the other Party's outside legal counsel with copies of all filings and communications between it and any such Governmental Authority with respect to this Agreement; provided, however, that such material may be redacted as necessary to (i) comply with contractual arrangements, (ii) address legal privilege concerns and (iii) comply with applicable Law; and (e) furnish the other Party's outside legal counsel with such necessary information and reasonable assistance as the other Party's outside legal counsel may reasonably request in connection with its preparation of necessary submissions of information to any such Governmental Authority. The Parties may, as they deem advisable and necessary, designate any competitively sensitive materials provided to the other under this Section 15.2 (Filings) as "outside counsel only." Such materials and the information contained therein shall be given only to outside counsel and outside economic consultants of the recipient and will not be disclosed by such outside counsel or outside economic consultants to employees, officers, or directors of the recipient without the advance written consent of the Party providing such materials. Notwithstanding anything to the contrary in this Section 15.2 (Filings), materials provided to the other Party or its outside legal counsel may be redacted to remove references concerning the valuation of the Licensed Assets.
- **15.3. Outside Date**. This Agreement will terminate at the election of either Party, immediately upon written notice to the other Party, in the event that the Antitrust Clearance Date will not have occurred on or prior to 120 days after the Execution Date and the Parties have not agreed in writing to extend the Antitrust Clearance Date. In the event of such termination, this Agreement will be of no further force and effect.

# 16. MISCELLANEOUS

- **16.1.** Assignment. Except as provided in this Section 16.1 (Assignment), this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the written consent of the other Party. Notwithstanding the foregoing, either Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part (a) to an Affiliate, *provided* that if the entity to which this Agreement is assigned ceases to be an Affiliate of the assigning Party, this Agreement will be automatically assigned back to the assigning Party or its successor, or (b) to a party that acquires, by or otherwise in connection with a merger, sale of assets, or otherwise, all or substantially all of the business of the assigning Party to which the subject matter of this Agreement relates. The assigning Party will remain responsible for the performance by its
  - 74

assignee of any obligation hereunder so assigned. Any purported assignment in violation of this Section 16.1 (Assignment) will be null, void, and of no legal effect.

**16.2. Governing Law**. This Agreement will be construed and the respective rights of the Parties determined in accordance with the substantive Laws of the State of New York, notwithstanding any provisions of New York Laws or any other Laws governing conflicts of laws to the contrary, and the patent Laws of the relevant jurisdiction without reference to any rules of conflicts of laws to the contrary.

## 16.3. Dispute Resolution.

**16.3.1.** Exclusive Dispute Resolution Mechanism. The Parties agree that, except as expressly set forth in this Agreement (including under Section 8.4.2 (Final Decision-Making Authority), and Section 14.4.3 (Intellectual Property License to Takeda)), the procedures set forth in this Section 16.3 (Dispute Resolution) will be the exclusive mechanism for resolving any dispute, controversy, or claim between the Parties arising out of or relating to this Agreement (whether based on contract, tort or otherwise) (each, a "Dispute," and collectively, the "Disputes").

### 16.3.2. Resolution by Executive Officers. [\*\*\*].

- **16.3.3.** Litigation. With the exception of legal actions, proceedings or claims described in Sections 16.3.4 (Preliminary Injunctions) and 16.3.5 (Patent and Trademark Disputes) below, any legal action or proceedings to resolve a Dispute that was subject to and not resolved under Section 16.3.2 (Resolution by Executive Officers) will be brought exclusively in a court of competent jurisdiction, federal or state, located in New York, New York, and in no other jurisdiction. Each Party hereby irrevocably consents to personal jurisdiction and venue in, and irrevocably agrees to service of process issued or authorized by, any such court in any such action or proceeding. The Parties hereby irrevocably waive any objection which they may now have or hereafter have to the laying of venue in the federal or state courts of New York in any such action or proceeding, and hereby irrevocably waive and agree not to plead or claim in any such court that any such action or proceeding brought in an inconvenient forum. The Parties hereby agree that any final judgment rendered by any such federal or state court of New York in any action or proceeding involving any Dispute, from which no appeal can be or is taken, may be enforced by the prevailing Party in any court of competent jurisdiction.
- **16.3.4. Preliminary Injunctions**. Notwithstanding any provision to the contrary set forth in this Agreement, in the event of an actual or threatened breach of a Party's covenants or obligations under this Agreement, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis.
- **16.3.5. Patent and Trademark Disputes**. Notwithstanding anything to the contrary set forth in this Agreement, any and all issues regarding the scope, construction, validity, and enforceability of any Patent Right or Trademark relating to a Licensed Product will be determined in a court or other tribunal, as the case may be, of competent jurisdiction
  - 75

