UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

For the transition period from_____to_____

Commission file number: 0-22705

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0525145**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
12780 El Camino Real, San Diego, CA	**92130**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value	The Nasdaq Stock Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

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. (Check one):

Large accelerated filer	☑	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. ☐

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

The aggregate market value of the common equity held by non-affiliates of the registrant as of June 30, 2018 totaled approximately $7,461,776,662 based on the closing price for the registrant's Common Stock on that day as reported by the Nasdaq Stock Market. Such value excludes Common Stock held by executive officers, directors and 10% or greater stockholders as of June 30, 2018. The identification of 10% or greater stockholders as of June 30, 2018 is based on applicable Schedule 13G and amended Schedule 13G reports. This calculation does not reflect a determination that such parties are affiliates for any other purposes.

As of February 1, 2019, there were 90,821,267 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	**10-K Part**
Portions of the registrant's notice of annual meeting of stockholders and proxy statement to be filed pursuant to Regulation 14A within 120 days after registrant's fiscal year end of December 31, 2018 are incorporated by reference into Part III of this report	III

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INGREZZA® is a registered trademark of Neurocrine Biosciences, Inc. Any other brand names or trademarks appearing in this Annual Report that are not the property of Neurocrine Biosciences, Inc. are the property of their respective holders.

PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the information incorporated herein by reference contain 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,” “pro forma,” 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,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” 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 1. *BUSINESS*

Overview

We were originally incorporated in California in January 1992 and reincorporated in Delaware in May 1996. We are a company focused on discovering, developing, and commercializing innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through our novel research and development (R&D) platform, focused on neurological and endocrine related diseases and disorders. Utilizing a portfolio approach to drug discovery, we have multiple small molecule drug candidates at various stages of pharmaceutical development. We develop proprietary pharmaceuticals for our pipeline, as well as collaborate with other pharmaceutical companies on our products and product candidates.

On April 11, 2017, the United States Food and Drug Administration (FDA) approved INGREZZA® (valbenazine) capsules for the treatment of adults with tardive dyskinesia (TD). We market INGREZZA for TD in the United States (U.S.) through our specialty sales force focused primarily on physicians who treat TD patients, including psychiatrists and neurologists. The commercial launch of INGREZZA occurred on May 1, 2017.

On July 24, 2018, we were notified by AbbVie Inc. (AbbVie) that FDA approval was granted for ORILISSA® (elagolix) for the management of moderate to severe endometriosis pain in women. Discovered and developed through Phase II clinical trials by us, ORILISSA, the first FDA-approved oral medication for the management of endometriosis with associated moderate to severe pain in over a decade, began to be marketed by AbbVie in August 2018 as part of a collaboration to develop and commercialize elagolix for women’s health.

Our clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients, elagolix for uterine fibroids partnered with AbbVie, NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH), and a vesicular monoamine transporter 2 (VMAT2) inhibitor and a first-in-class central nervous system (CNS) compound each with potential use in the treatment of neurologic and psychiatric disorders.

AbbVie initiated Phase III studies of elagolix in patients with uterine fibroids in early 2016. The Phase III program included two replicate, pivotal, six-month efficacy and safety studies followed by a six-month safety and efficacy extension study. AbbVie provided positive topline efficacy data from the Phase III studies in women with uterine fibroids in the first quarter of 2018 and additional data from the six-month safety extension study in the third quarter of 2018. We believe the results from these studies will form the basis for an anticipated new drug application (NDA) submission to the FDA in the middle of 2019 for the approval of elagolix in the treatment of uterine fibroids.

We currently have three major collaborations. Two of these collaborations involve out-licensing of our proprietary technology to pharmaceutical partners. In June 2010, we announced an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively, GnRH compounds). In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe) for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. The third collaboration agreement, which was entered into in February 2017, is one in which we in-licensed technology from BIAL – Portela & Ca, S.A. (BIAL) for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson's disease, in the U.S. and Canada.

On January 28, 2019, we entered into a collaboration and license agreement with a clinical-stage gene therapy company, Voyager Therapeutics, Inc., or Voyager. The collaboration is focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platforms. The four programs consist of Voyager's VY-AADC program for Parkinson's disease and VY-FXN01 program for Friedreich's ataxia, as well as rights to two programs to be determined by the parties in the future. The effectiveness of the agreement is subject to certain conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions. Refer to Note 13 to the consolidated financial statements for more information on the agreement.

Our Product Pipeline

The following table summarizes our approved products and our most advanced product candidates currently in clinical development and is followed by detailed descriptions of each program:

Program	Target Indication(s)	Status	Rights
Approved products:			
INGREZZA	Tardive Dyskinesia	Marketed	Neurocrine/Mitsubishi Tanabe (Asia-Pacific)
ORILISSA	Endometriosis	Marketed	AbbVie
Product candidates in clinical development:			
elagolix	Uterine Fibroids	Phase III	AbbVie
opicapone	Parkinson's Disease	Phase III	Neurocrine (U.S. and Canada)/BIAL
NBI-74788	Classic Congenital Adrenal Hyperplasia	Phase II	Neurocrine
New VMAT2 Inhibitor	Neurology/Psychiatry Disorders	Phase I	Neurocrine
New CNS Compound	Neurology/Psychiatry Disorders	Phase I	Neurocrine

"Marketed" indicates that we or our collaborator have received FDA regulatory approval of the product, for the specified target indication.

"Phase III" indicates that we or our collaborators are conducting large-scale, multicenter comparative clinical trials on patients afflicted with a target disease in order to provide substantial evidence for efficacy and safety of the product candidate.

"Phase II" indicates that we or our collaborators are conducting clinical trials on groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages, and expanded evidence of safety of the product candidate.

"Phase I" indicates that we are conducting or initiating clinical trials with a smaller number of subjects to determine early safety profile, maximally tolerated dose, and pharmacological properties of the product candidate in human volunteers.

INGREZZA (valbenazine) – VMAT2 Inhibitor

VMAT2 is a protein concentrated in the human brain that is essential for the transmission of nerve impulses between neurons. VMAT2 is primarily responsible for packaging and transporting monoamines (dopamine, norepinephrine, serotonin, and histamine) in neurons. Specifically, dopamine enables neurotransmission among nerve cells that are involved in voluntary and involuntary motor control. Disease states such as TD, Tourette syndrome, Huntington's chorea, schizophrenia, and tardive dystonia are characterized in part by a hyperdopaminergic state in the brain, and modulation of neuronal dopamine levels may provide symptomatic benefits for patients with these conditions, among others.

INGREZZA as a Treatment for TD. TD is defined by hyperkinetic involuntary movements which arise after months or years of treatment with dopamine receptor blocking agents, e.g. antipsychotics used for treating schizophrenia, bipolar disorder, and depression, and Reglan® (metoclopramide) for nausea and vomiting and gastric emptying in patients with gastroparesis. Features of

TD may include grimacing, tongue protrusion, lip smacking, puckering and pursing of the lips, and rapid eye blinking. Rapid movements of the extremities may also occur. The impact on daily function and the quality of life for individuals suffering from TD can be substantial. While the prevalence rates of TD can vary greatly in accordance with the population being studied, it is estimated that approximately 500,000 individuals are affected by TD in the U.S. alone (Kantar Health).

On April 11, 2017, INGREZZA became the first drug approved by the FDA for the treatment of TD. INGREZZA provides a once-daily dosing treatment option for TD causing reversible reduction of dopamine release at the nerve terminal by selectively inhibiting the pre-synaptic VMAT2. In vitro, INGREZZA is a highly selective inhibitor of human VMAT2 showing little or no affinity for VMAT1, other receptors, such as dopamine D2 receptors, other transporters or ion channels. INGREZZA for TD has two dosing options (40 mg and 80 mg) with 40 mg taken for the first seven days of treatment with an option of 40 mg or 80 mg thereafter depending on a patient's dosing needs. INGREZZA was generally well tolerated during our clinical trials with no apparent drug-drug interactions with the most common emergent adverse event being mild and transient somnolence.

In connection with the FDA approval of INGREZZA for TD, we committed to conduct certain post-marketing studies including Phase 1 (e.g., pharmacokinetics in volunteers with renal impairment) and Phase 4 (e.g., randomized placebo-controlled withdrawal in TD patients) studies. We expect to conduct these studies over the next four years.

Valbenazine as a Treatment for Tourette Syndrome. In the fourth quarter of 2017, we initiated T-Force GOLD, a Phase IIb study of valbenazine in pediatric patients with Tourette syndrome, a neurological disorder that consists of rapid, non-rhythmic stereotyped motor and vocal tics. T-Force GOLD was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluating the safety, tolerability and efficacy, with optimized dosing of once-daily valbenazine in approximately 120 pediatric patients with moderate to severe Tourette syndrome over 12 weeks of treatment. In the second quarter of 2018, we started T-Force PLATINUM, a double-blind, placebo-controlled, randomized withdrawal study of valbenazine in pediatric patients with Tourette syndrome. This study is designed to evaluate longer term efficacy and safety in patients who initial responded to open-label therapy with optimized doses of valbenazine. On December 12, 2018, we announced that topline data from the T-Force GOLD study failed to meet the primary endpoint as assessed by the placebo adjusted change from baseline in Yale Global Tic Severity Scale assessed at week 12. We continue to analyze the complete dataset from the study to determine the next steps for valbenazine in Tourette syndrome.

elagolix – GnRH Antagonist

GnRH is the endogenous peptide that binds to the GnRH receptor and stimulates the secretion of the pituitary hormones that are responsible for sex steroid production and normal reproductive function. Researchers have found that chronic administration of GnRH agonists, after initial stimulation, reversibly shuts down this transmitter pathway and is clinically useful in treating hormone-dependent diseases such as endometriosis and uterine fibroids. Several companies have developed peptide GnRH agonists on this principle, such as Lupron® and Zoladex®. However, since these molecules are peptides, they must be injected via a depot formulation rather than the preferred oral route of administration. In addition, GnRH agonists can take up to several weeks to exert their desired effect once the initial stimulation has occurred, a factor not seen with the use of GnRH antagonists. Upon administration, GnRH agonists have shown a tendency to exacerbate the condition via a hormonal flare. More importantly the profound suppression effect observed with GnRH agonists is similar to that seen after menopause and can be associated with hot flushes and the loss of bone mineral density.

Orally active, nonpeptide GnRH antagonists potentially offer several advantages over injectable GnRH peptide drugs, including rapid onset of hormone suppression without hormonal flare. Also, injection site reactions commonly observed in peptide depots are avoided and dosing can be rapidly discontinued if necessary – a clinical management option not available with long-acting depot injections. Additionally, by using GnRH antagonists, it may be possible to alter the level of pituitary GnRH suppression thereby titrating circulating hormone levels.

In June 2010, we entered into an exclusive worldwide collaboration with AbbVie to develop and commercialize GnRH compounds for women's and men's health indications. Under the terms of the agreement, AbbVie is responsible for all development, marketing and commercialization costs and has responsibility for all regulatory interactions with the FDA related to elagolix and other GnRH compounds covered by the collaboration. Following our entry into the collaboration, AbbVie undertook the development of elagolix in uterine fibroids.

Endometriosis. Endometriosis is associated with a multitude of symptoms, some of the most common of which include pain related both to menstruation (dysmenorrhea) and sexual intercourse (dyspareunia) as well as chronic pelvic pain throughout the menstrual cycle, infertility, and menorrhagia, among many others. The wide range of symptoms associated with endometriosis serves to complicate and delay diagnosis due to the significant overlap of symptoms with the disease profiles of other conditions. The World Endometriosis Research Foundation estimates that there are over 170 million women worldwide who suffer from endometriosis, including approximately 7.5 million women in the U.S. alone. We believe that the availability of an oral treatment, lacking the side effect profile of the currently available peptide GnRH agonists, may be a desirable alternative to current pharmaceutical therapies and ultimately encourage a significantly higher treatment rate.

During the third quarter of 2017, AbbVie submitted an NDA for elagolix for the treatment of endometriosis to the FDA. The NDA was accepted for priority review by the FDA. In July and October 2018, respectively, AbbVie announced FDA and Health Canada approval for ORILISSA, for the management of endometriosis with associated moderate to severe pain in women. AbbVie began commercialization of ORILISSA in the U.S. in August 2018.

Uterine Fibroids. Uterine fibroids are benign hormonally responsive tumors that form in the wall of the uterus. They are the most common solid tumor in women with a prevalence rate of at least 25% (American College of Obstetricians and Gynecologists). While many women do not have symptoms, depending on the size, location and number, uterine fibroids can cause symptoms such as: longer, more frequent, or heavy menstrual bleeding, menstrual pain, vaginal bleeding at time other than menstruation, pain in the abdomen or lower back, pain during sex, difficulty urinating, frequent urination, constipation or rectal pain. Due to the severity of symptoms, treatment sometimes requires surgery, including the removal of the uterus. In fact, uterine fibroids is a leading indication for hysterectomy in the U.S., with approximately 250,000 hysterectomies performed each year related to uterine fibroids (Whiteman *et al AJOG* 2008, *198*, e1). We believe that a safe and effective oral therapy would be a preferred treatment regimen rather than surgical intervention.

AbbVie initiated Phase III studies of elagolix in patients with uterine fibroids in early 2016. The Phase III program included two replicate, pivotal, six-month efficacy and safety studies followed by a six-month safety and efficacy extension study. AbbVie evaluated 300mg of elagolix dosed twice daily both alone and in combination with hormonal add-back therapy (estradiol/norethindrone acetate). The primary endpoint in these Phase III studies was the same as that employed in the Phase IIb study: percent of subjects with reduction in uterine blood flow as measured by the alkaline hematin method.

AbbVie provided positive top-line efficacy data from the two Phase III studies in women with uterine fibroids in the first quarter of 2018 and additional data from the six-month safety extension study in the third quarter of 2018. The ELARIS UF-I and UF-II studies of elagolix met all primary and ranked secondary endpoints at month six. These replicate Phase III studies were randomized, parallel, double-blind, placebo-controlled clinical trials evaluating elagolix alone or in combination with low-dose hormone (add-back) therapy in women with heavy uterine bleeding associated with uterine fibroids. The studies enrolled approximately 400 patients each for an initial six-month placebo-controlled dosing period. At the end of the six months of placebo-controlled evaluation, patients were eligible to enter an additional six-month safety extension study. The primary efficacy endpoint of the study was an assessment of the change in menstrual blood loss utilizing the alkaline hematin method comparing baseline to month six. Additional secondary efficacy endpoints were evaluated including the change in fibroid volume and hemoglobin. Bone mineral density was assessed via dual-energy x-ray absorptiometry scan at baseline, at the conclusion of dosing, and at six months post-dosing. We believe the results from these studies will form the basis for an anticipated NDA submission to the FDA in the middle of 2019 for the approval of elagolix in the treatment of uterine fibroids.

opicapone – Catechol-O-methyltransferase Inhibitor

Catechol-O-methyltransferase (COMT) inhibitors are utilized to prolong the duration of effect of levodopa, the primary treatment option for Parkinson's disease patients. Administration of levodopa often results in adequate control of Parkinson's symptoms, also referred to as "on-time," however, there are periods of the day where the effects of levodopa wear off and motor symptoms worsen. These periods are considered "off-time." Opicapone is a novel, once-daily, peripherally-acting, highly-selective COMT inhibitor utilized as adjunct therapy to levodopa/carbidopa in patients with Parkinson's disease experiencing motor fluctuations. Opicapone works through decreasing the conversion rate of levodopa into 3-O-methyldopa, thereby reducing the off-time period in patients with Parkinson's and extending the on-time period.

In February 2017, we entered into an exclusive license agreement with BIAL for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson's disease, in the U.S. and Canada. Under the terms of the agreement, we will be responsible for the development and commercialization of opicapone in the U.S. and Canada.

Parkinson's Disease. Parkinson's disease is a chronic and progressive movement disorder that affects approximately 1 million people in the United States. The disease is characterized by a loss of neurons in the substantia nigra, the area of the brain where dopamine is produced. Dopamine production and synthesis is necessary for coordination and movement. As Parkinson's progresses, dopamine production steadily decreases resulting in tremor, slowed movement (bradykinesia), impaired posture and balance, and speech and writing problems. There is no present cure for Parkinson's and management consists of controlling the motor symptoms primarily through administration of levodopa therapies. While this improves the control of Parkinson's symptoms, as the disease progresses the beneficial effects of levodopa begin to wear off, symptoms worsen, and patients experience motor fluctuations. These motor fluctuations are improved with the addition of a COMT inhibitor to levodopa.

In June 2016, the European Medicines Agency authorized ONGENTYS® (opicapone) as an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors in adult patients with Parkinson's disease and end-of-dose motor fluctuations who cannot be stabilized on those combinations. This approval was based on data from a clinical development program that included 28 clinical studies of more than 900 patients treated with opicapone in 30 countries worldwide.

The two pivotal Phase III studies utilized for approval with the European Medicines Agency, BIPARK-I and BIPARK-II, demonstrated that opicapone once-daily achieved a statistically significant decrease in off-time periods for Parkinson's patients compared to placebo. The BIPARK-I study was a placebo-controlled study of approximately 600 patients that also included entacapone as an active comparator. The results of this study also showed that once-daily opicapone was non-inferior to entacapone which is dosed multiple times per day. The BIPARK-II study was a placebo-controlled study of approximately 400 patients that also showed a significant decrease in off-time periods for Parkinson's patients. In both studies, opicapone was associated with significant improvements in both patient and clinician global assessments of change. The data from these two Phase III trials also demonstrated that opicapone improved motor fluctuations in levodopa-treated patients regardless of concomitant dopamine agonist or monoamine oxidase type B inhibitors used. Opicapone was generally well tolerated and was not associated with relevant electrocardiographic or hepatic adverse events.

Both of the BIPARK Phase III trials included a one-year open-label extension where opicapone sustained the decrease in off-time and increase in on-time periods that was demonstrated during the double-blind placebo-controlled portion of the studies.

We held a meeting with the FDA in January 2018 to discuss a potential NDA submission for opicapone. Based upon the BIPARK-I and BIPARK-II pivotal Phase III studies conducted by BIAL, the FDA did not require additional Phase III trials in connection with an NDA submission for opicapone. We anticipate submitting an NDA to the FDA for opicapone in the second quarter of 2019.

NBI-74788 – Corticotropin-Releasing Factor Receptor$_1$ Antagonist

Corticotropin-releasing factor$_1$ (CRF_1) is a hypothalamic hormone released directly into the hypophyseal portal vasculature which acts on the CRF_1 receptor, a G protein-coupled receptor (GPCR), in the anterior pituitary to stimulate the release of adrenocorticotropin hormone (ACTH). The primary role of ACTH is the stimulation of the synthesis and release of adrenal steroids including cortisol. Cortisol from the adrenals have a negative feedback role at the level of the hypothalamus that decreases CRF_1 release as well as at the level of the pituitary to inhibit the release of ACTH. This tight control loop is known as the hypothalamic-pituitary-adrenal axis. Blockade of CRF_1 receptors at the pituitary has been shown to decrease the release of ACTH and subsequently attenuate the production and release of adrenal steroids.

Classic CAH. Classic CAH is a group of autosomal recessive genetic disorders that affects approximately 20,000-30,000 people in the U.S. and results in an enzyme deficiency altering the production of adrenal steroids. Because of this deficiency, the adrenal glands have little to no cortisol biosynthesis resulting in a potentially life-threatening condition. If left untreated, classic CAH can result in salt wasting, dehydration, and eventually death. Even with cortisol replacement, persistent elevation of ACTH from the pituitary gland results in excessive androgen levels leading to virilization of females including precocious puberty, menstrual irregularity, short stature, hirsutism, acne and fertility problems.

Corticosteroids are the current standard of care for classic CAH and are used chronically to both correct the endogenous cortisol deficiency and to reduce the excessive ACTH levels and androgen excess. However, the dose and duration of steroid use required to suppress ACTH is well above the normal physiological level of cortisol; resulting in metabolic syndrome, bone loss, growth impairment, and Cushing's syndrome as common and serious side effects.

NBI-74788 is a potent, selective, orally-active, CRF_1 receptor antagonist as demonstrated in a range of in vitro and in vivo assays. Blockade of CRF_1 receptors at the pituitary has been shown to decrease the release of ACTH, which in turn decreases the production of adrenal steroids including androgens, and potentially the symptoms associated with classic CAH. Lower ACTH levels would also reduce the amount of exogenous corticosteroid necessary for classic CAH patients to thrive avoiding the side-effects currently associated with excessive steroid therapy.

We conducted a Phase I single ascending dose study of NBI-74788 in healthy volunteers in 2017. Based on the positive results of this Phase I study, we initiated a Phase II clinical trial of NBI-74788 in adult patients with classic CAH. This clinical study is designed to be an open-label, pharmacokinetic/pharmacodynamic study assessing two ascending dose levels of 14 days dosing of NBI-74788 in up to 20 study participants. Key pharmacodynamic biomarker measurements include ACTH, 17-hydroxyprogesterone (17-OHP), androgen, and cortisol levels collected the morning following bedtime dosing on Day 1 and Day 14. We recently expanded this study to include up to 10 additional patients to further optimize dosing flexibility and convenience. Initial results from this study are expected in the first quarter of 2019.

We intend to apply for orphan drug designation for NBI-74788 in the treatment of classic CAH. Orphan drug designation is granted by the FDA to medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S. and provides sponsors with development and commercial incentives for such designated compounds and medicines.

New VMAT2 Inhibitor

We have filed an investigational new drug application (IND) and completed dosing in the single ascending dose portion of a Phase I study designed to assess initial safety, tolerability, and pharmacokinetics of a novel, internally discovered VMAT2 inhibitor. This compound has the potential to be used in the treatment of several neurology and/or psychiatry disorders. The multiple dosing portion of this Phase 1 study is ongoing and expected to be completed during the first half of 2019.

New CNS Compound

We have filed an IND and completed dosing in a Phase I single ascending dose study for an internally discovered first-in-class CNS compound with potential use in the treatment of several neurology and/or psychiatry disorders. This study is a randomized, double-blind, single ascending dose study to evaluate the safety, tolerability, and pharmacokinetic profile of the compound in healthy participants. We are currently analyzing the data from this study to inform the design of future clinical studies for the program.

Research Programs

Our R&D focus is on addressing diseases and disorders of the central nervous and endocrine systems, which include therapeutic categories ranging from hypothalamic-pituitary-adrenal disorders to stress-related disorders and neurological/neuropsychiatric diseases. CNS and endocrinology drug therapies are among the largest therapeutic categories, accounting for over $110 billion in drug sales in the U.S. alone according to IQVIA (2018).

CNS and Neuroendocrine Disorders (Targeted by GPCRs, Solute Carrier Proteins, and Ion Channels)

GPCRs are the largest known gene superfamily of the human genome. Greater than 30% of all marketed prescription drugs act on GPCRs; which makes this class of proteins historically the most successful therapeutic target family. However, only a small fraction of the GPCR gene superfamily has been exploited. Ion channels appear to be represented by approximately 400 genes in the human genome and are currently the targets for approximately 7% of the current marketed drugs. We believe that next-generation therapies derived from targeting GPCRs and ion channels will be discovered through the understanding of the complex relationships of drug/receptor interactions and their subsequent impact on efficacy, downstream signaling networks and regulation.