under the applicable patent or trademark laws of the country in which such Patent Rights or Trademarks were granted or arose.

- **16.3.6. Confidentiality**. Any and all activities conducted under this Section 16.3 (Dispute Resolution), including any and all proceedings and decisions hereunder, will be deemed Confidential Information of each of the Parties, and will be subject to Article 10 (Confidentiality and Publication), to the extent permitted in accordance with applicable Law.
- **16.4.** Entire Agreement; Amendments. This Agreement, including its Schedules, contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes all previous arrangements with respect to the subject matter hereof, whether written or oral. In the event of any inconsistency between any Co-Funded Development Plan, Co-Funded Commercialization Plan, or Co-Funded Medical Affairs Plan and this Agreement, in each case, the terms of this Agreement will prevail. This Agreement may be amended, or any term hereof modified or waived, only by a written instrument duly[]executed by authorized representatives of both Parties.
- **16.5. Severability**. If any provision hereof is held invalid, illegal, or unenforceable in any respect in any jurisdiction, then the Parties will negotiate in good faith to promptly substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that most closely effectuate the original economic intent of the Parties. In case such valid provisions cannot be agreed upon, the invalid, illegal, or unenforceable nature of one or several provisions of this Agreement will not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal, or unenforceable provisions.
- **16.6. Headings**. The captions to the Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Sections hereof.
- **16.7. 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 will be construed against the drafting Party will not apply.
- **16.8. Interpretation**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation" and will not be interpreted to limit the provision to which it relates; (c) the word "will" will be construed to have the same meaning and effect as the word "shall"; (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (e) any reference herein to any Person will be construed to include the Person's successors and

assigns; (f) the words "herein," "hereof," and "hereunder," and words of similar import, will be construed to refer to this Agreement in its entirety, as the context requires, and not to any particular provision hereof; (g) all references herein to Sections or Schedules will be construed to refer to sections or schedules of this Agreement, and references to this Agreement include all Schedules hereto; (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; (i) provisions that require that a Party, the Parties, or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e[mail and instant messaging); (j) references to any specific law, rule, or regulation, or article, section, or other division thereof; (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or" unless preceded by the word "either" or other language indicating the subjects of the conjunction are, or are intended to be, mutually exclusive; and (l) unless otherwise specified, "day" means a calendar day.

- **16.9. No Implied Waivers; Rights Cumulative**. No failure on the part of Neurocrine or Takeda to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at Law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege, or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.
- **16.10.** Notices. All notices which are required or permitted hereunder will be in writing and sufficient if delivered personally, sent by email with confirmation of receipt, sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Neurocrine, to:

Neurocrine Biosciences, Inc. 12780 El Camino Real San Diego, CA 92130 Attention: Chief Business Development and Strategy Officer Email: [\*\*\*]

With a copy (which will not constitute notice) to:

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

Cooley LLP and a copy (which will not constitute notice) to: 4401 Eastgate Mall San Diego, CA 92121 Attention: Jason Kent Email: [\*\*\*] If to Takeda, to: Takeda Pharmaceutical Company Limited 1-1, Doshomachi 4-Chome, Chuo-ku Osaka 540-8645, Japan Attention: General Manager, Global Business Development Takeda Pharmaceutical Company Limited With a copy (which will not constitute notice) to: 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan Attention: Head of IP Licensing & R&D Contract, Japan Legal Millennium Pharmaceuticals, Inc. 40 Landsdowne Street Cambridge, MA 02139 Attention: Head of the Center for External Innovation **Ropes & Grav LLP** Prudential Tower 800 Boylston Street Boston, MA 02199[]3600 Attention: David M. McIntosh Email: [\*\*\*]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) when delivered if personally delivered on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) when sent if sent by email on a Business Day (or if sent on a non-Business Day, then on the next Business Day); (c) on the Business Day of receipt if sent by overnight courier; or (d) on the Business Day of receipt if sent by mail.

- **16.11. Compliance with Export Regulations**. Neither Party will export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export Laws and regulations.
- **16.12.** Force Majeure. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in achieving any objective, satisfying any condition, or performing any obligation under this Agreement to the extent that such failure or delay is caused by or results from acts or events beyond the reasonable control of such Party, including acts of God, embargoes, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotions, strikes, lockouts, or other labor disturbances (other than strikes, lockouts, or labor disturbances involving a Party's own employees), government actions, fire, earthquakes, floods, epidemics, pandemics, the spread of infectious diseases, and quarantines ("Force Majeure"). The Parties agree the effects of the COVID-19

pandemic that is ongoing as of the Effective Date (including related government orders) may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing and those effects may be reasonably foreseeable (but are not known for certain) as of the Effective Date. In addition, a Force Majeure may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to any epidemic, pandemic, or spread of infectious disease (including the COVID-19 pandemic), or other Force Majeure event, such as requiring employees to stay home, closures of facilities, delays of Clinical Trials, or cessation of activities in response to an epidemic or other Force Majeure event. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder due to any such Force Majeure circumstances affecting such Party. The affected Party will notify the other Party in writing of any Force Majeure circumstances that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon a reasonably practicable under the circumstances. If the Force Majeure circumstance continues, then, to the extent reasonably possible under the circumstances, the affected Party will update such written notice to the other Party on a bi-weekly basis, or more frequently if requested by the other Party, to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume.

- **16.13. Independent Parties**. It is expressly agreed that Neurocrine and Takeda will be independent contractors and that, except as otherwise required by applicable Law, the relationship between Neurocrine and Takeda will not constitute a partnership (including for U.S. federal Tax purposes), joint venture, or agency. Neurocrine will not have the authority to make any statements, representations, or commitments of any kind, or to take any action, that will be binding on Takeda, without the prior written consent of Takeda, and Takeda will not have the authority to make any statements, representations, or commitments of any kind, or to take any action, that will be binding on Takeda, without the prior written consent of Takeda, and Takeda will not have the authority to make any statements, representations, or commitments of any kind, or to take any action, that will be binding on Neurocrine, without the prior written consent of Neurocrine. The Parties (and any successor, assignee, transferee, or Affiliate of a Party) will not treat or report the relationship between the Parties arising under this Agreement as a partnership for United States tax purposes to the extent reasonably permitted based upon advice of the applicable Party's tax return preparer.
- **16.14. Further Assurances**. The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Agreement, and will (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.
- **16.15. Performance by Affiliates**. Each Party acknowledges and accepts that the other Party may exercise its rights and perform its obligations (including granting or continuing licenses and other rights) under this Agreement either directly or through one or more of its Affiliates. A Party's Affiliates will have the benefit of all rights (including all licenses and other rights) of such Party under this Agreement. Accordingly, in this Agreement "Takeda" will be interpreted to mean "Takeda or its Affiliates" and "Neurocrine" will be interpreted to mean "Neurocrine or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to such Party in this Agreement and the ability to perform its obligations (including granting or
  - 79

continuing licenses and other rights) under this Agreement; *provided, however*, that in any event each Party will remain responsible for the acts and omissions, including financial liabilities, of its Affiliates.