Our GPCR research platform has met this requirement by integrating drug discovery research efforts with a suite of assays and assay systems and automated analytical techniques. This process, now also applied to solute carrier proteins and ion channels, provides an unbiased profile of pharmacological protein/ligand interactions coupled with *in vivo* efficacy using discrete animal models allowing for rapid discovery of initial leads and advancement into preclinical and clinical development. Importantly, this design cycle is not limited to GPCRs, solute carrier proteins, or ion channel targets, but can be utilized for other recently identified proteins that play a role in human disease where current treatments or therapies are either inadequate or nonexistent.

Our Business Strategy

Our goal is to become the leading biopharmaceutical company focused on neurological and endocrine-related diseases and disorders. The following are the key elements of our business strategy:

Maintaining Certain Commercial Rights to Our Product Portfolio to Evolve into a Fully-Integrated Pharmaceutical Company. In April 2017, we received approval from the FDA for INGREZZA for the treatment of TD. We market INGREZZA for TD in the U.S. The commercial launch of INGREZZA occurred on May 1, 2017. We have built a specialty sales force in the U.S. of approximately 250 experienced sales professionals. This specialty sales force focuses on promotion to physicians who treat TD patients, primarily neurologists and psychiatrists. Our commercial team is comprised of experienced professionals in marketing, access and reimbursement, managed markets, market research, commercial operations, and sales force planning and management. In addition, our commercial infrastructure includes capabilities in manufacturing, medical affairs, quality control, and compliance. We intend to retain commercial rights to certain products, including INGREZZA, that we can effectively and efficiently develop, secure regulatory approval and commercialize, which includes products with a concentrated prescriber base and well-defined patient population that can be accessed with an efficient patient and prescriber outreach program.

Advancing Life-Changing Discoveries in Neurology, Neuro-Endocrinology, and Psychiatry. We believe that by continuing to advance and extend our product pipeline, we can mitigate some of the clinical development risks associated with drug development. We currently have multiple programs in various stages of research and development. Our two lead late-stage clinical programs are elagolix, a GnRH antagonist in Phase III development for uterine fibroids that is partnered with AbbVie, and opicapone, a highly-selective COMT inhibitor that is an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors for adult patients with Parkinson’s disease and was in-licensed from BIAL. In addition, we are conducting a Phase II study of NBI-74788 in adult patients with classic CAH, a group of autosomal recessive genetic disorders. We take a portfolio approach to managing our pipeline that balances the size of the market opportunities with clear and defined clinical and regulatory paths to approval. By doing so, we focus our internal development resources on innovative therapies with improved probabilities of technical and commercial success.

Selectively Establishing Corporate Collaborations with Global Pharmaceutical Companies to Assist in the Development of Our Products and Mitigate Financial Risk while Retaining Significant Commercial Upside. We leverage the development, regulatory, and commercialization expertise of our corporate collaborators to accelerate the development of certain of our product candidates, while typically retaining co-promotional rights, and at times commercial rights, in North America. For example, we have collaborated with AbbVie for the development and commercialization of ORILISSA, which has received FDA and Health Canada approval for the management of endometriosis, and with respect to our collaboration with Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe) for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. We intend to further leverage our resources by selectively entering into additional strategic alliances to enhance our internal development and commercialization capabilities by licensing our technology.

Identifying Novel Drugs to Address Unmet Market Opportunities. We seek to identify and validate novel drugs on characterized targets for internal development or collaboration. For example, in 2018, we initiated Phase I studies for a new VMAT2 inhibitor and a new CNS compound. In 2017, based on the positive results of a Phase I study we conducted of NBI-74788 in healthy volunteers, we initiated a Phase II study of NBI-74788 in adult patients with classic CAH. We believe the creativity and productivity of our discovery research group will continue to be a critical component for our continued success.

Acquiring Rights to Complementary Drug Candidates and Technologies. We plan to continue to selectively acquire rights to products in various stages of development to take advantage of our drug development capabilities. For example, in October 2018, we entered into a research collaboration with Jnana Therapeutics, Inc. aimed at discovering novel small molecule therapeutics for multiple targets for CNS disorders. Under the terms of the agreement, we will work jointly to identify novel compounds, after which time we will be responsible for further lead optimization, and the development and commercialization of any potential therapies arising from the collaboration. In February 2017, we entered into an exclusive license agreement with BIAL for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson's disease, in the U.S. and Canada. Under the terms of the agreement, we will be responsible for the development and commercialization of opicapone in the U.S. and Canada.

Our Corporate Collaborations and Strategic Alliances

One of our business strategies is to utilize strategic alliances to enhance our development and commercialization capabilities. The following is a summary of our significant collaborations/alliances:

AbbVie. In June 2010, we announced an exclusive worldwide collaboration with AbbVie to develop and commercialize GnRH Compounds for women's and men's health. AbbVie made an upfront payment of $75 million and has agreed to make additional development and regulatory event-based payments of up to $480 million and up to an additional $50 million in commercial event-based payments. Under the terms of the agreement, AbbVie is responsible for all development, marketing and commercialization costs. We received funding for certain internal collaboration expenses which included reimbursement from AbbVie for internal and external expenses related to the GnRH Compounds and personnel funding through the end of 2012. We are 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. In such event, we would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to us. Since the inception of the agreement, we have recorded revenues of $75 million related to the amortization of up-front license fees, $115 million in milestone revenue, $37 million in sponsored development revenue, and approximately $1.6 million in sales-based royalty revenue on AbbVie net sales of ORILISSA.

Mitsubishi Tanabe. In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. Mitsubishi Tanabe made an up-front license fee payment of $30 million and has agreed to make additional development and commercialization event-based payments totaling up to $85 million, payments for the manufacture of pharmaceutical products, and royalties on product sales in select territories in Asia. Under the terms of the agreement, Mitsubishi Tanabe is responsible for all development, marketing, and commercialization costs in Japan and other select Asian markets, with the exception of a single Huntington's chorea trial to be performed by us, at an estimated cost of approximately $12 million, should Mitsubishi Tanabe request the clinical trial. We will 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. Mitsubishi Tanabe 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. Since the inception of the agreement, we have recorded revenues of $19.8 million related to the up-front license fee, and $15 million in milestone revenue.

BIAL. In February 2017, we entered into an exclusive license agreement with BIAL for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson's disease, in the U.S. and Canada. Under the terms of the agreement, we are responsible for the management and cost of all opicapone development and commercialization activities in the U.S. and Canada. Under the terms of the agreement, we paid BIAL an upfront license fee of $30 million. In addition, during the first quarter of 2018, the FDA provided guidance on the regulatory path forward to support an NDA for opicapone for Parkinson's disease, in which the FDA did not request that we conduct an additional Phase III study in connection with the submission of an NDA to the FDA, resulting in a $10 million event-based milestone payment to BIAL. We may also be required to pay up to an additional $105 million in milestone payments associated with the regulatory approval and net sales of products containing opicapone. In addition, we will pay BIAL a percentage of net sales (with a floor minimum) in exchange for the manufacture and supply of

opicapone drug product. Either party may terminate the agreement earlier 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 or fail to file an NDA for a licensed product by a specified date or under certain circumstances involving a change of control.

Intellectual Property

We seek to protect our lead compounds, compound libraries, expressed proteins, synthetic organic processes, formulations, assays, cloned targets, screening technology and other technologies by filing, or by causing to be filed on our behalf, patent applications in the U.S. and abroad. Additionally, we have licensed from institutions the rights to issued U.S. patents, pending U.S. patent applications, and issued and pending foreign filings. We face the risk that one or more of the above patent applications may be denied. We also face the risk that issued patents that we own, or license, may be challenged or circumvented or may otherwise not provide protection for any commercially viable products we develop.

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. If this occurs, we may be required to obtain licenses to patents or proprietary rights of others in order to continue with the commercialization of our products.

In addition to the granted and potential patent protection, the U.S., the European Union (EU), and Japan all provide data and marketing exclusivity for new medicinal compounds. If this protection is available, no competitor may use the original applicant's data as the basis of a generic marketing application during the period of data and marketing exclusivity. This period of exclusivity is generally five years in the U.S., six years in Japan and ten years in the EU, measured from the date of FDA, or corresponding foreign regulatory authority, approval.

INGREZZA, our highly selective VMAT2 inhibitor is covered by U.S. Patent No. 8,039,627, which expires in 2029 (not including a potential patent term extension of up to two years) and U.S. Patent No. 8,357,697, which expires in 2027.

Elagolix, our small molecule GnRH antagonist currently in clinical trials for the treatment of endometriosis and uterine fibroids, is covered by six issued U.S. patents relating to composition of matter, pharmaceutical compositions, and methods of use. U.S. Patent Nos. 6,872,728, 7,179,815 and 7,462,625 are due to expire in 2021 (not including potential patent term extensions of up to five years) while U.S. Patent Nos. 7,056,927, 7,176,211 and 7,419,983 are due to expire in 2024 (not including potential patent term extensions of up to five years).

Opicapone, a highly selective COMT inhibitor for Parkinson's disease is covered by U.S. Patent No. 8,168,793, among others, which expires in 2029 (not including a potential patent term extension of up to five years).

Manufacturing and Distribution

We currently rely on, and expect to continue to rely on, contract manufacturers to produce INGREZZA, as well as for our existing and future product candidates. We believe this outsourcing manufacturing strategy will enable us to direct our financial resources to our commercialization efforts without devoting the resources and capital required to build manufacturing facilities.

We have established an internal pharmaceutical development group to develop manufacturing methods for our product candidates, to optimize manufacturing processes, and to select and transfer these manufacturing technologies to our suppliers. We have also established an internal commercial supply team to manage all aspects related to the INGREZZA commercial supply chain. We have entered into long-term contracts with multiple manufacturers to ensure adequate product supply and to mitigate risk, and we expect to continue to expand and diversify our third-party manufacturing relationships during 2019.

There currently are a limited number of these manufacturers. Furthermore, some of the contract manufacturers that we have identified to date only have limited experience at manufacturing, formulating, analyzing and packaging our products and product candidates in quantities sufficient for conducting clinical trials or for commercialization. We attempt to acquire adequate inventory of materials and/or finished product to avoid significant supply disruption.

Additionally, we have retained third-party service providers to perform a variety of functions related to the distribution of INGREZZA, including shipping, warehousing, customer service, order-taking and processing, invoicing, collections, and other distribution-related activities.

We have entered into distribution agreements for INGREZZA with a limited number of specialty pharmacies (SPs) and a specialty distributor (SD) (collectively, customers), and all of our product sales are to these customers. SPs subsequently dispense INGREZZA to patients based on the fulfillment of a prescription and the SD sells INGREZZA primarily to closed-door pharmacies and government facilities. Our agreements with SPs and the SD provide for transfer of title to the product at the time the product is delivered to the SPs or SD. Our three largest customers represented approximately 93% of our product revenue for the year ended December 31, 2018.

INGREZZA Manufacturers

We entered into a commercial supply agreement with Fabbrica Italiana Sintetici S.p.A. (F.I.S.) in March 2017, for F.I.S.'s manufacture of commercial supplies of the active pharmaceutical ingredient, or API, for INGREZZA at F.I.S.'s manufacturing site in Italy. Under the terms of the agreement, F.I.S. is responsible for manufacturing the INGREZZA API, conducting quality control, quality assurance, validation activities, stability testing, packaging, and other services related to the manufacture of the INGREZZA API. In the second quarter of 2018, we received our first order of INGREZZA API under this agreement.

The agreement requires two years' notice prior to a termination without cause, provided that no such notice may be given prior to March 2022.

We entered into a master manufacturing services agreement with Patheon UK Limited (Patheon) in November 2016, and two associated product agreements in 2017 and 2018, for Patheon's manufacture of commercial supplies of INGREZZA at its manufacturing sites. Under the terms of the agreements, we are responsible for supplying the API for INGREZZA to Patheon. Patheon is responsible for manufacturing the INGREZZA capsules, conducting quality control, quality assurance, validation activities, stability testing, packaging and providing related services for the manufacture of the INGREZZA capsules.

Pursuant to the agreements, we have agreed to order from Patheon certain annual binding minimum amounts of INGREZZA capsules based on an agreed upon pricing schedule. The agreements have an initial term ending in December 2021 and will automatically renew after the initial term for successive terms of two years, unless either party gives notice of its intention to terminate the agreements within at least 18 months prior to the end of the then current term.

Commercial Packaging Agreements

We entered into two commercial packaging agreements with third-party vendors that provide, among other things, services related to the packaging of INGREZZA, tooling purchases and repairs, analytical work, auditing of suppliers, and storage. One such vendor is located in Illinois and the other is located in Pennsylvania. We do not believe that these commercial packaging related agreements are material because our business is not substantially dependent on any individual agreement.

Marketing and Sales

During 2017, we built a specialty sales force in the U.S of experienced sales professionals. This specialty sales force focuses on educating physicians who treat TD patients, primarily neurologists and psychiatrists. Our commercial team is comprised of experienced professionals in marketing, access and reimbursement, managed markets, market research, commercial operations, and sales force planning and management. During 2018, we expanded our sales force by approximately 50% to approximately 250 experienced sales professionals to enhance our ability to develop the TD market. In addition, our commercial infrastructure includes capabilities in manufacturing, medical affairs, quality control, and compliance.

Government Regulation

Our business activities, which include the manufacture and marketing of INGREZZA as well as our other potential products currently in research and development, are subject to extensive regulation by the U.S. and other countries. Regulation by government authorities in the U.S. and foreign countries is a significant factor in the development, manufacture, distribution, marketing and sale of our proposed products and in our ongoing research and product development activities. All of our products in development will require regulatory approval by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical studies and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The process of obtaining these approvals and the subsequent compliance with appropriate federal and state statutes and regulations require the expenditure of substantial time and financial resources. In the U.S., various federal and state statutes and regulation also govern or influence testing, manufacturing, safety, labeling, storage, and record-keeping of human therapeutic products and their marketing. Recent federal legislation imposes additional obligations on pharmaceutical manufacturers regarding product tracking and tracing.

In addition, federal and state healthcare laws restrict business practices in the pharmaceutical industry. These laws include, without limitation, federal and state 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. We have a comprehensive compliance program to ensure our business practices remain compliant.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, and the federal civil monetary penalties law, which prohibit among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, requires certain types of individuals and entities to abide by standards relating to the privacy and security of individually identifiable health information, including the adoption of administrative, physical and technical safeguards to protect such information. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal Physician Payments Sunshine Act 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 the Centers for Medicare and Medicaid Services (CMS) information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.

Failure to comply with these laws, where applicable, can result in significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, 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 of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Development and Marketing Approval for Products

Preclinical studies generally are conducted in laboratory animals to evaluate the potential safety and efficacy of a product. Drug developers submit the results of preclinical studies to the FDA as a part of an IND application before clinical trials can begin in humans. Typically, clinical evaluation involves a time consuming and costly three-phase process.

Phase I	Clinical trials are conducted with a small number of subjects to determine the early safety profile, maximum tolerated dose and pharmacokinetic properties of the product in human volunteers. It is rare to evidence pharmacology in these early studies.
Phase II	Clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety.
Phase III	Large-scale, multi-center, comparative clinical trials are conducted with patients afflicted with a specific disease in order to determine safety and efficacy as primary support for regulatory approval by the FDA to market a product candidate for a specific disease.

The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted in the U.S. and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. Institutional Review Boards, Institutional Ethics Committees, and Data Safety Monitoring Boards may also place holds on our clinical trials or recommend that we voluntarily do so. To date, we have also conducted some of our clinical trials in Europe, Canada, Oceania, and South Africa. Clinical trials conducted in foreign countries are also subject to oversight by regulatory authorities in those countries.

Once Phase III trials are completed, drug developers submit the results of preclinical studies and clinical trials to the FDA in the form of an NDA or a biologics license application for approval to commence commercial sales. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (PDUFA) guidelines that are currently

in effect, the FDA has a goal of ten months from the date of filing of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003 as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy plan to ensure that the benefits of the drug outweigh its risks. The risk evaluation and mitigation strategy plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with current Good Manufacturing Practice requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with Good Clinical Practice requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase IV clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a risk evaluation and mitigation strategy, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

We will also have to complete an approval process similar to that in the U.S. in virtually every foreign target market for our products in order to commercialize our product candidates in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. Foreign approvals may not be granted on a timely basis, or at all. In addition, regulatory approval of prices is required in most countries other than the U.S. The resulting prices may not be sufficient to generate an acceptable return to us or our corporate collaborators.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000, there is no

reasonable expectation that sales of the drug in the U.S. will be sufficient to offset the costs of developing and making the drug available in the U.S. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If the FDA approves a sponsor's marketing application for a designated orphan drug for use in the rare disease or condition for which it was designated, the sponsor is eligible for a seven-year period of marketing exclusivity, during which the FDA may not approve another sponsor's marketing application for a drug with the same active moiety and intended for the same use or indication as the approved orphan drug, except in limited circumstances, such as if a subsequent sponsor demonstrates its product is clinically superior. During a sponsor's orphan drug exclusivity period, competitors, however, may receive approval for drugs with different active moieties for the same indication as the approved orphan drug, or for drugs with the same active moiety as the approved orphan drug, but for different indications. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for a drug with the same active moiety intended for the same indication before we do, unless we are able to demonstrate that grounds for withdrawal of the orphan drug exclusivity exist, or that our product is clinically superior. Further, if a designated orphan drug receives marketing approval for an indication broader than the rare disease or condition for which it received orphan drug designation, it may not be entitled to exclusivity.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten-month review periods are measured from the filing date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution,

advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase IV clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with current Good Manufacturing Practices (cGMP) requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a risk evaluation and mitigation strategies program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such drug products.

In the U.S., third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Nonetheless, our products or product candidates, including INGREZZA, may not be considered medically necessary or cost-effective.

Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party payor reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The marketability of any product or product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if third-party payors fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care in the U.S. has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party payor reimbursement rates may change at any time. 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.

Healthcare Reform

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the ACA, was signed into law, which 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 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.

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. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private third-party payor.

Some of the provisions of the ACA have yet to be fully implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, the current presidential administration has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the newly enacted federal income tax law, known as the Tax Cuts and Jobs Act, includes a provision repealing, 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". On January 22, 2018, the current presidential administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In July 2018, CMS published a 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. On December 14, 2018, a Texas U.S. District Court Judge 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. While the Texas U.S. District Court Judge, as well as the current presidential administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare 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 fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, 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 U.S. Department of Health and Human Services has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective Congress and the current presidential 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.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, 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 pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Competition

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

In April 2017, INGREZZA, was approved by the FDA for TD. There are currently two FDA approved drug therapies for TD; INGREZZA and AUSTEDO® (deutetrabenazine), a deuterium labeled version of XENAZINE® (tetrabenazine) and VMAT2 inhibitor that was developed by Teva Pharmaceutical Industries Ltd. (Teva). In addition, off-label treatment regimens for TD consist of utilizing various atypical antipsychotic medications (e.g., clozapine), benzodiazepines (off-label) or botulinum toxin injections to treat the movements associated with TD.

Other potential indications for our VMAT2 inhibitors include the chorea associated with Huntington's disease, tardive dystonia, and other potential diseases and disorders. Currently, AUSTEDO, XENAZINE, which is marketed by Lundbeck, and generic alternatives to XENAZINE are approved for the chorea associated with Huntington's disease.

On July 24, 2018, AbbVie, in collaboration with us, announced FDA approval for ORILISSA for the management of endometriosis with associated moderate to severe pain in women. In addition, in conjunction with our partner AbbVie, we are developing elagolix for the treatment of heavy menstrual bleeding associated with uterine fibroids. AbbVie initiated Phase III studies of elagolix in patients with uterine fibroids in early 2016. The Phase III program included two replicate, pivotal, six-month efficacy and safety studies followed by a six-month safety and efficacy extension study. AbbVie provided positive top-line efficacy data from the two Phase III studies in women with uterine fibroids in the first quarter of 2018 and additional data from the six-month safety extension study in the third quarter of 2018. We believe the results from these studies will form the basis for an anticipated NDA submission to the FDA in 2019 for the approval of elagolix in the treatment of uterine fibroids. There are no current pharmaceutical therapies approved in the U.S. for the chronic treatment of uterine fibroids. ObsEva SA has initiated a Phase IIb endometriosis study with its GnRH receptor antagonist, OBE2109, and has initiated Phase III studies of uterine fibroids patients with the same molecule. Myovant Sciences, Inc. is investigating its GnRH receptor antagonist, relugolix, in Phase III trials of endometriosis, uterine fibroids and prostate cancer patients. LUPRON DEPOT® (leuprolide), marketed by AbbVie, is approved for short-term use to improve the outcome of uterine fibroid surgery. However, approximately 250,000 hysterectomies are performed annually in the U.S. as a direct result of uterine fibroids, as well as myomectomies (surgery) to remove the fibroids. Our oral small molecule pharmaceutical agent, elagolix, would compete directly with these current invasive standards of care.

LUPRON DEPOT, SYNAREL® (nafarelin), and depo-subQ provera104® (medroxyprogesterone), which are marketed by Pfizer, are products that have been approved for the treatment of endometriosis, infertility, and central precocious puberty. These drugs, and any generic alternatives, may compete with any small molecule non-peptide GnRH antagonists we, in conjunction with our collaborative partner AbbVie, develop for these indications. Approximately 130,000 hysterectomies are performed annually in the U.S. as a direct result of endometriosis, as well as a significant number of laparoscopic procedures to ablate endometrial explants. Our oral small molecule pharmaceutical agent, elagolix, would also compete directly with these current invasive standards of care.

Opicapone is a COMT inhibitor to be utilized as an adjunct therapy in the treatment of Parkinson's disease. COMT inhibitors prolong the duration of effect of levodopa which is the primary treatment option for Parkinson's disease patients. There are currently two FDA approved COMT inhibitors, COMTAN® (entacapone) originally developed by Orion Pharma and TASMAR® (tolcapone) originally developed by Hoffman-LaRoche Inc. Opicapone would compete directly with these two drugs and their generic equivalents.

NBI-74788 is currently being investigated for the treatment of classic CAH, for which there are limited therapies. 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. However, the level of dose as well as the duration of steroid use required to suppress ACTH is well above the normal physiological level of cortisol; resulting in metabolic syndrome, bone loss, growth impairment, and Cushing's syndrome as common and serious side effects. Both Millendo Therapeutics, with its acetyl-CoA acetyltransferase 1 inhibitor ATR-101, and Spruce Biosciences, with its CRF_1 antagonist SPR001, are in clinical development for the treatment of classic CAH.

If one or more of these competitive products or programs are successful, it may reduce or eliminate the market for our products.

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

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

Any of these competitive factors could harm our business, prospects, financial condition and results of operations, which could negatively affect our stock price.

Employees

As of December 31, 2018, we had approximately 585 full-time employees. None of our employees are represented by a collective bargaining arrangement, and we believe our relationship with our employees is good.

Insurance

We maintain product liability insurance coverage for INGREZZA and our clinical trials in amounts consistent with industry standards. However, insurance coverage is becoming increasingly expensive, and we may not be able to obtain or maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website at *www.neurocrine.com* , as soon as reasonably practicable after such reports are available on the Securities and Exchange Commission (SEC) website at *www.sec.gov*.

Additionally, copies of our Annual Report will be made available, free of charge, upon written request.

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 Annual Report on Form 10-K and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations.

Risks Related to Our Company

We have limited marketing experience, and have only recently established our sales force, distribution and reimbursement capabilities, and 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 third-party reimbursement if and when they are approved by the FDA. Our limited experience in marketing and selling pharmaceutical products began with INGREZZA approval in 2017, when we hired our sales force and established our distribution and reimbursement capabilities, all of which are necessary to successfully commercialize INGREZZA. 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 or any product candidate approved by the FDA in the future. If we fail to maintain successful marketing, sales and reimbursement capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues may suffer.

Use of our approved products or those of our collaborators, including INGREZZA and ORILISSA, 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 and ORILISSA, could be associated with side effects or adverse events which can vary in severity (from minor 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 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.

We currently depend on single source suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA, could materially and adversely affect our ability to successfully commercialize INGREZZA.

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 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, including 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, and compliance with strictly enforced U.S., state, and non-U.S. regulations. We depend on single source suppliers for each of the production of INGREZZA and its active pharmaceutical ingredients. If our third-party suppliers for INGREZZA encounter these or any other manufacturing, quality or compliance difficulties, we may be unable to meet commercial demand for INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA. We also depend on BIAL, and its suppliers, for the production of opicapone drug substance and drug product.

In addition, if our suppliers fail or refuse to supply us with INGREZZA or its active pharmaceutical ingredient 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 active pharmaceutical ingredients 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 opicapone drug product for any reason, we have limited opportunity to qualify a new supplier. The inability to obtain sufficient quantities of opicapone drug product could materially and adversely affect our ability to successfully commercialize opicapone.

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

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

We are subject to ongoing obligations and continued regulatory review for INGREZZA, which may result in significant additional expense and market withdrawal. Additionally, our other product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

We received FDA regulatory approval for INGREZZA in April 2017. This approval and other regulatory approvals for any of our product candidates may also 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. With respect to the FDA's approval of INGREZZA for TD, we are subject to certain post-marketing requirements and commitments. Failure to comply with these post-marketing requirements and commitments could result in withdrawal of our marketing approval for INGREZZA. 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. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency (especially for a product, such as INGREZZA, which has been administered in only a limited patient population to date), or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, 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 FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any of our product candidates or future indications for currently approved products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability on a sustained basis.

If physicians and patients do not accept INGREZZA 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 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 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 coverage and adequate reimbursement for the products;
- the success of existing products addressing our target markets or the emergence of equivalent or superior products; and
- the cost-effectiveness of the products.

In addition, market acceptance depends on the effectiveness of our marketing strategy and distribution support, and, to date, although we have hired experienced sales and marketing professionals, we have very limited sales and marketing experience. We may face difficulties related to managing the growth of our sales and marketing organization, and it is possible that the rapid expansion in our sales and marketing team may have a short-term negative effect on our external sales and marketing efforts given the need to devote significant time to the training and integration of these personnel. If our sales and marketing efforts are not effective and 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.

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

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

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

- the FDA or similar foreign regulatory authority may not allow an IND application or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA may require additional preclinical studies as a condition of the initiation of Phase I clinical studies, or additional clinical studies for progression from Phase I to Phase II, or Phase II to Phase III, or for NDA approval;
- the product candidate may not prove to be effective or as effective as other competing product candidates;
- we may discover that a product candidate may cause harmful side effects or results of required toxicology 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;
- patients may drop out of the trials; and
- regulatory requirements may change.

These risks and uncertainties impact all of our clinical programs. For example, any of the clinical, regulatory or operational events described above could change our planned clinical and regulatory activities for the opicapone program in Parkinson's disease and/or our NBI-74788 program for the treatment of 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.

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, and ORILISSA (partnered with AbbVie), which has been approved by the FDA for the management of moderate to severe endometriosis pain in women. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

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

We depend on our current collaborators for the development and commercialization of our products and product candidates that we out-license and in-license 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 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.

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

- does not successfully commercialize ORILISSA for endometriosis;
- fails to gain regulatory approval of elagolix;
- for uterine fibroids, and if applicable, successfully launch and commercialize elagolix for that indication;
- does not conduct its collaborative activities in a timely manner;
- does not devote sufficient time and resources to our partnered program;
- 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 March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe to develop and commercialize INGREZZA in Japan and other select Asian markets. We will rely on Mitsubishi Tanabe to achieve certain development, regulatory and commercial milestones which, if achieved, could generate significant future revenue for us. Our collaboration with Mitsubishi Tanabe is subject to risks and uncertainties similar to those described above. In addition, we may need to enter into other out-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.

In February 2017, we entered into a license agreement with BIAL for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson’s disease, in the U.S. and Canada. Under the terms of the agreement, we are responsible for the management of all opicapone development and commercialization activities; however, we will depend on BIAL to supply all drug product and investigation medicinal product for our development and commercialization activities. In addition, pursuant to the license agreement, the parties have established a joint steering committee with overall coordination and strategic oversight over activities under the agreement and to provide a forum for regular exchange of information, and BIAL has the right to co-promote licensed products during certain periods of time and to engage in certain marketing-related activities in cooperation with us. Accordingly, our strategy for developing and commercializing opicapone is dependent upon maintaining our current collaboration with BIAL. Because of our reliance on BIAL for certain aspects related to the development and commercialization of opicapone, any disagreement with BIAL, or BIAL’s decision to not devote sufficient time and resources to our collaboration or to not conduct activities in a timely manner, could substantially delay and/or prohibit our ability to develop and commercialize opicapone.

These issues and possible disagreements with AbbVie, Mitsubishi Tanabe, BIAL, 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 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 ORILISSA, 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 ORILISSA 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 ORILISSA, 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.

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, 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 U.S. 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. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize INGREZZA 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.

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 develop and commercialize opicapone, if we fail to use commercially reasonable efforts, fail to submit an NDA for a licensed product by a specified date, or otherwise breach the license agreement. 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.

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

We depend on independent clinical investigators and contract research organizations (CROs) to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If 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 could face liability if a regulatory authority determines that we are promoting INGREZZA, 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 U.S. 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. 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, 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. A significant number of companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the federal civil False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

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 (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, if triggered, may adversely affect our financial condition, operating results, or liquidity.

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

We have a history of losses and expect to increase our expenses for the foreseeable future, and we may never achieve sustained profitability.

Since our inception, we have incurred significant net losses and negative cash flow from operations. As a result of historical operating losses, we had an accumulated deficit of approximately $1.2 billion as of December 31, 2018.

In April 2017, we received FDA approval of INGREZZA for TD, and in July 2018, our partner AbbVie received FDA approval for ORILISSA for management of moderate to severe endometriosis pain in women. However, we have not yet obtained regulatory approvals for any other product candidates. Even if we succeed in commercializing INGREZZA or developing and commercializing any of our other product candidates, we may not be profitable. We also expect to continue to incur significant operating and capital expenditures as we:

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

We expect to increase our expenses and other investments in the coming years as we fund our operations, in-licensing or acquisition opportunities, and capital expenditures. While we were profitable for the year ended December 31, 2018, 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.

As of December 31, 2018, we had approximately 585 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 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, 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.

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 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 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 and our 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 and our 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.

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 commercial sales of INGREZZA, 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 and contract research payments. In addition, we recently received regulatory approval from the FDA for INGREZZA in TD and our revenues will be dependent on our ability to sell INGREZZA and to secure adequate third-party reimbursement. 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 year ended December 31, 2018, 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.

U.S. federal income tax reform could adversely affect our business and financial condition.

On December 22, 2017, U.S. federal income tax legislation was signed into law (H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018", informally titled the Tax Cuts and Jobs Act, or the Tax Act). The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, repeal of the alternative minimum tax for corporations, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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 U.S. tax law. Under the Tax Act, our federal NOLs generated in tax years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs generated in tax years beginning after December 31, 2017, is limited. It is uncertain if and to what extent various states will conform to the Tax 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 thereafter 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 passage of the newly enacted federal income tax law, 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. 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 12 months, the price of our common stock has ranged from approximately $127.00 per share to approximately $65.00 per share. The market price of our common stock may fluctuate in response to many factors, including:

- sales of INGREZZA and ORILISSA;
- the status and cost of our post-marketing commitments for INGREZZA;
- the results of our clinical trials;

- reports of safety issues related to INGREZZA or ORILISSA;
- 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; and
- public concern as to the safety of our drugs.

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, 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 12 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 and/or ORILISSA;
- 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. For example, for so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, we can utilize a shelf registration statement currently on file with the SEC, to allow us to issue an unlimited number of securities from time to time. 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. 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 Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and Nasdaq rules, are creating uncertainty for companies such as ours. These laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased 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 U.S., 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 U.S. will continue to put pressure on the rate of adoption and pricing of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. Additionally, other recent federal 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 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.

Some of the provisions of the ACA have yet to be fully implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, two 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. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act includes a provision repealing, 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". On January 22, 2018, a continuing resolution was enacted on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a 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. On December 14, 2018, a Texas U.S. District Court Judge 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. While the Texas U.S. District Court Judge, as well as the current presidential administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, 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 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare 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 fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. 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 U.S. Department of Health and Human Services has already started the process of soliciting feedback on certain of these measures and, additionally, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these, and other potential, proposals will require authorization through additional legislation to become effective, Congress and the executive branch 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. 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.

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, 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. For example, in August 2017, Teva received approval for AUSTEDO to treat TD.

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.

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 U.S. 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 U.S. 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 U.S.

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 U.S. 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.

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 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; state and local laws that require the registration of pharmaceutical sales representatives; state and local “drug takeback” 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. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, 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 U.S. will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

The use of any of our potential products in clinical trials, and the sale of any approved products, including INGREZZA, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of $25 million per occurrence and $25 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. Upon FDA approval of INGREZZA we expanded our insurance coverage to include product liability insurance related to the sale of INGREZZA in the amount of $25 million per occurrence and $25 million in the aggregate. However, we may be unable to obtain commercially reasonable product liability insurance for any products approved in the future for marketing. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us would decrease our cash reserves and could cause our stock price to fall. 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, 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 and 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. 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 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. 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 U.S. The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue or 20 million euros, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as 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.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

None.

ITEM 2. *PROPERTIES*

We lease our corporate headquarters, which are located in San Diego, California, and consist of 140,000 square feet of laboratory and office space located at 12780 El Camino Real, 45,000 square feet of office space located at 12777 High Bluff Drive, and 7,500 square feet of office space located at 12790 El Camino Real.

We believe that our property and equipment are generally well maintained and in good operating condition.

ITEM 3. *LEGAL PROCEEDINGS*

The information set forth under Note 12 "Commitments and Contingencies" to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K is incorporated herein by reference.

ITEM 4. *MINE SAFETY DISCLOSURES*

None.

PART II

ITEM 5. ***MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***

Our common stock is traded on the Nasdaq Global Select Market under the symbol "NBIX." The following table sets forth for the periods indicated the high and low sale price for our common stock. These prices do not include retail markups, markdowns or commissions.

	High	Low
Year Ended December 31, 2018		
1st Quarter	$ 92.98	$ 74.12
2nd Quarter	$ 106.26	$ 74.34
3rd Quarter	$ 126.98	$ 96.98
4th Quarter	$ 125.59	$ 64.72
Year Ended December 31, 2017		
1st Quarter	$ 47.43	$ 38.38
2nd Quarter	$ 55.38	$ 39.21
3rd Quarter	$ 61.51	$ 44.75
4th Quarter	$ 78.05	$ 57.71

As of February 1, 2019, there were approximately 51 stockholders of record of our common stock. We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

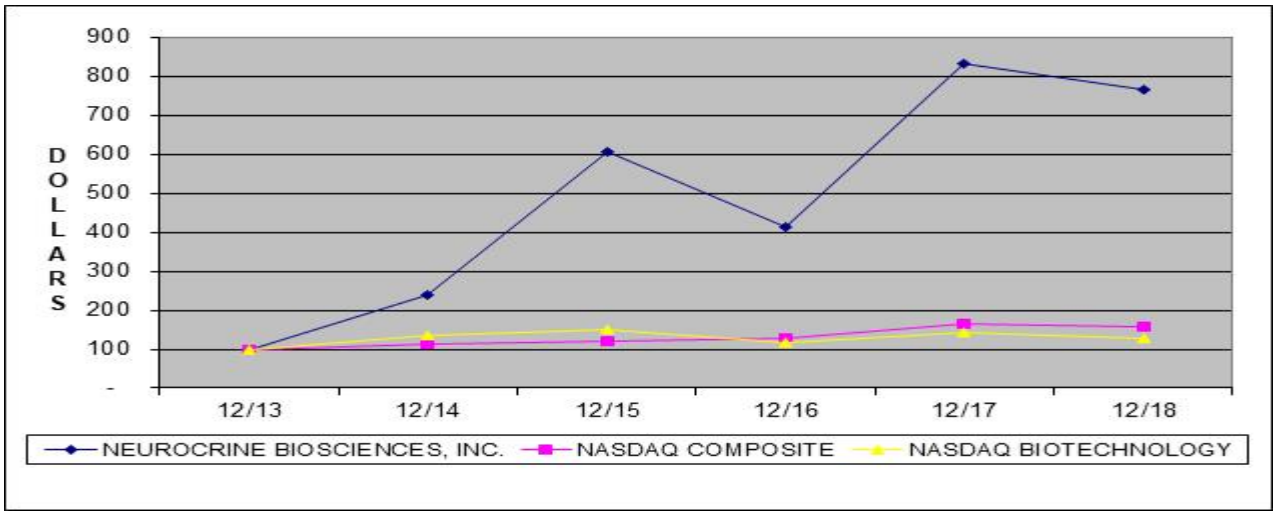
Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities during fiscal 2018.

Stock Performance Graph and Cumulative Total Return*

The graph below shows the cumulative total stockholder return assuming the investment of $100 on December 31, 2013 (and the reinvestment of dividends thereafter) in each of (i) Neurocrine Biosciences, Inc.'s common stock, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index. The comparisons in the graph below are based upon historical data and are not indicative of, or intended to forecast, future performance of our common stock or Indexes.



* *The material in this section is not "soliciting material", is not deemed "filed" with the Securities and Exchange Commission (SEC) and is not to be incorporated by reference into any of our SEC filings whether made before or after the date hereof and irrespective of any general incorporation language in any such SEC filing except to the extent we specifically incorporate this section by reference.*

ITEM 6. ***SELECTED FINANCIAL DATA***

The following selected financial data have been derived from our audited financial statements. The information set forth below is not necessarily indicative of our results of future operations and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K.

(in thousands, except per share data)	2018	2017	2016	2015	2014
STATEMENT OF COMPREHENSIVE INCOME (LOSS) DATA					
Revenues:					
Product sales, net	$ 409,608	$ 116,626	$ —	$ —	$ —
Collaboration revenue	41,632	45,000	15,000	19,769	—
Total revenues	451,240	161,626	15,000	19,769	—
Operating expenses:					
Cost of sales	4,889	1,254	—	—	—
Research and development	160,524	121,827	94,291	81,491	46,425
Sales, general and administrative	248,932	169,906	68,081	32,480	17,986
Total operating expenses	414,345	292,987	162,372	113,971	64,411
Income (loss) from operations	36,895	(131,361)	(147,372)	(94,202)	(64,411)
Other (expense) income:					
Interest expense	(30,530)	(19,523)	—	—	—
Investment income and other, net	15,476	8,342	6,282	5,273	3,869
Total other (expense) income	(15,054)	(11,181)	6,282	5,273	3,869
Income (loss) before provision for income taxes	21,841	(142,542)	(141,090)	(88,929)	(60,542)
Provision for income taxes	730	—	—	—	—
Net income (loss)	$ 21,111	$ (142,542)	$ (141,090)	$ (88,929)	$ (60,542)
Net income (loss) per share:					
Basic	$ 0.23	$ (1.62)	$ (1.63)	$ (1.05)	$ (0.81)
Diluted	$ 0.22	$ (1.62)	$ (1.63)	$ (1.05)	$ (0.81)
Shares used in calculation of net income (loss) per share:					
Weighted average common shares outstanding, basic	90,235	88,089	86,713	84,496	74,577
Weighted average common shares outstanding, diluted	95,386	88,089	86,713	84,496	74,577
BALANCE SHEET DATA					
Cash, cash equivalents and investments	$ 866,941	$ 763,290	$ 350,840	$ 461,679	$ 231,301
Working capital	649,544	500,493	280,028	358,359	182,539
Total assets	993,151	817,591	365,086	474,785	243,033
Convertible senior notes	388,496	369,618	—	—	—
Accumulated deficit	(1,177,755)	(1,198,866)	(1,056,324)	(915,234)	(826,305)
Total stockholders' equity	480,765	372,138	314,877	424,454	208,699

ITEM 7.*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 pertaining to, among other things, the commercialization of our product and product candidates, the expected continuation of our collaborative agreements, the receipt of research and development payments thereunder, the future achievement of various milestones in product development and the receipt of payments related thereto, the potential receipt of royalty payments, preclinical testing and clinical trials of potential products, the period of time that our existing capital resources will meet our funding requirements, and our financial results of operations. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various risks and uncertainties, including those set forth in this Annual Report on Form 10-K under the heading "Item 1A. Risk Factors." See "Forward-Looking Statements" in Part I of this Annual Report on Form 10-K.

Overview

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

On April 11, 2017, the United States Food and Drug Administration (FDA) approved INGREZZA® (valbenazine) capsules for the treatment of adults with tardive dyskinesia (TD). We market INGREZZA for TD in the United States (U.S.) through our specialty sales force focused primarily on physicians who treat TD patients, including psychiatrists and neurologists. The commercial launch of INGREZZA occurred on May 1, 2017.

On July 24, 2018, we were notified by AbbVie Inc. (AbbVie) that FDA approval was granted for ORILISSA® (elagolix) for the management of moderate to severe endometriosis pain in women. Discovered and developed through Phase II clinical trials by us, ORILISSA, the first FDA-approved oral medication for the management of endometriosis with associated moderate to severe pain in over a decade, began to be marketed by AbbVie in August 2018 as part of a collaboration to develop and commercialize elagolix for women's health.

Our clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients, elagolix for uterine fibroids partnered with AbbVie, NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH), and a vesicular monoamine transporter 2 (VMAT2) inhibitor and a first-in-class central nervous system (CNS) compound each with potential use in the treatment of neurologic and psychiatric disorders.

AbbVie initiated Phase III studies of elagolix in patients with uterine fibroids in early 2016. The Phase III program included two replicate, pivotal, six-month efficacy and safety studies followed by a six-month safety and efficacy extension study. AbbVie provided positive topline efficacy data from the Phase III studies in women with uterine fibroids in the first quarter of 2018 and additional data from the six-month safety extension study in the third quarter of 2018. We believe the results from these studies will form the basis for an anticipated new drug application (NDA) submission to the FDA in the middle of 2019 for the approval of elagolix in the treatment of uterine fibroids.

We currently have three major collaborations. Two of these collaborations involve out-licensing of our proprietary technology to pharmaceutical partners. In June 2010, we announced an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively, GnRH Compounds). In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe) for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. The third collaboration agreement, which was entered into in February 2018, is one in which we in-licensed technology from BIAL – Portela & Ca, S.A. (BIAL) for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson's disease, in the U.S. and Canada.

On January 28, 2019, we entered into a collaboration and license agreement with a clinical-stage gene therapy company, Voyager Therapeutics, Inc., or Voyager. The collaboration is focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platforms. The four programs consist of Voyager's VY-AADC program for Parkinson's disease and VY-FXN01 program for Friedreich's ataxia, as well as rights to two programs to be determined by the parties in the future. The effectiveness of the agreement is subject to certain conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions. Refer to Note 13 to the consolidated financial statements for more information on the agreement.

We have funded our operations primarily through private and public offerings of our common stock, debt securities, and payments received under collaboration agreements. While we independently develop many of our product candidates, we entered into collaborations for several of our programs and intend to rely on our product revenues and existing and future collaborations to meet our funding requirements. While we were profitable for the year ended December 31, 2018, our future operating results and profitability may fluctuate from period to period as product candidates are advanced through the various stages of clinical development and as we proceed with the commercial launch of INGREZZA and other potential future pipeline products. As of December 31, 2018, we had an accumulated deficit of approximately $1.2 billion.

Results of Operations

Revenues

The following table presents our revenues by category during the periods presented:

	Year Ended December 31,		
(in thousands)	2018	2017	2016
Revenues:			
INGREZZA product sales, net	$ 409,608	$ 116,626	$ —
Collaboration revenue	41,632	45,000	15,000
Total revenues	$ 451,240	$ 161,626	$ 15,000

Product Sales, net

In April 2017, the FDA approved INGREZZA for the treatment of TD. INGREZZA became available for prescription in late April 2017. Net product sales were $409.6 million for 2018 and $116.6 million for 2017. There were no net product sales for 2016.

Collaboration Revenue

In July 2018, we were notified by AbbVie that FDA approval was granted for ORILISSA for the management of moderate to severe endometriosis pain in women, resulting in the achievement of a $40 million event-based milestone, which we recognized as revenue in the third quarter of 2018. We also recognized sales-based royalties of approximately $1.6 million for 2018, which are payable to us by AbbVie on quarterly net sales of ORILISSA.

In October 2017, AbbVie's NDA submission for elagolix in endometriosis was accepted as filed by the FDA, resulting in the achievement of a $30 million event-based milestone, which we recognized as revenue in the fourth quarter of 2017. We also recognized $15 million in development event-based payments as revenue in 2017, resulting from Mitsubishi Tanabe's initiation of Phase II/III development of INGREZZA in TD in Asia.

In 2016, we recognized $15 million in event-based revenue as a result of AbbVie initiating Phase III clinical studies of elagolix in patients with uterine fibroids.

Operating Expenses

Cost of Sales

Cost of sales was $4.9 million for 2018 and $1.3 million for 2017. Cost of sales for product sold in 2018 and 2017 excluded costs that were previously charged to R&D expense prior to FDA approval of INGREZZA for TD. This reduced cost drug product had a positive impact on our cost of sales and related product gross margins for 2018 and 2017. In the first quarter of 2019, we will begin to incur a higher cost of sales that includes the cost of INGREZZA active pharmaceutical ingredients produced following FDA approval. There was no cost of sales for 2016.

Research and Development

R&D expenditures include costs related to preclinical and clinical trials, scientific personnel, equipment, consultants, sponsored research, share-based compensation, and allocated facility and depreciation costs. We do not track fully burdened R&D costs separately for each of our drug candidates. We review our R&D expenses by focusing on the following categories: external development, personnel, facility and depreciation, and other. External development expenses consist of costs associated with our external preclinical and clinical trials, including pharmaceutical development and manufacturing. In-process R&D expenses and collaboration payments include upfront and milestone payments made in connection with strategic licensing arrangements we have entered into with third parties. Personnel expenses include salaries and wages, share-based compensation, payroll taxes, and benefits for those individuals involved in ongoing R&D efforts. Other R&D expenses primarily represent lab supply expenses and scientific consulting expenses.