- **16.16. Binding Effect; No Third Party Beneficiaries**. As of the Effective Date, this Agreement will be binding upon and inure to the benefit of the Parties and their respective permitted successors and permitted assigns. Except as expressly set forth in this Agreement, no Person other than the Parties and their respective Affiliates and permitted assignees hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.
- **16.17. Counterparts**. This Agreement may be executed in two or more counterparts, including by facsimile or PDF signature pages, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

[THE REMAINDER OF THIS PAGE HAS BEEN LEFT INTENTIONALLY BLANK]

IN WITNESS WHEREOF, the Parties have caused this Exclusive License Agreement to be executed by their duly authorized representatives as of the Execution Date.

# TAKEDA PHARMACEUTICAL COMPANY LIMITED

BY: <u>/s/ Kentaro Kume</u>

- NAME: Kentaro Kume
- TITLE: <u>Head of R&D Partnership Office Asia Pacific</u>

[Signature Page to Exclusive License Agreement]

IN WITNESS WHEREOF, the Parties have caused this Exclusive License Agreement to be executed by their duly authorized representatives as of the Execution Date.

# **NEUROCRINE BIOSCIENCES, INC.**

BY: <u>/s/ Kevin Gorman</u>

NAME: Kevin Gorman

TITLE: <u>CEO</u>

[Signature Page to Exclusive License Agreement]

# SCHEDULE 1.45

# **DEFENSIVE PATENT RIGHTS**

### **SCHEDULE 1.89**

# LICENSED ASSETS

Licensed Asset	Mechanism of Action	
Phase II Asset		
TAK-831	DAAO inhibitor	
Phase I Assets		
TAK-653	AMPA potentiator	
TAK-041	GPR139 agonist	
Nonclinical Assets		
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	

## SCHEDULE 1.188

# TAKEDA KNOW-HOW

Structure-activity relationship data and *in vitro* and *in vivo* data for the following chemical series:

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

#### **SCHEDULE 2.7**

#### TRANSFERRED INVENTORY

Unless otherwise agreed by the JSC, Neurocrine will have [\*\*\*] from the Effective Date (a) to negotiate an agreement with a qualified vendor for purposes of the transfer and storage of inventory of Licensed Product and (b) notify Takeda in writing as to the location of such qualified vendor to which Takeda should transfer inventory of each Licensed Asset. Unless otherwise agreed by the JSC, Takeda will complete the transfer to Neurocrine's qualified vendor (i) no later than [\*\*\*] after the later of completion of the Ongoing Phase II Activities and Takeda's receipt of the notice described in the foregoing clause (b), with respect to inventory of all other Licensed Product held inventory by Takeda. For each day after such applicable [\*\*\*] period that Neurocrine has not notified Takeda that it has in place a qualified vendor by providing the notice described in clause (b), Takeda may, starting from [\*\*\*] after the Effective Date (other than with respect to the transfer of Phase II Assets, for which Takeda may not provide an invoice until [\*\*\*] after the completion of the Ongoing Phase II Activities, invoice Neurocrine for any storage fees incurred by or on behalf of Takeda to store such inventory of Licensed Products, and Neurocrine will pay the undisputed invoiced amounts within [\*\*\*] after the date of such invoice.

# SCHEDULE 4.1.1

# Preliminary Co-Funded Development Plan

# SCHEDULE 4.2.3(d)

# Phase II ONGOING Activities PLAN AND BUDGET

# **SCHEDULE 5.2.3**

# **REGULATORY SUBMISSIONS DATES**

### SCHEDULE 9.2.1

# PROFIT AND LOSS SHARE

This Schedule 9.2.1 to the Agreement covers financial planning, accounting policies and procedures to be followed in determining the Operating Profits or Losses and each of the Parties' PSP P&L Share.

1. [\*\*\*].