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

(in millions)	Year Ended December 31, 2018	2017	2016
External development expense:			
VMAT2	$ 37.5	$ 20.9	$ 32.4
CRF_1	9.8	3.9	2.5
Other	5.6	3.4	1.0
Total external development expense	52.9	28.2	35.9
In-process R&D expenses and collaboration payments	15.0	30.0	—
R&D personnel expense	62.0	42.2	34.1
R&D facility and depreciation expense	8.1	5.8	6.3
Other R&D expense	22.5	15.6	18.0
Total R&D expense	$ 160.5	$ 121.8	$ 94.3

R&D expense increased $38.7 million, from $121.8 million in 2017 to $160.5 million in 2018, primarily due to the ongoing progression of our product candidate pipeline and increased personnel expenses on higher headcount, including increased non-cash share-based compensation of $11.7 million, which included a non-recurring charge of $7.7 million related to the modification of certain options and RSUs. In-process R&D expenses and collaboration payments decreased from $30 million in 2017 to $15 million in 2018, primarily due to a $20 million decrease in payments to BIAL. Excluding the decrease in payments to BIAL, R&D expense for 2018 increased $58.7 million compared to 2017.

R&D expense increased $27.5 million, from $94.3 million in 2016 to $121.8 million in 2017, primarily due to a $30 million payment to BIAL to in-license opicapone.

Sales, General and Administrative

Sales, general and administrative (SG&A) expense increased $79.0 million, from $169.9 million in 2017 to $248.9 million in 2018, primarily due to our commercial launch for INGREZZA in April 2017 and the subsequent sales force expansion in the third quarter of 2018, which included higher personnel related costs of $32.0 million compared to 2017, including increased non-cash share-based compensation of $3.9 million.

SG&A expense increased to $101.8 million, from $68.1 million in 2016 to $169.9 million in 2017, primarily due to our commercial launch for INGREZZA in April 2017, an increase of $56.7 million in personnel related costs, including increased non-cash share-based compensation of $8.2 million, and an increase of $36.6 million in external costs resulting from market research, patient support, commercial launch activities, and other professional services.

Other (Expense) Income

Other expense, net, increased $3.9 million, from $11.2 million in 2017 to $15.1 million in 2018, due to higher interest expense in 2018 resulting from our issuance of $517.5 million of 2.25% convertible senior notes due May 15, 2024 (2024 Notes) in May 2017.

Other expense, net, increased $17.5 million, from an income position of $6.3 million in 2016 to an expense position of $11.2 million in 2017, due to the incurrence of interest expense resulting from our issuance of the 2024 Notes in May 2017.

Provision for Income Taxes

Our provision for income taxes for 2018 was $0.7 million for estimated current state income taxes. As of December 31, 2018, we have recorded a full valuation allowance against our net deferred tax assets as realization is uncertain. As a result, our tax expense varies from the statutory tax rate primarily due to the change in the valuation recorded for the year, net of other permanent book/tax differences, tax credits generated, and impacts of changes in tax laws. We did not record a provision for income taxes for 2017 or 2016.

Net Income (Loss)

Net income for 2018 was $21.1 million, or $0.22 diluted net income per share, compared to a net loss of $142.5 million, or $1.62 net loss per share, for 2017 and a net loss of $141.1 million, or $1.63 net loss per share, for 2016. The change from 2017 to 2018 was primarily the result of increased INGREZZA net product sales, offset by ongoing support for the commercial launch of INGREZZA for TD and progression of our clinical pipeline. The change from 2016 to 2017 was primarily the result of increased operating expenses due to the in-licensing of opicapone and costs associated with the commercial launch of INGREZZA for TD, offset by increased revenues primarily driven by sales of INGREZZA.

Liquidity and Capital Resources

At December 31, 2018, our cash, cash equivalents, and investments totaled $866.9 million compared to $763.3 million at December 31, 2017.

Net cash provided by operating activities in 2018 was $101.4 million, compared to net cash used in operating activities of $94.3 million in 2017 and $106.2 million in 2016. The significant change to positive cash flow generated from operations from 2017 to 2018 was primarily driven by increased INGREZZA net product sales and the achievement of the $40.0 million event-based milestone related to the FDA's approval of ORILISSA. The net loss from 2017 increased by $1.4 million over 2016 levels but included increased non-cash share-based compensation of $14.1 million and the amortization of the debt discount of approximately $10.9 million resulting from our issuance of the 2024 Notes in May 2017.

Net cash used in investing activities was $242.9 million in 2018 and $251.3 million in 2017, compared to net cash provided by investing activities of $113.0 million in 2016. The change in net cash used in investing activities resulted primarily from timing differences in investment purchases, sales and maturities of investments, fluctuation of our portfolio-mix between cash equivalents and short-term and long-term investment holdings, and an increase in additions to our property and equipment, which in 2018 consisted predominantly of tenant improvements to our corporate facilities.

Net cash provided by financing activities was $29.5 million in 2018, $516.6 million in 2017, and $2.4 million in 2016. The change in cash provided by financing activities was primarily due to net proceeds of approximately $502.8 million from our issuance of the 2024 Notes in May 2017. Proceeds from stock option exercises were approximately $29.5 million in 2018, $13.9 million in 2017, and $2.4 million in 2016.

Shelf Registration Statement. In February 2017, we filed an automatic shelf registration statement which immediately became effective by rule of the Securities and Exchange Commission (SEC). For so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, this shelf registration statement allows us to issue an unlimited number of securities from time to time. We sold no securities under this shelf registration statement in 2018 or 2017.

Convertible Debt. In May 2017, we issued the 2024 Notes. Refer to Note 5 to the consolidated financial statements for more information on the 2024 Notes.

Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenue recognition and share-based compensation. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Historically, revisions to our estimates have not resulted in a material change to the financial statements. The items in our financial statements requiring significant estimates and judgments are as follows:

Product Revenue Recognition

Our net product sales consist of U.S. sales of INGREZZA and are recognized when the customer obtains control of our product in an amount that reflects the consideration we expect to receive from the customer in exchange for that product. If the consideration promised under the associated contract includes a variable amount, we estimate the consideration we expect to receive for transferring the good to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and; (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

Revenue from product sales is recorded at the net sales (transaction) price, which includes an estimate of variable consideration for which reserves are established and which results from contractual discounts, returns, chargebacks, rebates, co-pay assistance, and other allowances relating to sales of our products. The following represent our significant categories of sales discounts and allowances:

Trade Discounts and Allowances: We generally provide customers with discounts, that include prompt payment, discounts for sales data, and other off-invoice discounts that are explicitly stated in the associated contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Product Returns: We offer our customers limited product return rights for damages and shipment errors provided it is within a very limited period after the original shipping date as set forth in the applicable individual distribution agreement. We do not allow product returns for product that has been dispensed to a patient or for drug expiration. We receive real-time shipping and inventory reports from our customers and have the ability to control the amount of product that is sold to our customers. Product returns to date have not been significant and we have not considered it necessary to record a reserve for product returns.

Government Rebates: We are subject to discount obligations under state Medicaid programs and Medicare prescription drug coverage gap program. We estimate our Medicaid and Medicare prescription drug coverage gap rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses on the consolidated balance sheet. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and we generally issue credits for such amounts following the customer's notification to us of the resale. Reserves for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to qualified healthcare providers.

Co-Payment Assistance: We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period.

Share-Based Compensation

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

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

Additional Information

Refer to Note 1 to the consolidated financial statements for information on accounting pronouncements that have impacted or are expected to materially impact our consolidated financial condition, results of operations, or cash flows.

Factors That May Affect Future Financial Condition and Liquidity

We anticipate increases in expenditures as we execute on our commercialization plan for INGREZZA and continue our R&D activities. Our strategies to develop some of our programs may include collaborative agreements with major pharmaceutical companies and sales of our securities in both public and private offerings. Such collaborative agreements may include a partial recovery of our research costs through license fees, contract research funding, and milestone revenues and such collaborators may be financially and managerially responsible for clinical development and commercialization. In these cases, the estimated completion date would largely be under the control of the collaborator. We cannot forecast, with any degree of certainty, which other proprietary products or indications, if any, will be subject to collaborative arrangements of this nature, in whole or in part, and how such arrangements would affect our capital requirements.

Our in-license, research, and clinical development agreements are generally cancelable with written notice within 180 days or less. In addition to the minimum annual payments due under certain in-license and research agreements, including a $30 million upfront license fee paid to BIAL in February 2017, we may be required to pay up to approximately $105 million in milestone payments, plus sales royalties, in the event that all scientific research, development and commercialization milestones under these agreements are achieved.

The funding necessary to execute our business strategies is subject to numerous uncertainties, which may adversely affect our liquidity and capital resources. Marketing of approved pharmaceuticals and completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate. It is also important to note that if a clinical candidate is identified, the further development of that candidate can be halted or abandoned at any time due to a number of factors. These factors include, but are not limited to, funding constraints, safety or a change in market demand.

The nature and efforts required to develop our product candidates into commercially viable products include research to identify a clinical candidate, preclinical development, clinical testing, FDA approval and commercialization. In the pharmaceutical industry, total R&D spend for a drug candidate that successfully completes all stages of R&D and is commercialized may exceed $2 billion. Further, it can take in excess of ten years to complete all stages of R&D for a drug candidate.

We test our potential product candidates in numerous preclinical studies to identify disease indications for which our product candidates may show efficacy. We may conduct multiple clinical trials to cover a variety of indications for each product candidate. As we obtain results from trials, we may elect to discontinue clinical trials for certain product candidates or for certain indications in order to focus our resources on more promising product candidates or indications. The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during the clinical trial protocol, including, among others, the following:

- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- we may discover that a product candidate may cause harmful side effects;
- patient recruitment may be slower than expected; and
- patients may drop out of the trials.

For each of our programs, we periodically assess the scientific progress and merits of the programs to determine if continued R&D is economically viable. Certain of our programs have been terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. Because of the uncertainties associated with R&D of these programs, we may not be successful in achieving commercialization. As such, the ultimate timeline and costs to commercialize a product cannot be accurately estimated.

Other than INGREZZA, which has been approved by the FDA for the treatment of TD, and ORILISSA (partnered with AbbVie), which has been approved by the FDA for the management of moderate to severe endometriosis pain in women, our product candidates have not yet achieved FDA regulatory approval, which is required before we can market them as therapeutic products in the U.S. In order to proceed to subsequent clinical trial stages and to ultimately achieve regulatory approval, the FDA must conclude that our clinical data establish safety and efficacy. We must satisfy the requirements of similar regulatory authorities in foreign countries in order to market products in those countries. The results from preclinical testing and early clinical trials may not be predictive of results in later clinical trials. It is possible for a candidate to show promising results in clinical trials, but subsequently fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals.

As a result of the uncertainties discussed above, among others, the duration and completion costs of our R&D projects, clinical trials, and post-marketing studies are difficult to estimate and are subject to considerable variation. Our inability to complete our R&D projects in a timely manner or our failure to enter into collaborative agreements, when appropriate, could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

We currently have limited experience in marketing and selling pharmaceutical products. If we fail to maintain successful marketing, sales, and reimbursement capabilities, or fail to enter into successful arrangements with third parties, our product revenues may suffer. We also may be required to make further substantial expenditures if unforeseen difficulties arise in other areas of our business. In particular, our future capital requirements will depend on many factors, including:

- the commercial success of INGREZZA and/or ORILISSA;
- 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 believe that our existing capital resources, together with investment income and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, we cannot guarantee that our existing capital resources and anticipated revenues will be sufficient to conduct and complete all of our research and development programs or commercialization activities as planned.

We may require additional funding to effectively commercialize INGREZZA, to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, the cost of product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We may seek to access the public or private equity markets whenever conditions are favorable. For example, we have an effective shelf registration statement on file with the SEC which allows us to issue an unlimited number of shares of our securities from time to time. In addition, we issued $517.5 million of convertible debt in May 2017 and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. We may also seek additional funding through strategic alliances or other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt may involve operating covenants that may restrict our business. If adequate funds are not available through these means, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies, products or product candidates. To the extent that we are unable to obtain third-party funding for such expenses, we expect that increased expenses will result in increased cash flow losses from operations. We cannot assure you that we will successfully develop our products under development or that our approved products will generate revenues sufficient to enable us to earn a profit.

Contractual Obligations

Our contractual obligations as of December 31, 2018, are as follows:

(in millions)	Total	2019	2020	2021	2022	2023 and Thereafter
Contractual obligations:						
2024 Notes and related interest (1)	$ 581.4	$ 11.6	$ 11.6	$ 11.6	$ 11.6	$ 535.0
Operating leases (2)	101.9	7.4	8.4	8.6	8.9	68.6
Total contractual obligations	$ 683.3	$ 19.0	$ 20.0	$ 20.2	$ 20.5	$ 603.6

(1) Amounts for the 2024 Notes and related interest in the table above assume that we will hold the 2024 Notes until maturity.

(2) Amounts for operating leases presented in the table above reflect future minimum rental commitments under non-cancelable operating leases as of December 31 for each of the periods presented.

2024 Notes and Related Interest. In May 2017, we completed a private placement of $517.5 million in aggregate principal amount of 2.25% convertible senior notes scheduled to mature on May 15, 2024, unless earlier converted, redeemed, or repurchased. We may not redeem the 2024 Notes prior to May 15, 2021. On or after this date, at our election, we may redeem all, or any portion, of the 2024 Notes under certain circumstances. The 2024 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness, or the issuance or repurchase of securities by us. There are customary events of default with respect to the 2024 Notes, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the 2024 Notes will automatically become due and payable. Refer to Note 5 to the consolidated financial statements for more information on the 2024 Notes.

Operating Leases. We lease our corporate headquarters, which consist of laboratory and office space located San Diego, California, under various operating lease agreements. In addition to minimum rental commitments, these operating leases may require us to pay additional amounts for taxes, insurance, maintenance, and other operating expenses. The non-cancelable lease terms for these operating leases expire at various dates between 2020 and 2029 and do not include renewal options. Refer to Note 10 to the consolidated financial statements for more information on the major facilities that we occupy under lease arrangements.

ITEM 7A.*QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

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 12 months. If a 10% change in interest rates were to have occurred on December 31, 2018, this change would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

NEUROCRINE BIOSCIENCES, INC.
INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of
Neurocrine Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Neurocrine Biosciences, Inc. (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 7, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1992.

San Diego, California
February 7, 2019

NEUROCRINE BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 141,714	$ 254,712
Short-term investments, available-for-sale	509,199	261,217
Accounts receivable	56,240	31,127
Inventory	10,864	1,024
Other current assets	19,760	6,839
Total current assets	737,777	554,919
Property and equipment, net	33,869	10,811
Long-term investments, available-for-sale	216,028	247,361
Restricted cash	5,477	4,500
Total assets	$ 993,151	$ 817,591
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 86,377	$ 53,520
Other current liabilities	1,856	906
Total current liabilities	88,233	54,426
Deferred gain on sale of real estate	7,312	8,043
Deferred revenue	10,231	10,231
Deferred rent	18,114	3,135
Convertible senior notes	388,496	369,618
Total liabilities	512,386	445,453
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 220,000,000 shares authorized; issued and outstanding shares were 90,797,087 and 88,793,903 at December 31, 2018 and 2017, respectively	91	89
Additional paid-in capital	1,660,361	1,572,765
Accumulated other comprehensive loss	(1,932)	(1,850)
Accumulated deficit	(1,177,755)	(1,198,866)
Total stockholders' equity	480,765	372,138
Total liabilities and stockholders' equity	$ 993,151	$ 817,591

See accompanying notes to consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
AND COMPREHENSIVE INCOME (LOSS)

(in thousands, except per share data)	Year Ended December 31, 2018	2017	2016
Revenues:			
Product sales, net	$ 409,608	$ 116,626	$ —
Collaboration revenue	41,632	45,000	15,000
Total revenues	451,240	161,626	15,000
Operating expenses:			
Cost of sales	4,889	1,254	—
Research and development	160,524	121,827	94,291
Sales, general and administrative	248,932	169,906	68,081
Total operating expenses	414,345	292,987	162,372
Income (loss) from operations	36,895	(131,361)	(147,372)
Other (expense) income:			
Interest expense	(30,530)	(19,523)	—
Investment income and other, net	15,476	8,342	6,282
Total other (expense) income	(15,054)	(11,181)	6,282
Income (loss) before provision for income taxes	21,841	(142,542)	(141,090)
Provision for income taxes	730	—	—
Net income (loss)	$ 21,111	$ (142,542)	$ (141,090)
Net income (loss) per share:			
Basic	$ 0.23	$ (1.62)	$ (1.63)
Diluted	$ 0.22	$ (1.62)	$ (1.63)
Shares used in the calculation of net income (loss) per share:			
Weighted average common shares outstanding, basic	90,235	88,089	86,713
Weighted average common shares outstanding, diluted	95,386	88,089	86,713
Other comprehensive income (loss):			
Net income (loss)	$ 21,111	$ (142,542)	$ (141,090)
Unrealized (loss) gain on available-for-sale securities	(82)	(1,532)	659
Comprehensive income (loss)	$ 21,029	$ (144,074)	$ (140,431)

See accompanying notes to consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Other Comprehensive (Loss) Gain	Accumulated Deficit	Total Stockholders' Equity
BALANCE AT DECEMBER 31, 2015	86,263	$ 86	$ 1,340,579	$ (977)	$ (915,234)	$ 424,454
Net loss	—	—	—	—	(141,090)	(141,090)
Unrealized gains on available-for-sale investments	—	—	—	659	—	659
Share-based compensation expense	—	—	28,464	—	—	28,464
Issuance of common stock for vested restricted stock units	284	—	—	—	—	—
Issuance of common stock for stock option exercises	336	1	2,389	—	—	2,390
BALANCE AT DECEMBER 31, 2016	86,883	$ 87	$ 1,371,432	$ (318)	$ (1,056,324)	$ 314,877
Net loss	—	—	—	—	(142,542)	(142,542)
Unrealized losses on available-for-sale investments	—	—	—	(1,532)	—	(1,532)
Share-based compensation expense	—	—	42,522	—	—	42,522
Issuance of common stock for vested restricted stock units	562	1	—	—	—	1
Issuance of common stock for stock option exercises	1,349	1	13,863	—	—	13,864
Equity component of convertible debt, net of issuance costs	—	—	144,948	—	—	144,948
BALANCE AT DECEMBER 31, 2017	88,794	$ 89	$ 1,572,765	$ (1,850)	$ (1,198,866)	$ 372,138
Net income	—	—	—	—	21,111	21,111
Unrealized losses on available-for-sale investments	—	—	—	(82)	—	(82)
Share-based compensation expense	—	—	58,068	—	—	58,068
Issuance of common stock for vested restricted stock units	429	—	—	—	—	—
Issuance of common stock for stock option exercises	1,574	2	29,528	—	—	29,530
BALANCE AT DECEMBER 31, 2018	90,797	$ 91	$ 1,660,361	$ (1,932)	$ (1,177,755)	$ 480,765

See accompanying notes to consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Year Ended December 31, 2018	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES			
Net income (loss)	$ 21,111	$ (142,542)	$ (141,090)
Reconciliation of net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	4,024	2,400	1,453
Amortization of debt discount	17,552	10,937	—
Amortization of debt issuance costs	1,326	848	—
Amortization of premiums on investments	1,449	1,756	3,520
Share-based compensation expense	58,068	42,522	28,464
Deferred rent	351	1,203	(294)
Gain on sales of assets, net	(760)	(2,104)	(3,431)
Cease-use expense	—	(544)	(584)
Change in operating assets and liabilities:			
Accounts receivable	(25,113)	(31,127)	—
Inventory	(3,524)	(1,024)	—
Reimbursements for tenant improvements	8,701	—	—
Accounts payable and accrued liabilities	24,223	27,338	4,398
Other current assets and liabilities, net	(6,044)	(3,994)	1,383
Net cash provided by (used in) operating activities	101,364	(94,331)	(106,181)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of investments	(545,962)	(583,408)	(298,776)
Sales and maturities of investments	327,825	339,088	415,826
Purchases of property and equipment	(24,812)	(6,940)	(4,108)
Proceeds from sales of property and equipment	34	7	13
Net cash (used in) provided by investing activities	(242,915)	(251,253)	112,955
CASH FLOWS FROM FINANCING ACTIVITIES			
Issuance of common stock	29,530	13,865	2,390
Proceeds from issuance of senior convertible notes, net	—	502,781	—
Net cash provided by financing activities	29,530	516,646	2,390
Net change in cash, cash equivalents, and restricted cash	(112,021)	171,062	9,164
Cash, cash equivalents, and restricted cash at beginning of the period	259,212	88,150	78,986
Cash, cash equivalents, and restricted cash at end of the period	$ 147,191	$ 259,212	$ 88,150
SUPPLEMENTAL DISCLOSURES			
Cash paid for interest	$ 11,644	$ 6,242	$ —
Non-cash capital expenditures	$ 2,318	$ —	$ —

See accompanying notes to consolidated financial statements.

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business Activities. Neurocrine Biosciences, Inc. (the Company or Neurocrine) 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 the Company. The Company also has two wholly-owned Irish subsidiaries, Neurocrine Therapeutics, Ltd. and Neurocrine Europe, Ltd. both of which were formed in December 2014 and are inactive. The Company discovers, develops, and commercializes innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through its novel research and development (R&D) platform, focused on neurological and endocrine related diseases and disorders.

The Company discovered, developed, and markets INGREZZA® (valbenazine), the first United States Food and Drug Administration (FDA)-approved product indicated for the treatment of adults with tardive dyskinesia (TD), an involuntary movement disorder. Discovered and developed through Phase II clinical trials by the Company, ORILISSA® (elagolix), the first FDA-approved oral medication for the management of endometriosis associated with moderate to severe pain in over a decade, is marketed by AbbVie Inc. (AbbVie) as part of a collaboration to develop and commercialize elagolix for women’s health. The Company’s clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in Parkinson's disease patients, elagolix for uterine fibroids partnered with AbbVie, NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH), and a vesicular monoamine transporter 2 (VMAT2) inhibitor and a first-in-class central nervous system (CNS) compound each with potential use in the treatment of neurologic and psychiatric disorders.

Principles of Consolidation. The consolidated financial statements include the accounts of Neurocrine as well as its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

Industry Segment and Geographic Information. The Company operates in a single industry segment – the discovery, development, and marketing of pharmaceuticals for the treatment of neurological and endocrine based diseases and disorders. The Company had no foreign based operations during any of the years presented.

Cash Equivalents. The Company considers all highly liquid investments that are readily convertible into cash and have an original maturity of three months or less at the time of purchase to be cash equivalents.

Short-Term and Long-Term Investments Available-for-Sale. Certain investments are classified as available-for-sale and carried at fair value, with any unrealized gains and losses reported in other comprehensive loss. The amortized cost of investments in debt securities is adjusted for the amortization of premiums and accretion of discounts to maturity, which are included in investment income and other, net. The cost of investments in debt securities sold is based on the specific identification method. Realized gains and losses, interest and dividends, and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in investment income and other, net.

Accounts Receivable. Accounts receivable are recorded net of customer allowances for prompt payment discounts, chargebacks, and any allowance for doubtful accounts. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers, and individual customer circumstances. To date, an allowance for doubtful accounts has not been required.

Fair Value of Financial Instruments. Certain financial instruments, including cash, cash equivalents, accounts receivable, accounts payable, and accrued liabilities are carried at cost, which the Company believes approximates fair value because of the short-term nature of these instruments. The $517.5 million of 2.25% convertible senior notes due May 15, 2024 (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 7-year term. The fair value of the 2024 Notes is estimated utilizing market quotations from an over-the-counter trading market and approximated 119% and 128% of the face value of the 2024 Notes at December 31, 2018 and 2017, respectively.

Inventory. Inventory is stated at the lower of cost or estimated net realizable value. The Company currently uses actual costing to determine the cost basis for its inventory. Inventory is valued on a first-in, first-out basis and consists primarily of third-party manufacturing costs. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management’s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed.

Prior to FDA approval of INGREZZA, all costs related to its manufacture were included in R&D expense in the period incurred. Historically, the Company's physical inventory included active pharmaceutical ingredients produced prior to FDA approval of INGREZZA and accordingly had no cost basis as the cost associated with producing this material was expensed in the period incurred. Costs associated with the manufacture of bulk drug product, finished bottling, and other labeling activities that occurred post FDA approval of INGREZZA are included in the inventory value.

The Company reduces its inventory to net realizable value for potential excess, dated, or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. To date, such reserves have not been significant.

Property and Equipment. Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets using the straight-line method. Equipment is depreciated over an average estimated useful life of 3 to 7 years. Leasehold improvements are depreciated over the shorter of their estimated useful lives or the remaining lease term. Depreciation expense was $4.0 million for 2018, $2.4 million for 2017, and $1.5 million for 2016.

Impairment of Long-Lived Assets. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the carrying amount is not recoverable, the Company measures the amount of any impairment by comparing the carrying value of the asset to the present value of the expected future cash flows associated with the use of the asset.

Revenue Recognition. The Company recognizes revenue when the customer obtains control of the product in an amount that reflects the consideration the Company expects to receive from the customer in exchange for that product. To determine revenue recognition, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the good transferred to the customer. Once a contract is determined to be within the scope of Accounting Standards Codification 606, Revenue from Contracts with Customers (Topic 606), at contract inception, the Company assesses the goods promised within the contract to determine those that are performance obligations and assesses whether each promised good is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Sales, Net. The Company's product sales consist of sales of INGREZZA in the U.S. INGREZZA was approved by the FDA on April 11, 2017 and the Company commenced shipments of INGREZZA to specialty pharmacies (SPs) and a specialty distributor (SD) (collectively, customers) in April 2017. The SPs dispense product to a patient based on the fulfillment of a prescription and the SD sells product to closed-door pharmacies and government facilities. The Company's agreements with the customers provide for transfer of title to the product at the time the product is delivered to the customers. In addition, except for limited circumstances, the customers have no right of product return. Product sales are recognized when the customers obtain control of the Company's product, typically upon delivery to the customers.

Revenue from product sales are recorded at the net sales price (transaction price), which includes an estimate of variable consideration for which reserves are established and which results from contractual discounts, returns, chargebacks, rebates, co-pay assistance, and other allowances relating to sales of the Company's products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amounts are payable to the customers) or a current liability (if the amounts are payable to parties other than the customers). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Shipping and handling costs related to the Company's product sales are included in sales, general and administrative expenses.

Collaborative and Other Revenue. The Company enters into collaboration and licensing agreements under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services; and royalties on net sales of licensed products.

As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

Royalty Revenue: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Sales-based royalties for ORILISSA are calculated as a percentage of AbbVie net sales as defined in the Company's agreement with AbbVie. Each quarterly period, sales-based royalties are recorded based on estimated quarterly net sales of ORILISSA. Differences between actual results and estimated amounts are adjusted for in the period in which they become known, which typically follows the quarterly period in which the estimate was made.

Licenses of Intellectual Property: If the license to the Company's intellectual property embedded within a collaboration and/or licensing arrangement is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company receives payments from its licensees based on billing schedules established in each agreement. Up-front payments and fees are recorded as deferred revenue upon receipt, or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Milestone Payments: At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. Performance milestone payments represent a form of variable consideration. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or that of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect milestone and license fees revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

Concentration of Credit Risk. The Company does not currently have any of its own manufacturing facilities, and therefore it depends on an outsourced manufacturing strategy for the production of INGREZZA for commercial use and for the production of its product candidates for clinical trials. The Company has contracts in place with one third-party manufacturer that is approved for the commercial production of INGREZZA's capsules at 2 separate sites and one third-party manufacturer that is approved for the production of INGREZZA's active pharmaceutical ingredient. Although there are potential sources of supply other than the Company's existing suppliers, any new supplier would be required to qualify under applicable regulatory requirements.

The Company has entered into distribution agreements with a limited number of SPs and SDs, and all of the Company's product sales are to these customers. The Company's 3 largest customers represented 93% of the Company's product revenue for the year ended December 31, 2018 and 2017 and substantially all of the Company's accounts receivable balance at December 31, 2018 and 2017.

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, investments, and accounts receivables. The Company established guidelines to limit its exposure to credit risk by placing investments with high credit quality financial institutions, diversifying its investment portfolio and placing investments with maturities that maintain safety and liquidity.

Cost of Sales. Cost of sales includes third-party manufacturing, transportation, freight, and indirect overhead costs associated with the manufacture and distribution of INGREZZA, sales-based license costs on AbbVie net sales of ORILISSA, as defined in the Company's agreement with AbbVie, and period costs resulting from certain inventory manufacturing services and variances and adjustment charges. A portion of the costs associated with the manufacture of INGREZZA sold to date was expensed as R&D prior to the FDA's approval of INGREZZA and is therefore excluded from cost of sales during this period.

Research and Development Expenses. R&D expenses consist primarily of salaries, payroll taxes, employee benefits, and share-based compensation charges for those individuals involved in ongoing research and development efforts; as well as scientific consulting fees, preclinical and clinical trial costs, R&D facilities costs, laboratory supply costs, and depreciation of scientific equipment. All such costs are charged to R&D expense as incurred. These expenses result from the Company's independent R&D efforts, as well as efforts associated with collaborations, in-licenses, and third-party funded research arrangements.

Advertising Expense. In connection with the FDA approval and commercial launch of INGREZZA in April 2017, the Company began to incur advertising costs, which are expensed when services are performed, or goods are delivered. The Company incurred advertising costs related to its marketed product, INGREZZA, of $20.5 million in 2018 and $10.1 million in 2017.

Share-Based Compensation. The Company grants stock options to purchase its common stock to eligible employees and directors and also grants certain employees restricted stock units (RSUs) and performance-based restricted stock units (PRSUs). Additionally, the Company allows employees to participate in an employee stock purchase plan (ESPP).

The Company estimates the fair value of stock options and shares to be issued under the ESPP using the Black-Scholes option-pricing model on the date of grant. Restricted stock units are valued based on the closing price of the Company's common stock on the date of grant. The fair value of equity instruments expected to vest are recognized and amortized on a straight-line basis over the requisite service period of the award, which is generally 3 to 4 years; however, certain provisions in the Company's equity compensation plans provide for shorter vesting periods under certain circumstances. The fair value of shares to be issued under the ESPP are recognized and amortized on a straight-line basis over the purchase period, which is generally 6 months. Additionally, the Company granted certain PRSUs that vest upon the achievement of certain pre-defined company-specific performance-based criteria. Expense related to these PRSUs is generally recognized ratably over the expected performance period once the pre-defined performance-based criteria for vesting becomes probable.

Net Income (Loss) Per Share. Basic net income (loss) per share is computed using the weighted average number of common shares outstanding during the period. Diluted net income per share is computed using the weighted average number of common and potentially dilutive shares outstanding during the period, including the potentially dilutive shares resulting from the conversion of the 2024 Notes, and excluding the effect of stock options and restricted stock outstanding for periods when their effect is anti-dilutive, using the treasury stock method.

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. The Company issued the 2024 Notes with a combination settlement feature, which the Company has the ability and intent to use upon conversion of the notes, to settle the principal amount of debt for cash and the excess of the principal portion in shares of its 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 would be considered dilutive under the treasury stock method. Further, approximately 0.3 million PRSUs have been excluded from the calculation of diluted net income per share as the performance condition has not been achieved. In loss periods, basic net loss per share and diluted net loss per share are identical because the otherwise dilutive potential common shares become anti-dilutive and are therefore excluded.

Recently Adopted Accounting Pronouncements.

In May 2014, the Financial Accounting Standards Board (FASB) issued Account Standards Update (ASU) No. 2014-09, "Revenue from Contracts with Customers (Topic 606)", which supersedes all existing revenue recognition requirements, including most industry-specific guidance. This new standard amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The Company adopted this standard on January 1, 2018, using the modified retrospective method, and applied the standard only to contracts that were not completed prior to January 1, 2018. The adoption of the new revenue standard did not change the Company's revenue recognition. As the Company did not identify any accounting changes that impacted the amount of reported revenues with respect to product revenues, or revenue from collaboration and license agreements, no adjustment to retained earnings was required upon adoption.

In November 2016, the FASB issued ASU 2016-18, “Statement of Cash Flows (Topic 230): Restricted Cash”, which clarifies the presentation of restricted cash and restricted cash equivalents in the statements of cash flows. Under this ASU, restricted cash and restricted cash equivalents are included with cash and cash equivalents when reconciling the beginning and end-of-period total amounts presented on the statements of cash flows. This ASU is intended to reduce diversity in practice in the classification and presentation of changes in restricted cash on the statement of cash flows. This ASU requires that the statement of cash flows explain the change in total cash and equivalents and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning and end-of-period total amounts. This ASU also requires a reconciliation between the total of cash and equivalents and restricted cash presented on the statement of cash flows and the cash and equivalents balance presented on the balance sheet. This amended guidance was retrospectively adopted on January 1, 2018 and requires that cash, cash equivalents, and restricted cash reported on the consolidated statements of cash flows now includes restricted cash of $5.5 million as of December 31, 2018 and $4.5 million as of December 31, 2017, as well as previously reported cash and cash equivalents.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842)”, which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. Topic 842 establishes a right-of-use (ROU) model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Topic 842 also requires disclosures to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases.

Topic 842 is effective for the Company beginning January 1, 2019, using a modified retrospective approach, with early adoption permitted. An entity may choose to use either the effective date or the beginning of the earliest comparative period presented in the financial statements as the date of initial application. The Company expects to adopt Topic 842 on January 1, 2019, using a modified retrospective approach, and to choose the effective date as the date of initial application. Consequently, financial information will not be updated, and the disclosures required under Topic 842 will not be provided for dates and periods prior to January 1, 2019.

Topic 842 provides a number of optional practical expedients and accounting policy elections. The Company expects to elect the package of practical expedients requiring no reassessment of whether any expired or existing contracts are or contain leases, the lease classification of any expired or existing leases, or initial direct costs for any existing leases. Further, the Company expects to elect accounting policies not to apply the recognition requirements under Topic 842 to any of the Company’s short-term leases, instead recognizing the lease payments in profit or loss on a straight-line basis over the lease term, and to account for each separate lease and associated nonlease components as a single lease component for all of its leases.

The Company expects Topic 842 will have a material effect on its consolidated balance sheets. However, the Company does not expect Topic 842 will have a material effect on its consolidated statements of operations and comprehensive income (loss) or consolidated statements of cash flows. While the Company continues to assess all of the effects of adoption, the most significant effects relate to (1) the recognition of right-of-use (ROU) assets of approximately $49 million and lease liabilities of approximately $69 million, primarily resulting from leases of office and laboratory space; (2) the recognition of an existing deferred gain on a sale of real estate of approximately $8 million as a cumulative-effect adjustment to equity; (3) the derecognition of deferred rent of approximately $20 million for certain lease incentives received; and (4) significant new disclosure requirements.

In June 2018, the FASB issued ASU 2018-07, “Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting”, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees and applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. This ASU does not apply to share-based payments used to effectively provide financing to the issuer or awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606. This update is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company does not expect this update will have a material impact on its consolidated financial statements and related disclosures.

NOTE 2. SIGNIFICANT COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Mitsubishi Tanabe Pharma Corporation. During 2015, the Company entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe) for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. Mitsubishi Tanabe made an up-front license fee of $30 million and has agreed to make payments up to $85 million in development and commercialization event-based payments, payments for the manufacture of pharmaceutical products, and royalties on product sales in select territories in Asia.

Under the terms of the agreement, Mitsubishi Tanabe is responsible for all third-party development, marketing and commercialization costs in Japan and other select Asian markets and the Company 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 the Company. The Company does not directly control when event-based payments will be achieved or when royalty payments will begin. Mitsubishi Tanabe may terminate the agreement at its discretion upon 180 days written notice to the Company. In such event, all INGREZZA product rights for Japan and other select Asian markets would revert to the Company.

The Company 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 trial of INGREZZA for Huntington's chorea, at an estimated cost of approximately $12 million, should Mitsubishi Tanabe request. The Company has the option to participate on the joint steering committee, but since participation is at its option it was deemed to not be a performance obligation. The option for Mitsubishi Tanabe to engage the Company 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, the Company 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, the Company determined that the up-front amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's 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 the Company's development activities to initiate a clinical trial 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. The Company believes a change in the assumptions used to determine its 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 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 its evaluation of the constraint, the Company considered numerous factors, including that achievement of the milestones is outside of its 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 Mitsubishi Tanabe and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

To date, the Company has recognized revenue under this agreement of $19.8 million associated with the delivery of a technology license and existing know-how, and $15 million in development event-based payments resulting from Mitsubishi Tanabe's initiation of Phase II/III development of INGREZZA in tardive dyskinesia (TD) in Asia. In accordance with the Company's continuing performance obligations, $10.2 million of the $30 million up-front payment is being deferred and recognized in future periods. Under the terms of the agreement, there is no general obligation to return the up-front payment for any non-contingent deliverable. No revenue was recognized under the Mitsubishi Tanabe agreement for 2018 or 2016. In 2017, the Company recognized $15 million in development event-based payments resulting from Mitsubishi Tanabe's initiation of Phase II/III development of INGREZZA in TD in Asia.

AbbVie. In June 2010, the Company announced an exclusive worldwide collaboration with AbbVie, to develop and commercialize elagolix and all next-generation gonadotropin-releasing factor (GnRH) antagonists (collectively, GnRH Compounds) for women's and men's health. AbbVie made an upfront payment of $75 million and has agreed to make additional development and regulatory event-based payments of up to $480 million, of which $115 million has been earned as of December 31, 2018, and up to an additional $50 million in commercial event-based payments.

Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing and commercialization costs. The Company will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. AbbVie may terminate the collaboration at its discretion upon 180 days written notice to the Company. In such event, the Company would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to the Company.

The Company evaluated the terms of this agreement under Topic 606 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 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 the Company's evaluation of the constraint, the Company considered numerous factors, including that achievement of the milestones is outside of its 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. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

On July 24, 2018, AbbVie received approval from the FDA for ORILISSA for the management of moderate to severe endometriosis pain in women, resulting in the achievement of a $40 million event-based milestone, which the Company recognized as revenue for 2018. The Company also recognized sales-based royalties on AbbVie net sales of ORILISSA of approximately $1.6 million for 2018. In 2017, event-based revenue of $30 million was recognized based on AbbVie's new drug application (NDA) submission for elagolix in endometriosis being accepted by the FDA. In 2016, event-based revenue of $15 million was recognized related to AbbVie's initiation of Phase III development of elagolix in uterine fibroids.

BIAL – Portela & Ca, S.A. In February 2017, the Company entered into an exclusive license agreement with BIAL – Portela & Ca, S.A. (BIAL) for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson's disease, in the U.S. and Canada. The Company paid BIAL an upfront license fee of $30 million, which was expensed in 2017 as in-process R&D. During the first quarter of 2018, the FDA provided guidance on the regulatory path forward to support an NDA for opicapone for Parkinson's Disease, in which the FDA did not request that the Company conduct an additional Phase III study, resulting in a $10 million event-based milestone payment to BIAL, which was expense as incurred. The Company may be required to pay up to an additional $105 million in milestone payments associated with the regulatory approval and net sales of opicapone. Prior to FDA approval of opicapone, the Company may also be required to pay up to an additional $10 million in milestones based on certain regulatory and clinical results and FDA acceptance of the Company's NDA submission for opicapone. Upon commercialization of opicapone, the Company agreed to determine certain annual sales forecasts. In the event the Company fails to meet the minimum sales requirements for a particular year, it would be required to pay BIAL an amount equal to the difference between the actual net sales and minimum sales requirements for such year. In the event the Company fails to meet the minimum sales requirements for any two years, BIAL may terminate the agreement.

Under the terms of the agreement, the Company is responsible for the management and cost of all opicapone development and commercialization activities in the U.S. and Canada. Further, unless terminated earlier, 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. Upon the Company's written request prior to the estimated expiration of the term in respect 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, the Company shall pay BIAL a trademark royalty based on the net sales of such licensed product. Either party may terminate the agreement earlier 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 the Company fails to use commercially reasonable efforts or to submit an NDA for a licensed product by a specified date or under certain circumstances involving a change of control of the Company. In certain circumstances where BIAL elects to terminate the agreement in connection with the Company's change of control, BIAL shall pay the Company a termination fee. The Company may terminate the agreement at any time for any reason upon six months written notice to BIAL if prior to the first NDA approval in the U.S., and upon 9 months written notice to BIAL if such notice is given after the first NDA approval in the U.S. If the Company's termination request occurs prior to the first NDA approval in the U.S., it shall pay BIAL a termination fee except under certain conditions specified in the agreement.

NOTE 3. INVESTMENTS

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

Investments at December 31, 2018 and 2017 consisted of the following:

(in thousands)	December 31, 2018	December 31, 2017
Commercial paper	$ 94,572	$ 75,362
Corporate debt securities	544,978	414,815
Securities of government-sponsored entities	85,677	18,401
Total investments	$ 725,227	$ 508,578

The following is a summary of investments classified as available-for-sale securities:

(in thousands)	Contractual Maturity (in years)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Estimated Fair Value
December 31, 2018:					
Classified as current assets:					
Commercial paper	Less than 1	$ 94,617	$ —	$ (45)	$ 94,572
Corporate debt securities	Less than 1	395,385	—	(1,598)	393,787
Securities of government-sponsored entities	Less than 1	20,887	8	(55)	20,840
Total short-term available-for-sale securities		$ 510,889	$ 8	$ (1,698)	$ 509,199
Classified as non-current assets:					
Corporate debt securities	1 to 2	$ 151,594	$ 66	$ (469)	$ 151,191
Securities of government-sponsored entities	1 to 2	64,676	162	(1)	64,837
Total long-term available-for-sale securities		$ 216,270	$ 228	$ (470)	$ 216,028
December 31, 2017:					
Classified as current assets:					
Commercial paper	Less than 1	$ 75,396	$ 1	$ (35)	$ 75,362
Corporate debt securities	Less than 1	178,776	—	(400)	178,376
Securities of government-sponsored entities	Less than 1	7,503	—	(24)	7,479
Total short-term available-for-sale securities		$ 261,675	$ 1	$ (459)	$ 261,217
Classified as non-current assets:					
Corporate debt securities	1 to 2	$ 237,749	$ —	$ (1,310)	$ 236,439
Securities of government-sponsored entities	1 to 2	11,004	—	(82)	10,922
Total long-term available-for-sale securities		$ 248,753	$ —	$ (1,392)	$ 247,361

The following table presents gross unrealized losses and fair value for those available-for-sale investments that were in an unrealized loss position as of December 31, 2018 and 2017, aggregated by investment category and length of time that individual securities have been in a continuous loss position:

	Less Than 12 Months		12 Months or Greater		Total	
(in thousands)	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
December 31, 2018:						
Commercial paper	$ 51,927	$ (45)	$ —	$ —	$ 51,927	$ (45)
Corporate debt securities	274,696	(746)	234,798	(1,321)	509,494	(2,067)
Securities of government-sponsored entities	4,999	(1)	10,947	(55)	15,946	(56)
Total	$ 331,622	$ (792)	$ 245,745	$ (1,376)	$ 577,367	$ (2,168)
December 31, 2017:						
Commercial paper	$ 62,602	$ (35)	$ —	$ —	$ 62,602	$ (35)
Corporate debt securities	386,728	(1,660)	28,087	(50)	414,815	(1,710)
Securities of government-sponsored entities	10,922	(82)	7,479	(24)	18,401	(106)
Total	$ 460,252	$ (1,777)	$ 35,566	$ (74)	$ 495,818	$ (1,851)

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are other-than-temporary. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, and the Company's intent and ability to hold the investment until recovery of its amortized cost basis. The Company intends, and has the ability, to hold its investments in unrealized loss positions until their amortized cost basis has been recovered. Based on its evaluation, the Company determined that its unrealized losses were not other-than-temporary at December 31, 2018 and 2017.

NOTE 4. FAIR VALUE MEASUREMENTS

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

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs include quoted prices for similar instruments in active markets and/or quoted prices for identical or similar instruments in markets that are not active near the measurement date; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company classifies cash equivalents and available-for-sale investments within Level 1 or Level 2. The fair value of the Company's high-quality investment grade corporate debt securities is determined using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or prices for similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company did not reclassify any investments between levels in the fair value hierarchy during the years ended December 31, 2018 and 2017.

The Company's assets, which are measured at fair value on a recurring basis as of December 31, 2018 and 2017, were determined using the inputs described above:

(in millions)	Carrying Value	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2018:				
Classified as current assets:				
Cash and money market funds	$ 141.7	$ 141.7	$ —	$ —
Commercial paper	94.6	—	94.6	—
Securities of government-sponsored entities	20.8	—	20.8	—
Corporate debt securities	393.8	—	393.8	—
Subtotal	650.9	141.7	509.2	—
Classified as long-term assets:				
Cash and money market funds	1.5	1.5	—	—
Certificates of deposit	4.0	4.0	—	—
Securities of government-sponsored entities	64.8	—	64.8	—
Corporate debt securities	151.2	—	151.2	—
Total	872.4	147.2	725.2	—
Less cash, cash equivalents and restricted cash	(147.2)	(147.2)	—	—
Total investments	$ 725.2	$ —	$ 725.2	$ —
December 31, 2017:				
Classified as current assets:				
Cash and money market funds	$ 170.2	$ 170.2	$ —	$ —
Commercial paper	159.9	—	159.9	—
Securities of government-sponsored entities	7.5	—	7.5	—
Corporate debt securities	178.4	—	178.4	—
Subtotal	516.0	170.2	345.8	—
Classified as long-term assets:				
Cash and money market funds	1.5	1.5	—	—
Certificates of deposit	3.0	3.0	—	—
Securities of government-sponsored entities	10.9	—	10.9	—
Corporate debt securities	236.4	—	236.4	—
Total	767.8	174.7	593.1	—
Less cash, cash equivalents and restricted cash	(259.2)	(174.6)	(84.6)	—
Total investments	$ 508.6	$ 0.1	$ 508.5	$ —

The fair value of the 2024 Notes, calculated utilizing market quotations from an over-the-counter trading market for these notes (Level 2), was approximately $616.1 million as of December 31, 2018 and $662.1 million as of December 31, 2017. Refer to Note 5 to the consolidated financial statements for more information on the 2024 Notes.