	[***]	[ <u>***</u> ]
[***]		
[***]		
[***]		
[***]		
[***]		
[***]		
[***]		
[***]		
[***]		

### **SCHEDULE 9.4.1**

# WIRE INSTRUCTIONS

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

#### SCHEDULE 10.2.3

### JOINT PRESS RELEASE

[Attached]





# News Release

[\*\*\*]

Neurocrine Biosciences and Takeda Announce Collaboration to Develop and Commercialize Potential Therapies for Psychiatric Disorders

- Strategic partnership agreement provides Neurocrine Biosciences exclusive worldwide rights to early-to-mid-stage psychiatry pipeline compounds within Takeda's Neuroscience portfolio
- Collaboration includes three clinical-stage assets with the most advanced molecule in Phase II for negative symptoms of schizophrenia
- Takeda retains ability to opt in or out of a 50:50 profit share on all clinical programs at certain development events

**SAN DIEGO and Osaka, Japan, June 10, 2020** – Neurocrine Biosciences, Inc. (Nasdaq: NBIX) and Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) ("Takeda") today announced a strategic collaboration to develop and commercialize compounds in Takeda's early-to-mid-stage psychiatry pipeline. Specifically, Takeda granted an exclusive license to Neurocrine Biosciences for seven pipeline programs, including three clinical stage assets for schizophrenia, treatment-resistant depression and anhedonia.

"We are excited to collaborate with Takeda to bring life-changing therapies to people living with serious, challenging and under-addressed psychiatric disorders who are in need of better treatment options," said Kevin Gorman, Ph.D., Chief Executive Officer at Neurocrine Biosciences. "With our deep understanding in the fields of psychiatry and neurology, we look forward to developing new treatments for schizophrenia, treatment-resistant depression and anhedonia as part of our diverse clinical development pipeline. This strategic partnership enhances our growing pipeline and strengthens our position as a leading neuroscience-focused biopharmaceutical company."

"With longstanding experience developing and commercializing therapies for serious neurological and psychiatric disorders, Neurocrine Biosciences is the ideal partner to continue to develop our early-to-mid-stage psychiatry portfolio and bring these potential new therapies to patients," said Sarah Sheikh, M.D., M.Sc., MRCP, Head, Neuroscience Therapeutic Area Unit at Takeda. "Takeda is deeply committed to Neuroscience as one of our core therapeutic areas. The strategic partnership with Neurocrine Biosciences allows us to continue to build on our leadership in psychiatry and deliver future medicines for these patients while advancing our clinical assets for rare neurological diseases, such as narcolepsy, developmental and epileptic encephalopathies and neurodegenerative conditions."

#### **Collaboration Details**

Under the terms of the agreement, Neurocrine Biosciences will be responsible for developing and commercializing all pipeline compounds included in the collaboration. Takeda will receive a total of \$120 million USD in upfront cash. Additionally, Takeda will be entitled to development milestones of up to \$495 million USD, commercial milestones of up to \$1.4 billion USD and up to double-digit royalties on net sales. At certain development events, Takeda may elect to opt in or out of a 50:50 profit share on all clinical programs on an asset-by-asset basis. For any asset in which Takeda is participating in a 50:50 profit share arrangement, Takeda will not be eligible to receive development or commercial milestones.

### **Conference Call Information**

Today, Neurocrine Biosciences will host a conference call and webcast at 8:00 a.m. ET to provide commentary on the collaboration. The live call may be accessed by dialing (877) 830-2586 (U.S.) or (785) 424-1734 (International) using the conference ID: 6249. A live audio webcast of the conference call will be available online on the Neurocrine Bioscience website under Investors at www.neurocrine.com. A replay of the webcast will be available on the website approximately one hour after the conclusion of the event and will be archived for approximately one month.

#### About Programs in the Collaboration Agreement

#### TAK-831

TAK-831 is a potential first-in-class D-Amino Acid Oxidase (DAAO) inhibitor that has completed multiple Phase I studies and is currently in on-going Phase II studies including the Phase II INTERACT proof-of-concept study in negative symptoms of schizophrenia.

#### **TAK-653**

TAK-653 is a potential first-in-class Alpha-Amino-3-Hydroxy-5-Methyl-4-Isoxazole Propionic Acid (AMPA) potentiator. TAK-653 has completed Phase I studies and is a Phase II study-ready compound with the potential to be developed for treatment-resistant depression.