NOTE 5. CONVERTIBLE SENIOR NOTES

On May 2, 2017, the Company 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 that sets forth the details of all the terms and conditions of the 2024 Notes (2024 Indenture). 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 the Company.

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

(i) during any calendar quarter commencing after the calendar quarter ending on September 30, 2017 (and only during such calendar quarter), if the last reported sale price of the Company's 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 5 business-day period immediately after any 5 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 the Company's 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 the Company's assets; or

(iv) if the Company calls the 2024 Notes for redemption, until the close of business on the business day immediately preceding the redemption date.

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

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

It is the Company's 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 indenture for the notes. 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 VWAP of the Company's 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 the Company's common stock. At the initial conversion rate, settlement of the 2024 Notes for shares of the Company's 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 the Company's common stock on the Nasdaq Global Select Market on April 26, 2017, the date the Company 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, the Company would be required to repay the $517.5 million in principal value and any conversion premium in any combination of cash and shares of its common stock (at the Company's option).

On or after, but not prior to May 15, 2021, the Company may redeem for cash all or part of the 2024 Notes if the last reported sale price (as defined in the 2024 Indenture) of its 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 the Company provides 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 the Company undergoes a fundamental change, as defined in the 2024 Indenture, subject to certain conditions, holders of the 2024 Notes may require the Company 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, the Company will, in certain circumstances, increase the conversion rate for a holder who elects to convert the 2024 Notes in connection with the make-whole fundamental change.

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

While the 2024 Notes are currently classified as long-term on the Company's consolidated balance sheets, the future convertibility and resulting balance sheet classification of this liability will be monitored at each quarterly reporting date and will be analyzed dependent upon market prices of the Company's common stock during the prescribed measurement periods. In the event that the holders of the 2024 Notes have the election to convert the 2024 Notes at any time during the prescribed measurement period, the 2024 Notes would then be considered a current obligation and classified as such.

As of December 31, 2018, the fair value of the 2024 Notes, which was estimated utilizing market quotations from an over-the-counter trading market, approximated 119% of their face value.

An entity must separately account for the liability and equity components of convertible debt instruments (such as the 2024 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's 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 is 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 7-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.

The Company 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 the Company. 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.

Convertible senior notes, net of discounts and deferred financing costs consisted of the following:

	December 31,	
(in thousands)	**2018**	**2017**
Principal	$ 517,500	$ 517,500
Deferred financing costs	(8,326)	(9,652)
Debt discount, net	(120,678)	(138,230)
Net carrying amount	$ 388,496	$ 369,618

NOTE 6. OTHER BALANCE SHEET DETAILS

Inventory consisted of the following:

	December 31,	
(in thousands)	**2018**	**2017**
Raw materials	$ 7,855	$ —
Work in process	2,208	491
Finished goods	801	533
Total inventory	$ 10,864	$ 1,024

Property and equipment, net, consisted of the following:

(in thousands)	December 31, 2018	2017
Tenant improvements	$ 19,857	$ 2,019
Furniture and fixtures	2,968	1,303
Scientific equipment	28,163	26,248
Computer equipment	11,152	8,821
	62,140	38,391
Less accumulated depreciation	(28,271)	(27,580)
Property and equipment, net	$ 33,869	$ 10,811

Accounts payable and accrued liabilities consisted of the following:

(in thousands)	December 31, 2018	2017
Accrued employee related costs	$ 27,341	$ 24,901
Accounts payable	13,801	5,648
Accrued development costs	7,069	4,799
Other accrued liabilities	38,166	18,172
Total accounts payable and accrued liabilities	$ 86,377	$ 53,520

NOTE 7. NET INCOME (LOSS) PER SHARE

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

(in thousands, except per share data)	Year Ended December 31, 2018	2017	2016
Net income (loss) - basic and diluted	$ 21,111	$ (142,542)	$ (141,090)
Weighted-average common shares outstanding:			
Basic	90,235	88,089	86,713
Effect of dilutive securities:			
Employee stock purchase program	11	—	—
Stock options	3,228	—	—
Restricted stock units	564	—	—
2024 Notes	1,348	—	—
Diluted	95,386	88,089	86,713
Net income (loss) per share:			
Basic	$ 0.23	$ (1.62)	$ (1.63)
Diluted	$ 0.22	$ (1.62)	$ (1.63)

Shares which have been excluded from diluted per share amounts because their effect would have been anti-dilutive include the following:

(in thousands)	Year Ended December 31, 2018	2017	2016
Stock options and restricted stock units	887	7,436	6,995

NOTE 8. SHARE-BASED COMPENSATION

Share-Based Compensation Plans. In May 2011, the Company adopted the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan (the 2011 Plan) pursuant to which 19 million shares of Company's common stock are authorized for issuance. The 2011 Plan provides for the grant of stock options that qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended (the Code), nonstatutory stock options, restricted stock awards, restricted stock unit awards (RSUs), stock appreciation rights, performance stock awards, performance-based restricted stock units (PRSUs) and other forms of equity compensation. In May 2018, the Company adopted the Neurocrine Biosciences, Inc. ESPP pursuant to which 300,000 shares of the Company's common stock are authorized for issuance. No purchases have occurred under the ESPP during the year ended December 31, 2018.

The Company also issues stock options and RSUs under the Neurocrine Biosciences, Inc. Inducement Plan (Inducement Plan) to certain employees. The Company granted 70,000 stock options and 20,000 RSUs pursuant to the Inducement Plan in 2018 and granted 410,000 stock options and 12,500 RSUs pursuant to the Inducement Plan in 2017. The Company did not grant any stock options or RSUs pursuant to the Inducement Plan during 2016. These stock option grants have a 4-year vesting period and the RSUs generally have vesting periods of 3 to 4 years. The Company currently has 245,162 in stock options and RSUs outstanding under this Inducement Plan.

As of December 31, 2018, approximately 6.8 million shares of common stock remained available for the future grant of awards under the 2011 Plan. Only share awards made under the 2011 Plan that are subsequently cancelled due to forfeiture or expiration are returned to the share pool available for future grants.

The Company issues new shares upon the exercise of stock options, the issuance of stock bonus awards, and the vesting of RSUs and PRSUs, and has 7.2 million shares of common stock reserved for such issuances as of December 31, 2018.

Vesting Provisions of Share-Based Compensation. Stock options generally have terms from 7 to 10 years from the date of grant, and generally vest over a 3 to 4-year period. The maximum contractual term for all options granted from the 2011 Plan is 10 years. RSUs granted under the 2011 Plan generally have vesting periods of 4 years. PRSUs granted under the 2011 Plan vest based on the achievement of certain pre-defined Company-specific performance criteria and expire 4 to 5 years from the grant date.

Share-Based Compensation. The compensation cost that has been included in the statement of comprehensive income (loss) for all share-based compensation arrangements is as follows:

	Year Ended December 31,		
(in thousands)	2018	2017	2016
Sales, general and administrative expense	$ 31,847	$ 27,951	$ 16,770
Research and development expense	26,221	14,571	11,694
Share-based compensation expense	$ 58,068	$ 42,522	$ 28,464

Stock Options. The exercise price of all stock options granted during the years ended December 31, 2018, 2017 and 2016 was equal to the closing price of the Company's common stock on the date of grant. The estimated fair value of each stock option award granted was determined on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions for option grants during the three years ended December 31, 2018:

	Year Ended December 31,		
(in thousands)	2018	2017	2016
Risk-free interest rate	2.5%	2.0%	1.4%
Expected volatility of common stock	59.5%	58.0%	60.0%
Dividend yield	0.0%	0.0%	0.0%
Expected option term	4.7 years	5.7 years	5.6 years

The Company estimates the fair value of stock options using a Black-Scholes option-pricing model on the date of grant. The fair values of equity instruments are recognized and amortized on a straight-line basis over the requisite service period. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, term, and interest rates. The expected volatility is based on the historical volatility of the Company's common stock over the most recent period commensurate with the estimated expected term of the Company's stock options. The expected option term is estimated based on historical experience as well as the status of the employee. For example, directors and officers have a longer expected option term than all other employees. The risk-free rate for periods within the contractual life of the option is based upon observed interest rates appropriate for the expected term of the Company's employee stock options. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

The Company's determination of fair value is affected by its stock price as well as a number of assumptions that require judgment. The weighted-average fair values of stock options granted during the years ended December 31, 2018, 2017 and 2016, estimated as of the grant date using the Black-Scholes option-pricing model, were $43.42, $25.11 and $21.49, respectively.

A summary of the status of the Company's stock options as of December 31, 2018, 2017 and 2016 and of changes in options outstanding under the plans during the three years ended December 31, 2018 is as follows:

	2018		2017		2016	
(in thousands, except weighted average data)	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at January 1	6,356	$ 28.83	6,112	$ 20.01	5,507	$ 15.63
Granted	1,040	84.97	1,807	46.55	1,077	40.19
Exercised	(1,592)	18.95	(1,353)	10.41	(341)	7.60
Canceled	(58)	64.67	(210)	43.05	(131)	34.35
Outstanding at December 31	5,746	$ 41.38	6,356	$ 28.83	6,112	$ 20.01

Stock options outstanding at December 31, 2018 had a weighted average remaining contractual term of 6.7 years.

For the year ended December 31, 2018, 2017 and 2016 share-based compensation expense related to stock options was $35.4 million, $28.2 million, and $18.4 million, respectively. As of December 31, 2018, there was approximately $55.4 million of unamortized compensation cost related to stock options, which is expected to be recognized over a weighted average remaining vesting period of approximately 2.3 years. As of December 31, 2018, there were approximately 3.9 million stock options exercisable with a weighted average exercise price of $31.07 and a weighted-average remaining contractual term of 5.9 years. The total intrinsic value, which is the amount by which the exercise price was exceeded by the sale price of the Company's common stock on the date of sale, of stock option exercises during the years ended December 31, 2018, 2017, and 2016 was $117.0 million, $61.4 million, and $13.2 million, respectively. As of December 31, 2018, the total intrinsic value of stock options outstanding and exercisable was $186.3 million and $158.2 million, respectively. Cash received from stock option exercises for the years ended December 31, 2018, 2017, and 2016 was $29.5 million, $13.9 million, and $2.4 million, respectively.

Restricted Stock Units. The fair value of RSUs is based on the closing sale price of the Company's common stock on the date of issuance. For the year ended December 31, 2018, 2017, and 2016, share-based compensation expense related to RSUs was $21.9 million, $13.9 million, and $8.3 million, respectively. As of December 31, 2018, there was approximately $51.6 million of unamortized compensation cost related to RSUs, which is expected to be recognized over a weighted average remaining vesting period of approximately 2.3 years.

The total intrinsic value of RSUs converted into common shares during the years ended December 31, 2018, 2017, and 2016 was $35.5 million, $14.9 million, and $12.2 million, respectively. The RSUs, at the election of eligible employees, may be subject to deferred delivery arrangement. The total intrinsic value of RSUs outstanding at December 31, 2018 was $80.9 million based on the Company's closing stock price on that date.

A summary of the status of the Company's RSUs as of December 31, 2018, 2017, and 2016 and of changes in RSUs outstanding under the plans for the three years ended December 31, 2018 is as follows:

	2018		2017		2016	
(in thousands, except weighted average data)	Number of Units	Weighted Average Grant Date Fair Value per Unit	Number of Units	Weighted Average Grant Date Fair Value per Unit	Number of Units	Weighted Average Grant Date Fair Value per Unit
Outstanding at January 1	1,080	$ 40.30	883	$ 29.33	910	$ 24.23
Granted	540	85.29	588	47.21	326	36.73
Cancelled	(58)	36.21	(41)	40.62	(69)	32.50
Converted into common shares	(429)	59.23	(350)	24.19	(284)	20.71
Outstanding at December 31	1,133	$ 62.31	1,080	$ 40.30	883	$ 29.33

Performance-Based Restricted Stock Units. During each of the years ended December 31, 2018 and 2016, the Company granted approximately 0.2 million PRSUs that vest based on the achievement of certain pre-defined Company-specific performance criteria and expire approximately 4 to 5 years from the grant date. No PRSUs were granted during the year ended December 31, 2017. Additionally, 0.2 million PRSUs were earned during the year ended December 31, 2017. The fair value of PRSUs is estimated based on the closing sale price of the Company's common stock on the date of grant. Expense recognition for PRSUs commences when attainment of the performance-based criteria is determined to be probable. During 2018, the Company recognized no expense related to PRSUs. During 2017 and 2016, the Company recognized approximately $0.4 million and $1.8 million, respectively, in expense related to PRSUs. At December 31, 2018, the total unrecognized estimated compensation expense related to PRSUs was $19.7 million

and the total intrinsic value of PRSUs outstanding was $23.6 million based on the Company's closing stock price on that date. The total intrinsic value of PRSUs converted into common shares was $8.8 million during the year ended December 31, 2017. No PRSUs were earned during the years ended December 31, 2018 or 2016.

Employee Stock Purchase Plan. Under the ESPP, eligible employees may purchase shares of the Company's common stock at a discount semi-annually based on a percentage of their annual compensation. The ESPP provides for the granting of up to 300,000 shares of the Company's common stock to eligible employees. The discounted purchase price is equal to the lower of 85% of (i) the market value per share of the common stock on the first day of the offering period or (ii) the market value per share of common stock on the purchase date. Share-based compensation expense recognized under the ESPP was $0.8 million for the year ended December 31, 2018.

NOTE 9. INCOME TAXES

The components of the income tax expense for continuing operations are as follows:

(in thousands)	2018	2017	2016
Current:			
Federal	$ (100)	$ —	$ —
State	830	—	—
Total income tax expense	$ 730	$ —	$ —

The provision for income taxes on earnings subject to income taxes differs from the statutory federal rate at December 31, 2018, 2017 and 2016, due to the following:

(in thousands)	2018	2017	2016
Federal income taxes at 21% for 2018 and 35% for 2017 and 2016	$ 4,587	$ (49,889)	$ (49,383)
State income tax, net of federal benefit	361	(4,013)	2
Tax effect on non-deductible expenses	446	433	(321)
Share-based compensation expense	(9,778)	(19,589)	(5,077)
Officer compensation	915	2,163	—
Change in tax rate	(198)	154,415	—
Expired tax attributes	13,874	2,998	6,708
Research credits	(13,526)	(5,596)	(5,554)
Change in valuation allowance	4,306	(79,966)	53,414
Other	(257)	(956)	211
	$ 730	$ —	$ —

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2018 and 2017 are listed below. A valuation allowance of $335.2 million and $330.9 million at December 31, 2018 and 2017, respectively, has been recognized to offset net deferred tax assets as realization of such assets is uncertain. Amounts are shown as of December 31 as of each respective year:

(in thousands)	2018	2017
Deferred tax assets:		
Net operating losses	$ 223,800	$ 238,500
R&D credits	62,200	47,500
Capitalized R&D	34,800	47,500
Share-based compensation	17,300	14,600
Other	28,600	14,600
Total deferred tax assets	366,700	362,700
Deferred tax liabilities:		
Convertible senior notes	(26,400)	(31,300)
Fixed assets	(5,100)	(500)
Total deferred tax liabilities	(31,500)	(31,800)
Net of deferred tax assets and liabilities	335,200	330,900
Valuation allowance	(335,200)	(330,900)
Net deferred tax assets	$ —	$ —

At December 31, 2018, the Company had federal and state income tax net operating loss carry forwards of approximately $1.0 billion and $398.0 million, respectively. The federal net operating losses will begin to expire in 2021, unless previously utilized.

A portion of the California net operating loss carry forwards expired in 2018. The remaining California net operating losses will begin to expire in 2028 and the net operating losses related to other states will begin to expire in 2026.

In addition, the Company has federal and California R&D tax credit carry forwards of $63.6 million and $41.6 million, respectively. A portion of the federal R&D tax credit carry forwards expired in 2018. The remaining federal R&D tax credits will continue to expire beginning in 2019, unless previously utilized. The California R&D tax credits carry forward indefinitely.

Additionally, the future utilization of the Company's net operating loss and R&D tax credit carry forwards to offset future taxable income may be subject to annual limitations, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that could result in the future. The Company has determined that no ownership changes have occurred through December 31, 2018.

On December 22, 2017, the Tax Cuts and Jobs Act (TCJA) was enacted, reducing the corporate income tax rate from 35% to 21% effective on January 1, 2018. The carrying value of the Company's deferred tax assets is also determined by the enacted U.S. corporate income tax rate. Consequently, any changes in the U.S. corporate income tax rate have impacted the carrying value of the Company's deferred tax assets. Under the new corporate income tax rate of 21%, deferred income taxes decreased, with a corresponding decrease to the valuation allowance. Therefore, the TCJA had no impact on the Company's 2017 earnings. As of December 31, 2018, the Company has completed its accounting of the tax effects from the enactment of the TCJA.

Under the FASB's accounting guidance related to uncertain tax positions, among other things, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, the FASB provides accounting guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

The Company's policy is to recognize interest or penalties related to income tax matters in income tax expense. Interest and penalties related to income tax matters were not material for the years ended December 31, 2018 or 2017.

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax years for 2001 (federal) and 2008 (California) and forward are subject to examination by the U.S. and state tax authorities due to the carry forward of unutilized net operating losses and R&D tax credits.

The following table summarizes the activity related to unrecognized tax benefits:

(in thousands)	2018	2017	2016
Balance as of the beginning of the year	$ 37,403	$ 34,112	$ 33,074
Increases related to prior year tax positions	6,103	—	260
Increases related to current year tax positions	11,726	3,291	2,211
Expiration of the statute of limitations for the assessment of taxes	(457)	—	(1,433)
Balance as of the end of the year	$ 54,775	$ 37,403	$ 34,112

The Company, under authoritative guidance, excluded those deferred tax assets that are not more-likely-than-not to be sustained under the technical merits of the tax position. These unrecognized tax benefits totaled $11.7 million for current year tax positions, as reflected in the table above.

As of December 31, 2018, the Company had $50.1 million of unrecognized tax benefits that, if recognized and realized, would affect the effective tax rate.

In the next 12 months, the Company does not expect a significant change in its unrecognized tax benefits.

NOTE 10. LEASES

In December 2007, the Company closed the sale of its facility and associated real property for a purchase price of $109 million. Concurrent with the sale, the Company retired the entire $47.7 million in mortgage debt previously outstanding with respect to the facility and associated real property and received cash of $61.0 million, net of transaction costs and debt retirement. The ultimate result of this real estate sale was a net deferred gain of $39.1 million, of which the Company recognized $0.7 million in 2018, $2.1 million in 2017, and $3.4 million in 2016. As of December 31, 2018, the remaining balance of the net deferred gain was approximately $7.3 million, which the Company expects to recognize as a cumulative-effect adjustment to equity upon adoption of Topic 842 on January 1, 2019. Refer to Note 1 to the consolidated financial statements for more information on the impact of adoption.

Upon the closing of the sale of the facility and associated real property, the Company entered into an agreement (original lease) whereby it leased back the Company’s corporate headquarters, comprised of two buildings located in San Diego, California, for an initial term of 12 years. In 2008 through 2011, the Company entered into a series of subsequent amendments to the original lease, whereby the Company vacated a building and continued to occupy one building.

In June 2017, the Company entered into an amendment to extend the current term of the original lease through December 31, 2029. Under the terms of the amendment, the Company reduced the base rental rate by approximately 8% and will continue to pay base annual rent (subject to an annual fixed percentage increase), plus a 3.5% annual management fee, property taxes, and other normal and necessary expenses, such as utilities, repairs, and maintenance. Certain incentives were included in the lease, including approximately $13.1 million in tenant improvement allowances, three months of rent abatement, and a reduction in the required security deposit amount from $4.7 million to $3.0 million. In lieu of a cash security deposit, Wells Fargo Bank, N.A. issued on the Company’s behalf a $3.0 million letter of credit, which is secured by a deposit of equal amount with the same bank. The Company has the right to extend the lease for 2 consecutive 10-year terms and right of first offer for future rental of adjacent office space owned by the landlord.

In May 2018, the Company entered into an agreement to lease 44,718 square feet of office space, which commenced on July 1, 2018, for a term of 10 years and 10 months. Under the terms of the lease, the Company will pay base annual rent (subject to an annual fixed percentage increase), plus property taxes, and other normal and necessary expenses, such as utilities, repairs, and maintenance. Certain incentives were included in the lease, including approximately $4.2 million in tenant improvement allowances and twelve months of rent abatement. In lieu of a cash security deposit, Wells Fargo Bank, N.A. issued on the Company’s behalf a $1.0 million letter of credit, which is secured by a deposit of equal amount with the same bank. The Company does not have the right to extend the lease or right of first offer for future rental of adjacent office space owned by the landlord.

The Company recognizes rent expense on a straight-line basis over the term of the associated lease. Accordingly, rent expense recognized in excess of rent paid is reflected as a liability in the Company’s consolidated balance sheets. Gross rent expense was approximately $6.9 million for 2018, $5.9 million for 2017, and $6.0 million for 2016.

NOTE 11. RETIREMENT PLAN

The Company has a 401(k) defined contribution savings plan (401(k) Plan). The 401(k) Plan is for the benefit of all qualifying employees and permits voluntary contributions by employees up to 60% of base salary limited by the IRS-imposed maximum. Employer contributions were $1.8 million, $1.1 million, and $0.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

NOTE 12. COMMITMENTS AND CONTINGENCIES

Product Liability. The Company's business exposes it to liability risks from its potential drug products. A successful product liability claim or series of claims brought against the Company could result in payment of significant amounts of money and divert management's attention from running the business. The Company may not be able to maintain insurance on acceptable terms, or the insurance may not provide adequate protection in the case of a product liability claim. To the extent that product liability insurance, if available, does not cover potential claims, the Company would be required to self-insure the risks associated with such claims. The Company believes that it carries reasonably adequate insurance for product liability claims.

Licensing and Research Agreements. The Company entered into in-licensing agreements with various universities and research organizations, which are generally cancelable at the option of the Company with terms ranging from 0-180 days written notice. Under the terms of these agreements, the Company received licenses to research tools, know-how, and technology claimed in certain patents or patent applications. The Company is required to pay fees, milestones, and/or royalties on future sales of products employing the technology or falling under claims of a patent, and some of the agreements require minimum royalty payments. Some of the agreements also require the Company to pay expenses arising from the prosecution and maintenance of the patents covering the in-licensed technology. The Company continually reassesses the value of the license agreements and cancels them when research efforts are discontinued on these programs. As of December 31, 2018, the Company may be required to pay milestone payments of up to $1.0 billion over the lives of these agreements, in addition to royalties on sales of the affected products at rates ranging up to 6%. Due to the uncertainties of the development process, the timing and probability of the milestone and royalty payments cannot be accurately estimated.

The Company is not aware of any proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

NOTE 13. SUBSEQUENT EVENTS

On January 28, 2019, the Company entered into a collaboration and license agreement with a clinical-stage gene therapy company, Voyager Therapeutics, Inc., or Voyager. The collaboration is focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platforms. The four programs consist of Voyager's VY-AADC program for Parkinson's disease, Voyager's VY-FXN01 program for Friedreich's ataxia, as well as rights to two programs to be determined by the parties in the future. In connection with the agreement, the Company agreed to pay Voyager a $115 million upfront cash payment and entered into an agreement to purchase $50 million of Voyager's common stock. Pursuant to development plans agreed to by the Company and Voyager, unless Voyager exercises the co-development and co-commercialization rights that are described below, the Company has agreed to be responsible for all development costs. Upon the occurrence of a specified event for each program, the Company has agreed to assume responsibility for development, manufacturing, and commercialization activities for such program. Additionally, Voyager may be entitled to earn up to $1.7 billion in development, regulatory, and commercial milestones across the four programs and royalties for net sales in and outside the U.S.

Under the terms of the agreement, on a program-by-program basis, upon the achievement of milestones or metrics specified in the agreement for VY-AADC and VY-FXN01, Voyager will have the option to co-develop and co-commercialize such program with the Company in the U.S. under cost- and profit-sharing arrangements, and Voyager agrees to forfeit certain milestones and royalties related to such program for which Voyager has exercised its co-develop and co-commercialize option.

The effectiveness of the agreement and the closing of the sale and issuance of the Voyager common stock described above are subject to certain conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions.

NOTE 14. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following is a summary of the quarterly results of the Company for the years ended December 31, 2018 and 2017:

(in thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2018:				
Revenues	$ 71,086	$ 96,905	$ 151,757	$ 131,492
Operating expenses	$ 108,533	$ 98,757	$ 97,434	$ 109,621
Net (loss) income	$ (41,818)	$ (5,913)	$ 50,764	$ 18,078
Net (loss) income per share:				
Basic	$ (0.47)	$ (0.07)	$ 0.56	$ 0.20
Diluted	$ (0.47)	$ (0.07)	$ 0.52	$ 0.19
Shares used in the calculation of net (loss) income per share:				
Basic	89,526	90,100	90,555	90,742
Diluted	89,526	90,100	96,798	95,724
2017:				
Revenues	$ —	$ 6,335	$ 60,774	$ 94,517
Operating expenses	$ 79,932	$ 63,603	$ 66,769	$ 82,683
Net (loss) income	$ (78,326)	$ (59,985)	$ (11,125)	$ 6,894
Net (loss) income per share:				
Basic	$ (0.90)	$ (0.68)	$ (0.13)	$ 0.08
Diluted	$ (0.90)	$ (0.68)	$ (0.13)	$ 0.07
Shares used in the calculation of net (loss) income per share:				
Basic	87,283	88,063	88,325	88,665
Diluted	87,283	88,063	88,325	92,659

ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***

Not applicable.

ITEM 9A. ***CONTROLS AND PROCEDURES***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports 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 year 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.

Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, 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, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Management has used the framework set forth in the report entitled Internal Control-Integrated Framework (2013 framework) published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), known as COSO, to evaluate the effectiveness of our internal control over financial reporting. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2018. Ernst & Young, LLP, our independent registered public accounting firm, has issued an attestation report on our internal control over financial reporting as of December 31, 2018, which is included herein.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of
Neurocrine Biosciences, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Neurocrine Biosciences, Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Neurocrine Biosciences, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 7, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California
February 7, 2019

ITEM 9B. ***OTHER INFORMATION***

None.

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

We have adopted a code of ethics that applies to our Chief Executive Officer, Chief Financial Officer, and to all of our other officers, directors, employees and agents. The code of ethics is available at the Corporate Governance section of the Investors page on our website at www.neurocrine.com. We intend to disclose future amendments to, or waivers from, certain provisions of our code of ethics on the above website within four business days following the date of such amendment or waiver.

ITEM 11. *EXECUTIVE COMPENSATION*

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS*

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

ITEM 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES*

Information required by this item will be contained in our Definitive Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2018. Such information is incorporated herein by reference.

PART IV

ITEM 15. ***EXHIBITS, FINANCIAL STATEMENT SCHEDULES***

(a) Documents filed as part of this report.

1. List of Financial Statements. The following are included in Item 8 of this report:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2018 and 2017

Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016

Notes to the Consolidated Financial Statements (includes unaudited Selected Quarterly Financial Data)

2. List of all Financial Statement schedules. All schedules are omitted because they are not applicable, or the required information is shown in the Financial Statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits. The following exhibits are filed as part of, or incorporated by reference into, this report:

Exhibit Number	**Description**
3.1	Certificate of Incorporation, as amended(1)
3.2	Bylaws, as amended(2)
4.1	Form of Common Stock Certificate(3)
4.2	Indenture, dated as of May 2, 2017, by and between the Company and U.S. Bank National Association, as Trustee(4)
4.3	Form of Note representing the Company's 2.25% Convertible Notes due 2024(5)
Collaboration and License Agreements	
10.1*	Collaboration Agreement dated June 15, 2010, by and between Abbott International Luxembourg S.a.r.l. and the Company as amended on August 31, 2011(6)
10.2*	First Amendment to Collaboration and License Agreement Dated August 31, 2011 between the Company and Abbott International Luxemburg S.a.r.l.(7)
10.3*	Collaboration and License Agreement dated March 31, 2015 between Mitsubishi Tanabe Pharma Corporation and the Company(8)
10.4*	License Agreement dated February 9, 2017 between BIAL– Portela & CA, S.A. and the Company(9)
10.5*	Collaboration and License Agreement dated January 28, 2019 between Voyager Therapeutics, Inc. and the Company
10.6	Stock Purchase Agreement dated January 28, 2019 between Voyager Therapeutics, Inc. and the Company
10.7	Investor Agreement dated January 28, 2019 between Voyager Therapeutics, Inc. and the Company
Manufacturing Agreements	
10.8*	Master Manufacturing Services Agreement dated November 28, 2016, by and between Patheon UK Limited and the Company(10)
10.9*	Product Agreement dated November 28, 2016, by and between Patheon UK Limited and the Company(11)
10.10*	Commercial Supply Agreement dated March 9, 2017 between F.I.S. – FABBRICA ITALIANA SINTETICI S.p.A. and the Company
10.11*	Amended and Restated Product Agreement dated June 27, 2017 by and between Patheon UK Limited and the Company(12)
Equity Plans and Related Agreements	

10.12**	Neurocrine Biosciences, Inc. 2003 Incentive Stock Plan, as amended and form of stock option agreement and restricted stock unit agreement(13)
10.13**	Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan, as amended(14)
10.14**	Form of Stock Option Grant Notice and Option Agreement for use under the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan, and Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for use under the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan(15)
10.15**	Neurocrine Biosciences, Inc. Inducement Plan, as amended(16)
10.16**	Form of Stock Option Grant Notice and Option Agreement for use under the Neurocrine Biosciences, Inc. Inducement Plan, and Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement for use under the Neurocrine Biosciences, Inc. Inducement Plan(17)
10.17**	Neurocrine Biosciences, Inc. 2018 Employee Stock Purchase Plan dated May 30, 2018(18)
Agreements with Officers and Directors	
10.18**	Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Kevin C. Gorman, Ph.D.(19)
10.19**	Amended and Restated Employment Agreement effective August 6, 2007 between the Company and Christopher F. O'Brien M.D.(20)
10.20**	Amended and Restated Employment Agreement effective August 14, 2007 between the Company and Haig P. Bozigian, Ph.D.(21)
10.21**	Form of Amendment to Employment Agreement for executive officers, effective as of December 15, 2010(22)
10.22**	Employment Agreement dated May 26, 2015 between the Company and Eric Benevich(23)
10.23**	Employment Agreement effective November 29, 2017 between the Company and Matthew C. Abernethy(24)
10.24**	Form of Indemnity Agreement entered into between the Company and its officers and directors(25)
Agreements Related to Real Property	
10.25	Amended and Restated Lease dated November 1, 2011 between the Company and Kilroy Realty, L.P.(26)
10.26	First Amendment to Amended and Restated Lease between the Company and Kilroy Realty, L.P., dated June 5, 2017(27)
10.27	Second Amendment to Amended and Restated Lease between the Company and Kilroy Realty, L.P., dated October 12, 2017(28)
10.28	Letter of Credit dated December 3, 2007, issued by Wells Fargo Bank, N.A. for the benefit of Kilroy Realty, L.P., as amended on November 20, 2014 and June 19, 2017(29)
21.1	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32***	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on November 5, 2018
(2) Incorporated by reference to Exhibit 3.2 of the Company's Quarterly Report on Form 10-Q filed on November 5, 2018

(3) Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-03172)
(4) Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on May 2, 2017
(5) Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on May 2, 2017
(6) Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2010
(7) Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on October 31, 2011
(8) Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on April 30, 2015
(9) Incorporated by reference to Exhibit 99.4 of the Company's Current Report on Form 8-K filed on April 25, 2017
(10) Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on April 25, 2017
(11) Incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on April 25, 2017
(12) Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on November 1, 2017
(13) Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on July 30, 2009
(14) Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on May 30, 2018
(15) Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on June 1, 2015
(16) Incorporated by reference to Exhibit 10.17 of the Company's Annual Report on Form 10-K filed on February 13, 2018
(17) Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2015
(18) Incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on May 30, 2018
(19) Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on August 3, 2007
(20) Incorporated by reference to Exhibit 10.35 of the Company's Annual Report on Form 10-K filed on February 10, 2011
(21) Incorporated by reference to Exhibit 10.37 of the Company's Annual Report on Form 10-K filed on February 11, 2008
(22) Incorporated by reference to Exhibit 10.35 of the Company's Annual Report on Form 10-K filed on February 11, 2008
(23) Incorporated by reference to Exhibit 10.32 of the Company's Annual Report on Form 10-K filed on February 14, 2017
(24) Incorporated by reference to Exhibit 10.26 of the Company's Annual Report on Form 10-K filed on February 13, 2018
(25) Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on November 1, 2017
(26) Incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on January 18, 2012
(27) Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 3, 2017
(28) Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on November 1, 2017
(29) Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed on December 10, 2007; Exhibit 10.5 of the Company's Annual Report on Form 10-K filed on February 9, 2015; and Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on August 3, 2017

* Confidential treatment has been granted with respect to certain portions of the exhibit.

** Management contract or compensatory plan or arrangement.

*** These certifications are being furnished solely to accompany this annual 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.

(c) Financial Statement Schedules. See Item 15(a)(2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

A Delaware Corporation

By: /s/ Kevin C. Gorman
Kevin C. Gorman
Chief Executive Officer

Date: February 7, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Kevin C. Gorman Kevin C. Gorman	Chief Executive Officer and Director (Principal Executive Officer)	February 7, 2019
/s/ Matthew C. Abernethy Matthew C. Abernethy	Chief Financial Officer (Principal Financial and Accounting Officer)	February 7, 2019
/s/ William H. Rastetter William H. Rastetter	Chairman of the Board of Directors	February 7, 2019
/s/ Gary A. Lyons Gary A. Lyons	Director	February 7, 2019
/s/ George J. Morrow George J. Morrow	Director	February 7, 2019
/s/ Richard F. Pops Richard F. Pops	Director	February 7, 2019
/s/ Alfred W. Sandrock, Jr. Alfred W. Sandrock, Jr.	Director	February 7, 2019
/s/ Stephen A. Sherwin Stephen A. Sherwin	Director	February 7, 2019

Exhibit 10.5
*****Text Omitted and Filed Separately**
with the Securities and Exchange Commission.
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Under 17 C.F.R. Sections 200.80(c) and Rule 24b-2

COLLABORATION AND LICENSE AGREEMENT

By and between

VOYAGER THERAPEUTICS, INC.

AND

NEUROCRINE BIOSCIENCES, INC.

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This COLLABORATION AND LICENSE AGREEMENT (the "Agreement") is entered into as of January 28, 2019 (the "Execution Date"), by and between Voyager Therapeutics, Inc., a Delaware corporation, having its principal place of business at 75 Sidney Street, Cambridge, MA 02139 ("Voyager"), and Neurocrine Biosciences, Inc., a Delaware corporation, having its principal place of business at 12780 El Camino Real, San Diego, CA 92130 ("Neurocrine"). Voyager and Neurocrine shall be referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, Voyager is a gene therapy company focused on the research and development of products for the treatment of diseases of the central nervous system and other neurodegenerative diseases;

WHEREAS, Neurocrine is a biopharmaceutical company focused on developing and commercializing treatments for neurological and endocrine-related disorders, and possesses expertise in the research, development, manufacturing and commercialization of human therapeutics;

WHEREAS, Voyager and Neurocrine desire to engage in a collaborative effort in which Voyager will carry out certain preclinical research activities and clinical development activities relating to the identification and development of Development Candidates (as defined herein), and pursuant to which Neurocrine will have certain rights to further develop and commercialize Collaboration Products (as defined herein); and

WHEREAS, Voyager and Neurocrine believe that combining their respective expertise will allow them to identify and develop more Development Candidates and bring Collaboration Products to market more quickly than they could without this Agreement, as well as to take advantage of other efficiencies stemming from their complementary expertise.

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

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following terms will have the meanings set forth in this Article 1 unless context dictates otherwise:

1.1 "AADC" means the enzyme aromatic L-amino acid decarboxylase, which is defined by the ENSEMBL Gene ID ENSG00000132437, or any naturally occurring variant thereof.

1.2 "AADC Program" means all activities under this Agreement directed to the Development, Manufacture and Commercialization of Gene Therapy Products intended to treat Parkinson's disease by delivery of a gene encoding AADC, which gene is the Target of the AADC Program (it being understood that the foregoing does not limit the rights granted to Neurocrine with respect to the Field).

1.3 "AADC Program Development Plan" means the plan and budget for the Development of VY-AADC through completion of Voyager's ongoing Pivotal Clinical Trial (1105) therefor (the "Existing Pivotal Trial"), as such plan and budget may be updated by the JSC from time to time in accordance with Section 2.1.3(a). The initial AADC Program Development Plan will be mutually agreed to by the Parties within [...***...] of the Effective Date.

1.4 "AAV" means a recombinant adeno-associated Virus Vector.

1.5 "Accounting Standards" means (a) GAAP (United States Generally Accepted Accounting Principles) or (b) IFRS (International Financial Reporting Standards), in either case, consistently applied, as reported in the applicable financial statements.

1.6 "Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a Party to this Agreement, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date, but only for so long as such control exists. A Person shall be deemed to "control" another Person if it (a) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

1.7 "Annual Net Sales" means, on a Collaboration Product-by-Collaboration Product basis, the total Net Sales of such Collaboration Product in the U.S. or in the Territory outside the U.S., as applicable, in a particular Calendar Year.

1.8 "Antitrust Laws" means any law relating to competition that is enforced by the U.S. Federal Trade Commission or the Antitrust Division of the U.S. Department of Justice.

1.9 "Biosimilar Product" means, with respect to a particular Collaboration Product in a particular country in the Territory, any Gene Therapy Product sold by a Third Party not authorized by or on behalf of Neurocrine, its Affiliates, or Sublicensees, that targets the same Target as the Collaboration Product and, on the basis of a prior Regulatory Approval granted to a Collaboration Product, (a) is approved by the FDA pursuant to Section 351(k) of the PHSA or successor thereto, (b) is approved by the EMA pursuant to EU Directive 2001/83/EC or successor thereto in the European Union or any member state thereof citing such Collaboration Product as the reference product, or (c) has received abbreviated Regulatory Approval from the applicable Regulatory Authority in another foreign jurisdiction.

1.10 "BLA" means a Biologics License Application submitted to the FDA pursuant to 21 U.S.C. §601.2 (or successor regulation thereto), for purposes of obtaining Regulatory Approval for a new biologic in the United States, or any equivalent filing in a country or regulatory jurisdiction other than the United States.

1.11 "Business Day" means a day on which banking institutions in Boston, Massachusetts or San Diego, California are open for business, excluding any Saturday or Sunday.

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1.12 "Calendar Quarter" means a period of three (3) consecutive months ending on the last day of March, June, September, or December, respectively; provided that, the first Calendar Quarter starts on the Effective Date and ends on March 31, 2019.

1.13 "Calendar Year" means a period of twelve (12) consecutive months beginning on January 1 and ending on December 31; provided that the first Calendar Year starts on the Effective Date and ends on December 31, 2019.

1.14 "[...***...] License Agreement" means that certain license agreement by and between Voyager and [...***...], dated [...***...] as of the Execution Date.

1.15 "cGMP" means the current Good Manufacturing Practices as provided for (and as amended from time to time) in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonized Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7 (ICH Q7), and the United States Code of Federal Regulations 21 CFR Parts 210 and 211, or any similar regulation in other applicable jurisdictions.

1.16 "Change of Control" means, with respect to a Party, (a) the acquisition of beneficial ownership, directly or indirectly, by any Third Party of securities or other voting interest of such Party representing a majority or more of the combined voting power of such Party's then outstanding securities or other voting interests, (b) any merger, consolidation or business combination involving such Party with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies) of the voting securities or other voting interests of such Party (or, if applicable, the ultimate parent of such Party) immediately prior to such merger, consolidation or business combination ceasing to hold beneficial ownership of more than fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, consolidation or business combination, or (c) any sale, lease, exchange, contribution or other transfer to a Third Party (in one transaction or a series of related transactions) of all or substantially all of the assets of such Party to which this Agreement relates. The acquiring or combining Third Party in any of clause (a), (b) or (c), is referred to herein as the "Acquirer".

1.17 "Clinical Trial" means a Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial or any other study in which human subjects or patients are dosed with a drug, whether approved or investigational.

1.18 "Collaboration Candidate" means (a) with respect to the AADC Program, VY-AADC and all other Gene Therapy Products Developed in the AADC Program and (b) with respect to each other Program, any form, formulation, or dosage of a Gene Therapy Product that is Developed by or on behalf of Voyager under such Program, or in the case of the FA Program, was Developed by Voyager prior to the Effective Date and is directed to the Target for the FA Program.

1.19 "Collaboration Product" means, with respect to each Program, a product containing a Collaboration Candidate in such Program, alone or in combination with other active or inactive components or ingredients, in any formulation, dosage or form. Except where the context otherwise requires, the term "Collaboration Product" includes any Co-Co Product.

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1.20 "Commercialization" and "Commercialize" means any and all activities undertaken relating to the marketing, obtaining pricing and reimbursement approvals, promotion (including advertising, detailing or continuing medical education), any other offering for sale or any sale of a product, including any distribution, importation, exportation or transport of a product for sales purposes. "Commercialization" shall not include Development, but may include Manufacturing to the extent applicable.

1.21 "Commercial Milestones" means the Milestone Events described in Section 8.2.4.

1.22 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party with respect to an agreed objective, such reasonable, diligent, and good faith efforts that a biopharmaceutical company of similar size would normally use taking into account the reasonable allocation of such company's resources under the circumstances to accomplish a similar objective for its own internally developed product that is of similar market potential at a similar stage in its Development, Commercialization or product life, taking into account all relevant factors, including (a) the potential profitability of the product, (b) the costs and risks of Developing, Manufacturing, having Manufactured, using and Commercializing the product, (c) scientific, safety and regulatory concerns, (d) product profile, (e) the competitiveness of the marketplace and (f) the proprietary position of the product. In addition, "Commercially Reasonable Efforts" shall be determined on a country-by-country or market-by-market basis (as most applicable) for a particular Collaboration Product, and it is anticipated that the level of effort will change over time, including to reflect changes in the status of the Collaboration Product and the countries (or markets) involved. For the avoidance of doubt, where a Party has an obligation to use Commercially Reasonable Efforts, the efforts of such Party and its Affiliates, subcontractors and Sublicensees shall be considered in determining whether such Party has satisfied such obligation.

1.23 "Competitive Product" means, with respect to a Program, a Gene Therapy Product (other than a Collaboration Product under the Collaboration) that is directed to the Target to which Collaboration Products in such Program are directed, provided, however, that to the extent such Target is a derivative or fragment of a gene that is (i) the same derivative or fragment of a different gene and (ii) is a potential Target for a Gene Therapy Product in a different indication, a Gene Therapy Product that is directed to such Target for use in such different indication shall not be a Competitive Product.

1.24 "Control" means, subject to Section 5.2.3, with respect to a Person and any Know-How or Patent Right, the possession by such Person of the right (whether through ownership or license (other than by a license under this Agreement) or control (as defined in Section 1.6) over an Affiliate with such right) to grant the licenses or sublicenses as provided herein without violating the terms of any agreement or other arrangement with any Third Party.

1.25 "Cover" means, in the absence of ownership of or a license granted under a Valid Claim, (a) with respect to a Collaboration Product, that the manufacture, use or sale of such Collaboration Product and (b) with respect to any other invention, that the practice of such invention, in each case (a) and (b) would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue).

1.26 "Develop" or "Development" means non-clinical, pre-clinical and clinical research and development activities, including discovery, identification, research, engineering, characterization, development, modification, optimization, drug metabolism and pharmacokinetics, translational research, toxicology, pharmacology toxicology studies, statistical analysis and report writing, formulation development and optimization, Clinical Trials, regulatory affairs (including preparation for a Regulatory Approval Application submission and other submission-related activities), product approval and registration activities, and all other activities necessary to conduct IND-enabling studies, conduct Clinical Trials, or seek, obtain and maintain Regulatory Approval. "Development" shall not include Commercialization, but may include Manufacturing to the extent applicable.

1.27 "Development Candidate" means (a) with respect to the AADC Program, VY-AADC, (b) with respect to the FA Program, initially, VY-FXN01, and (c) on a Program-by-Program basis, other than with respect to the AADC Program, a Gene Therapy Product that (i) is Developed by or on behalf of Voyager in the course of such Program, (ii) has been nominated as a development candidate by either Voyager or Neurocrine in accordance with Section 2.1.9(a) and (iii) either (A) has been determined to meet the development candidate criteria developed by the JSC (the "Development Candidate Criteria") or (B) has otherwise been selected by the JSC as a Development Candidate notwithstanding its failure to meet the Development Candidate Criteria, in each case (A) and (B) pursuant to Section 2.1.9(b).

1.28 "Development Costs" means the FTE Costs (at the then-current FTE Rate) and the Out-of-Pocket Costs (without markup) incurred by or on behalf of a Party or any of its Affiliates in the conduct of the Development of a Collaboration Product.

1.29 "Development Milestones" means the Milestone Events described in Sections 8.2.1, 8.2.2 and 8.2.3.

1.30 "Development Plan" means an Existing Program Development Plan or a Discovery Program Development Plan, as applicable.

1.31 "Discovery Program" means, with respect to each Discovery Target, all activities under this Agreement directed to the Development, Manufacture and Commercialization of Gene Therapy Products directed to such Discovery Target.

1.32 "Discovery Target" means each of two Targets approved for the Discovery Programs by the JSC pursuant to Section 2.1.2.