#### **TAK-041**

TAK-041 is a potential first-in-class G Protein-Coupled Receptor 139 (GPR139) agonist. TAK-041 has completed multiple Phase I studies and is a Phase II study-ready compound with the potential to be developed for the treatment of anhedonia in depression. Anhedonia is a psychological condition characterized by the inability to experience pleasure.

#### **Preclinical Programs**

The collaboration includes the rights to four preclinical programs.

#### **About Neurocrine Biosciences**

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with 28 years of experience discovering and developing lifechanging treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, Parkinson's disease endometriosis\* and uterine fibroids\* and clinical development programs in multiple therapeutic areas including a gene therapy for Parkinson's disease, chorea in Huntington disease, congenital adrenal hyperplasia, epilepsy and polycystic ovary syndrome\*. Headquartered in San Diego, Neurocrine Biosciences specializes in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit neurocrine.com, and follow the company on LinkedIn. (\*in collaboration with AbbVie)

#### Takeda's Commitment to Neuroscience

Takeda's Neuroscience therapeutic area is driven by the immense unmet need of patients suffering from neurological diseases. Our mission is to bring innovative and potentially disease-modifying medicines to these patients. Our commitment to patients extends beyond our research and development efforts by supporting several neuroscience patient and provider organizations to raise awareness, educate and broaden access to therapies.

#### About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing Better Health and a Brighter Future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Diseases, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries. For more information, visit https://www.takeda.com.

#### **Neurocrine Biosciences Forward-Looking Statements**

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements related to the benefits to be derived from transactions with Takeda Pharmaceutical Company Limited; our potential milestone and royalty payments to Takeda; the development of our product candidates and the timing of completion of our clinical, regulatory, and other development activities. 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 the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risks and uncertainties related to any COVID-19 quarantines, shelter-in-place and similar government orders that are currently in place or that may be put in place in the future, including the impact of such orders on our business operations and the business operations of the third parties on which we rely; our future financial and operating performance; risks or uncertainties related to the development of the our product candidates; risks that the FDA or other regulatory authorities may make adverse decisions regarding our product candidates; risks that clinical development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for a product candidate; risks that the benefits of the agreements with Takeda may never be realized; risks that our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and other risks

described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2020. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

#### **Takeda Pharmaceutical Company Limited Forward-Looking Statements**

This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda's future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as "targets", "plans", "believes", "hopes", "continues", "expects", "aims", "intends", "ensures", "will", "may", "should", "would", "could" "anticipates", "estimates", "projects" or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda's global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations; the success of or failure of product development programs; decisions of regulatory authorities and the timing thereof; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda's operations and the timing of any such divestment(s); and other factors identified in Takeda's most recent Annual Report on Form 20-F and Takeda's other reports filed with the U.S. Securities and Exchange Commission, available on Takeda's website at: https://www.takeda.com/investors/reports/sec-filings/ or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda's future results.

###

#### **Contacts:**

Neurocrine Biosciences, Inc. Takeda Pharmaceuticals

# SCHEDULE 11.2.1

# TAKEDA PATENT RIGHTS

# SCHEDULE 11.2.2

# TAKEDA TECHNOLOGY

# SCHEDULE 11.2.4

# **OWNERSHIP OF TAKEDA TECHNOLOGY**

# SCHEDULE 11.4.4

# DOMAIN NAMES

Domain	Registrant
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

# SCHEDULE 13.2.1(a)

# ANNUITIES AND MAINTENANCE FEES

# SCHEDULE 14.4.3

# [\*\*\*] DISPUTE RESOLUTION

#### 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: August 3, 2020

/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: August 3, 2020

/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 June 30, 2020 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.

August 3, 2020

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 June 30, 2020 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.

August 3, 2020

By:/s/ Matthew C. AbernethyName:Matthew C. AbernethyTitle:Chief Financial Officer