1.33 "Dollars" or "$" means the legal tender of the U.S.

1.34 "Effective Date" means the HSR Clearance Date.

1.35 "EMA" means the European Medicines Agency, and any successor entity thereto.

1.36 "Executive Officers" means the Chief Executive Officer, or his or her designee, in the case of Voyager, and the Chief Executive Officer, or his or her designee, in the case of Neurocrine.

1.37 "Existing In-License Agreement" means those in-licenses of Voyager or any of its Affiliates set forth on Schedule 1.37 attached hereto.

1.38 "Existing Program" means each of (a) the AADC Program and (b) the FA Program.

1.39 "Existing Program Development Plan" means each of (a) the AADC Program Development Plan and (b) the FA Program Development Plan.

1.40 "Exploit" or "Exploitation" means to make, have made, import, use, sell, or offer for sale, Develop, Manufacture or Commercialize.

1.41 "FA" means Friedreich's Ataxia.

1.42 "FA Program" means all activities under this Agreement directed to the Development, Manufacture and Commercialization of Gene Therapy Products intended to treat FA. The Target of the FA Program is the gene encoding Frataxin.

1.43 "FA Program Development Plan" means the plan and budget for the Development of VY-FXN01 (or any successor Development Candidate in the FA Program) through completion of the Phase 1 Clinical Trial therefor, the initial version of which will be mutually agreed to by the Parties within [...***...] of the Effective Date, as such plan and budget may be updated by the JSC from time to time in accordance with Section 2.1.3(a).

1.44 "FDA" means the U.S. Food and Drug Administration, and any successor entity thereto.

1.45 "Field" means all human and veterinary diagnostic, prophylactic, and therapeutic uses.

1.46 "First Commercial Sale" means, with respect to a Collaboration Product and a country in the Territory, the first sale for end use or consumption of such Collaboration Product in such country after all Regulatory Approvals and pricing and reimbursement approvals legally required for such sale have been granted by the applicable Regulatory Authority of such country or, if Regulatory Approval is not required, after the date on which sales are permitted by applicable Law.

1.47 "Frataxin" means the protein encoded by the *FXN* gene which is defined by ENSEMBL Gene ID ENSG00000165060, or any naturally occurring variant thereof.

1.48 "FTE" means one (1) person (or the equivalent of one (1) person) working full time for one (1) twelve (12) month period in a Development, regulatory or other relevant capacity (excluding persons employed in general and administrative, non-technical management or other non-technical capacities) employed by Voyager or Neurocrine or any of their respective Affiliates and assigned to perform specified work, with such commitment of time and effort to constitute one (1) employee performing such work on a full-time basis, which for purposes hereof shall be [...***...] hours per year. No additional payment shall be made with respect to any person who works more than [...***...] hours per year (which person shall be deemed one (1) FTE) and any person who devotes less than [...***...]

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[...***...] hours per year shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by [...***...].

1.49 "FTE Costs" means the FTE Rate multiplied by the applicable number of FTEs who perform a specified activity pursuant to this Agreement.

1.50 "FTE Rate" means $[...***...] per FTE for the period commencing on the Effective Date and ending December 31, 2019. On January 1, 2020 and on January 1st of each subsequent Calendar Year, the foregoing rate shall be increased for the Calendar Year then commencing by the percentage increase, if any, in the Consumer Price Index ("CPI") as of December 31 of the then most recently completed Calendar Year with respect to the level of the CPI on December 31, 2019. Consumer Price Index or CPI means the Consumer Price Index – Urban Wage Earners and Clerical Workers, US City Average, All Items, 1982-84 = 100, published by the United States Department of Labor, Bureau of Labor Statistics (or its successor equivalent index).

1.51 "Future In-License Agreement" means any agreement between Voyager (or any of its Affiliates), on the one hand, and a Third Party, on the other hand, entered into after the Effective Date, pursuant to which Voyager or any of its Affiliates acquires Control of any Know-How or Patent Right that, subject to Section 5.2, would be Voyager IP.

1.52 "GCP" means the then-current good clinical practice standards for clinical trials for pharmaceuticals, as set forth in the United States Food, Drug and Cosmetic Act, as amended from time to time (the "Act"), or other applicable law, and such standards of good clinical practice as are required by the Regulatory Authorities of the EU and other organizations and Governmental Authorities in countries for which the applicable Collaboration Candidate or Collaboration Product is intended to be developed, to the extent such standards are not less stringent than United States GCP.

1.53 "Gene Therapy Product" means a Virus Vector, including without limitation AAV, that delivers a polynucleotide to certain cells of a patient for a purpose in the Field. Gene Therapy Products include, but are not limited to, Development Candidates, other Collaboration Candidates and Collaboration Products.

1.54 "Genzyme Agreement" means that certain Collaboration Agreement by and between Voyager and Genzyme Corporation ("Genzyme") dated February 11, 2015, as amended March 28, 2017, including the Post-Termination Under Collaboration Agreement dated December 8, 2017.

1.55 "GLP" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, or comparable regulatory standards in jurisdictions outside the United States.

1.56 "Governmental Authority" means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.

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1.57 "HSR Act" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time.

1.58 "HSR Clearance Date" means the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act in the U.S.

1.59 "HSR Filing" means filings by Neurocrine and Voyager with the U.S. Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

1.60 "In-License Agreement" means (a) any Existing In-License Agreement and (b) any Future In-License Agreement.

1.61 "IND" means an investigational new drug application submitted to the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the U.S. for the investigation of any product in any other country or group of countries.

1.62 "Initiation" means, with respect to a Clinical Trial, the first dosing of the first subject enrolled in such Clinical Trial with a Collaboration Product.

1.63 "Invention" means any new invention, discovery, process, method, machine, manufacture, design, composition of matter, material or improvement thereof (whether patentable or not).

1.64 "Joint IP" means the Joint Know-How and Joint Patent Rights.

1.65 "Joint Know-How" means Joint Inventions and other Know-How that is jointly invented, discovered, conceived or generated by one or more employees, agents or consultants of Voyager, on the one hand, and one or more employees, agents or consultants of Neurocrine, on the other hand, in the conduct of activities under this Agreement, including in the conduct of the Development, Manufacture or Commercialization of Collaboration Products.

1.66 "Joint Patent Right" means any Patent Right that Covers Joint Know-How.

1.67 "Know-How" means all information, know-how and data, including trade secrets, inventions (whether patentable or not), discoveries, methods, specifications, processes, expertise, technology, other non-clinical, pre-clinical and clinical data, documentation and results (including pharmacological, toxicological, biological, chemical, physical, safety and manufacturing data and results), analytical and quality control data and results, Regulatory Filings and other technical information. "Know-How" excludes in any event any Patent Rights.

1.68 "Knowledge" means (a) with respect to Voyager, the knowledge after reasonable investigation of the individuals set forth on Schedule 1.68, and (b) with respect to Neurocrine, the knowledge after reasonable investigation of the individuals set forth on Schedule 1.68.

1.69 "Law" means any law, statute, rule, regulation, order, judgment or ordinance having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

1.70 "[...***...]" means any of the following: [...***...].

1.71 "Manufacture" or "Manufacturing" means all activities related to the manufacturing of a Collaboration Candidate and/or Collaboration Product, including test method development and stability testing, formulation, process development, manufacturing scale-up, manufacturing for use in non-clinical and clinical studies, manufacturing for commercial sale, packaging, release of product, quality assurance/quality control development, quality control testing (including in-process, in-process release and stability testing) and release of product or any component or ingredient thereof, and regulatory activities related to all of the foregoing. "Manufacturing" may be included as part of Development or Commercialization, to the extent applicable.

1.72 "Net Sales" means, with respect to any Collaboration Product, the gross amount invoiced by Neurocrine, any of its Affiliates and or any Sublicensee (each, a "Selling Party") to a Third Party (including a customer, distributor, wholesaler or end user) for sales of such Collaboration Product, less the following deductions as calculated in accordance with the applicable Accounting Standard as consistently applied:

1.72.1 normal trade, cash, quantity and other customary discounts actually given to customers in the ordinary course of business;

1.72.2 rebates, credits and allowances given by reason of rejections, returns, damaged or defective product or recalls;

1.72.3 government-mandated rebates and any other compulsory payments, credits, adjustments and rebates actually paid or deducted;

1.72.4 price adjustments, allowances, credits, chargeback payments, discounts, rebates, fees and reimbursements or similar payments granted or made to managed care organizations, group purchasing organizations or other buying groups, pharmacy benefit management companies, health maintenance organizations and any other providers of health insurance coverage, health care organizations or other health care institutions (including hospitals), health care administrators, patient assistance or other similar programs, or to federal state/provincial, local and other governments, including their agencies, or to wholesalers, distributors or other trade customers;

1.72.5 reasonable and customary freight, shipping, insurance and other transportation expenses, if actually borne by the applicable Selling Party without reimbursement from any Third Party;

1.72.6 reasonable distributors' and inventory management fees, including fees for services provided by wholesalers and warehousing chains, in connection with the sale and distribution of such Collaboration Product;

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1.72.7 that portion of administrative fees paid to group purchasing organizations, pharmacy benefit managers, Medicare prescription drug plans or any other facilitator of drug access for patients relating specifically to such Collaboration Product;

1.72.8 uncollectible amounts or reasonable reserves accrued therefor (it being understood that any subsequent reductions in such accrual amounts due to collections in subsequent periods shall be included in Net Sales when such reductions occur);

1.72.9 that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) and reasonably allocable to sales of such Collaboration Product;

1.72.10 sales, value-added, excise taxes, tariffs and duties, and other taxes and government charges directly related to the sale, delivery or use of such Collaboration Product (but not including taxes assessed against the net income derived from such sale); and

1.72.11 any other similar and customary deductions that are consistent with Accounting Standards, as agreed by the Parties in writing or, if the Parties fail to agree on any such deductions proposed by Neurocrine, as determined by a mutually agreed independent accounting expert, whose decision will be final and binding on the Parties.

If non-monetary consideration is received for any Collaboration Product, Net Sales will be calculated based on the average price charged for such Collaboration Product during the preceding Calendar Quarter in the relevant country, or in the absence of such sales, the fair market value of the Collaboration Product, as determined by the Parties in good faith.

Resales or sales of a Collaboration Product made in good faith between or among Neurocrine, any of its Affiliates or any Sublicensee shall not be included in the calculation of Net Sales as long as, with respect to such resales or sales, the first sale thereafter to a non-Sublicensee Third Party is included in the calculation of Net Sales.

Net Sales shall not include any amounts received for Collaboration Products supplied for use in clinical trials, or supplied at or below the fully-burdened cost of good thereof under early access, compassionate use, named patient, indigent access, patient assistance or other reduced pricing programs.

In the event that a Collaboration Product under this Agreement is sold by a Selling Party in combination (a "Combination Product") with one or more therapeutically active compound(s) that are not Collaboration Products ("Supplemental Ingredient(s)"), then "Net Sales" of the Combination Product shall be calculated using one of the following methods:

(x) By multiplying the Net Sales of the Combination Product (calculated prior to the application of this formula) by the fraction A/(A+B), where A is the average gross selling price, during the applicable Calendar Quarter in the country concerned, of the Collaboration Product when sold separately, and B is the average gross selling price, during the applicable Calendar Quarter in the country concerned, of the Supplemental Ingredient(s) when sold separately; or

(y) In the event that no such separate sales are made of the Collaboration Product or any of the Supplemental Ingredients in such Combination Product during the applicable Calendar Quarter in the country concerned, Net Sales shall be calculated using the above formula where A is the reasonably estimated commercial value of the Collaboration Product sold separately and B is the reasonably estimated commercial value of the Supplemental Ingredient(s) sold separately. Any such estimates shall be determined using criteria to be mutually agreed upon by the Parties. If the Parties are unable to agree on the criteria for determining such estimates, the Parties will submit such dispute for resolution to a mutually agreed independent accounting expert, whose decision will be final and binding on the Parties.

1.73 "Neurocrine IP" means the Neurocrine Know-How and the Neurocrine Patent Rights.

1.74 "Neurocrine Know-How" means (a) all Know-How that (i) is Controlled by Neurocrine or any of its Affiliates on the Effective Date or during the Term, (ii) prior to any disclosure to Voyager hereunder or under the Existing Confidentiality Agreement was not generally known to the public and (iii) is necessary or reasonably useful to Exploit in the Field in the Territory any Collaboration Product; and (b) Neurocrine's interest in the Joint Know-How. Notwithstanding anything in this Agreement to the contrary, Neurocrine Know-How shall not include any Know-How to the extent Controlled by any Person that acquires all or any part of Neurocrine or an Affiliate of Neurocrine, or any affiliates of such Person, in each case (x) which is Controlled by such Person immediately prior to the effective date of the acquisition (and such Control was not acquired through acquisition or license from Neurocrine or any Affiliate of Neurocrine in existence prior to the effective date of such acquisition) or (y) which is Controlled by such Person on or after the effective date of acquisition but is not Controlled by Neurocrine or an Affiliate of Neurocrine (excluding for purposes of this provision, such Person and Affiliates of Neurocrine that are such Affiliates by virtue of controlling, being controlled by or under common control with such Person and were not Affiliates of Neurocrine prior to the acquisition) and was developed, invented or obtained without the direct or indirect use of any non-public Neurocrine Know-How.

1.75 "Neurocrine Patent Rights" means (a) all Patent Rights Controlled by Neurocrine or any of its Affiliates as of the Effective Date or during the Term, that Cover any Collaboration Product; and (b) Neurocrine's interest in the Joint Patent Rights. Notwithstanding anything in this Agreement to the contrary, Neurocrine Patent Rights shall not include any Patents to the extent owned or Controlled by any Person that acquires all or any part of Neurocrine or an Affiliate of Neurocrine, or any affiliates of such Person, in each case (x) which is Controlled by such Person immediately prior to the effective date of the acquisition (and such Control was not acquired through acquisition or license from Neurocrine or any Affiliate of Neurocrine in existence prior to the effective date of such acquisition) or (y) which is Controlled by such Person on or after the effective date of acquisition but is not Controlled by Neurocrine or an Affiliate of Neurocrine (excluding for purposes of this provision, such Person and Affiliates of Neurocrine that are such Affiliates by virtue of controlling, being controlled by or under common control with such Person and were not Affiliates of Neurocrine prior to the acquisition) and was developed, invented, or obtained without the direct or indirect use of any non-public Neurocrine Know-How.

1.76 "[...***...] Agreement" means that certain [...***...] Agreement by and between [...***...] and Voyager, dated [...***...].

1.77 "Out-of-Pocket Costs" means actual out-of-pocket costs and expenses paid by a Party or any of its Affiliates to Third Parties, including to a consultant or contractor of such Party.

1.78 "Patent Right" means (a) any patent or patent application (including any provisional application) in any country or multinational jurisdiction in the Territory (including any converted application, continuation, continuation-in-part, continued prosecution application or divisional of any such application, any reissue, renewal, extension, substitution, reexamination, supplementary protection certificate, pediatric exclusivity period or the like of any such patent); (b) any foreign equivalent of any patent or patent application described in clause (a); and (c) all rights of priority in any of the foregoing.

1.79 "PHSA" means the Public Health Service Act as set forth in 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.80 "PMDA" means the Pharmaceuticals and Medical Devices Agency in Japan, and any successor entity thereto.

1.81 "Person" means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority, or any other entity not specifically listed in this Section 1.81.

1.82 "Phase 1 Clinical Trial" means a human clinical trial (or a portion of a human clinical trial) of a product in any country, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, that would satisfy the requirements of 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

1.83 "Phase 2 Clinical Trial" means a human clinical trial (or a portion of a human clinical trial) of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(b) and whose design is intended to explore a variety of doses, dose response, and duration of effect, and to generate initial evidence of clinical safety and activity in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

1.84 "Phase 3 Clinical Trial" means a human clinical trial (or a portion of a human clinical trial) of a product in any country that would satisfy the requirements of 21 C.F.R. 312.21(c) and whose design is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

1.85 "Pivotal Clinical Trial" means a Clinical Trial that is designed to be sufficient to support the filing of a BLA for such product.

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1.86 "Program" means, with respect to a Target, all activities under this Agreement directed to the Development, Manufacture and Commercialization of Collaboration Products directed to such Target. The Term "Program" includes any Existing Program or Discovery Program or Co-Co Program, but specifically excludes any Terminated Program.

1.87 "Proof of Mechanism" means, with respect to the FA Program and each Discovery Program, achievement of the milestones or metrics determined by the JSC and identified as such in the applicable Development Plan.

1.88 "Prosecution and Maintenance" or "Prosecute and Maintain" means, with regard to a Patent Right, the preparation, filing, prosecution and maintenance of such Patent Right, as well as re-examinations, reissues, appeals, and requests for patent term adjustments and patent term extensions with respect to such Patent Right. For clarification, "Prosecution and Maintenance" or "Prosecute and Maintain" shall not include any enforcement actions taken with respect to a Patent Right.

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

1.90 "Regulatory Approval" means all approvals of the applicable Regulatory Authority necessary for the commercial marketing and sale of a product in a country(ies), excluding any pricing and reimbursement approvals that may be required.

1.91 "Regulatory Approval Application" means (a) a BLA, or (b) any other application to seek Regulatory Approval of a product in any country or multinational jurisdiction, as defined in applicable Laws and filed with the relevant Regulatory Authorities of such country or jurisdiction.

1.92 "Regulatory Authority" means the FDA in the United States or any Governmental Authority in another country or regulatory jurisdiction in the Territory that is a counterpart to the FDA and holds responsibility for granting Regulatory Approval for a product in such country or regulatory jurisdiction, including the EMA and PMDA, and any successor(s) thereto.

1.93 "Regulatory Exclusivity" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to any Collaboration Product, excluding Patent Rights, that precludes the use of any clinical data collected and filed for such Collaboration Product for the benefit of any Regulatory Approval for a generic or biosimilar product (for any use), including orphan or pediatric exclusivity where applicable.

1.94 "Regulatory Filing" means, with respect to a product, any documentation comprising any filing or application with any Regulatory Authority with respect to such product, or its use or potential use in the Field, any document submitted to any Regulatory Authority, including any IND and any Regulatory Approval Application, and any correspondence to, from or

with any Regulatory Authority with respect to such product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).

1.95 "Target" means a gene as defined by a specific gene ID, all mutants of such gene, derivatives or fragments with similar functional properties to such gene, or allelic variants of such gene, (a) whose DNA is delivered, replaced, substituted for, or altered upon administration of a Gene Therapy Product; (b) whose level of expressed RNA (including mRNA) or protein is modulated, silenced, augmented or eliminated upon administration of a Gene Therapy Product; or (c) whose protein expression product serves in whole or in part as an antigen and whereby, upon binding by an immunoglobulin encoded by a Gene Therapy Product such protein is neutralized or destroyed. All of the Gene Therapy Products described in the preceding clauses (a), (b) and (c) are considered "directed to" such Target.

1.96 "Terminated Program" shall mean a Program that is terminated by the JSC pursuant to Section 3.1.2(q), by the mutual agreement of the Parties or pursuant to Article 14.

1.97 "Territory" means (a) with respect to the AADC Program and each Discovery Program, all countries in the world (excluding any countries for which this Agreement has been terminated with respect to such Program) and (b) with respect to the FA Program, the United States and, upon expiration of Genzyme's option to the FA Program without exercise thereof, all countries in the world (excluding any countries for which this Agreement has been terminated with respect to such Program).

1.98 "Third Party" means any Person that is neither a Party nor an Affiliate of a Party.

1.99 "Transition Date" means the date upon which the applicable Transition Event occurs.

1.100 "Transition Event" means (a) with respect to the AADC Program, Voyager's receipt of topline data with respect to the Existing Pivotal Trial, (b) with respect to the FA Program, Voyager's receipt of topline data with respect to the first Phase 1 Clinical Trial for a Product in the FA Program, and (c) with respect to the Discovery Programs, preparation by Voyager and approval by Neurocrine of the IND to be filed by Neurocrine for the first Development Candidate in each such Discovery Program.

1.101 "United States" or "U.S." means the United States of America and all of its territories and possessions.

1.102 "Valid Claim" means (a) a claim of an issued and unexpired patent, which claim has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction and that has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise, or (b) a claim of a patent application that has been pending less than [...***...] from the date of filing of the earliest patent application from which such patent application claims priority, which claim has not been cancelled, withdrawn or abandoned or finally rejected by an administrative agency action from which no appeal can be taken.

1.103 "Vectorization IP" means all Vectorization Know-How and Vectorization Patent Rights.

1.104 "Vectorization Know-How" means all Know-How, including Inventions, that is conceived, discovered, developed or otherwise made or acquired under any Program during the Term (a) by or on behalf of either Party (or its Affiliates or its or their (sub)licensees/Sublicensees) or (b) jointly by or on behalf of Neurocrine (or its Affiliates or its or their Sublicensees), on the one hand, and Voyager (or its Affiliates or its or their licensees), on the other hand, in each case ((a) and (b)), that is directed to Vectorization Technology. Vectorization Know-How shall be considered the Confidential Information of Voyager.

1.105 "Vectorization Patent Rights" means any Patent Rights that Cover Vectorization Know-How.

1.106 "Vectorization Technology" means Voyager's proprietary Virus Vector platform, including any of the following aspects of such platform: (a) Virus Capsids or (b) Know-How regarding the design, Manufacture or optimization of Virus Capsids for the creation of vectorized payloads, including (i) Voyager's system of manufacturing recombinant adeno-associated virus ("rAAV"), comprising molecular materials and methods of generating baculovirus expression vectors (BEVs) that express AAV structural and non-structural proteins essential for replication; (ii) processes for purifying rAAV from the cell culture; (iii) genetic modifications to the Spodoptera frugiperda (Sf9) cell line and baculovirus and (d) Know-How regarding the administration or delivery of any Virus Vectors as therapeutics. For clarity, Vectorization Technology shall not include Know-How related to specific Collaboration Products or Targets or the manufacture of specific Collaboration Products.

1.107 "Vector Genome" means a polynucleotide, whether single stranded (ss) or self-complementary (sc), having a configuration capable of selectively encoding one (1) or more payloads or including one or more transgenes when encapsulated by a Virus Capsid.

1.108 "Virus Capsid" means an engineered or naturally occurring capsid protein or proteins (or the encoding nucleic acid sequence thereof), including, but not limited to, from an AAV, that is capable of encapsulating a Vector Genome.

1.109 "Virus Vector" means a virus comprising a Virus Capsid and Vector Genome encapsulated therein.

1.110 "Voyager IP" means the Voyager Know-How, Voyager Licensed Patent Rights and all Vectorization IP.

1.111 "Voyager Know-How" means (a) all Know-How that (i) is Controlled by Voyager or any of its Affiliates on the Effective Date or during the Term, (ii) prior to any disclosure to Neurocrine hereunder or under the Existing Confidentiality Agreement was not generally known to the public and (iii) is necessary or reasonably useful to Exploit in the Field in the Territory any Collaboration Product; (b) Vectorization Know-How; and (c) Voyager's interest in the Joint Know-How. Notwithstanding anything in this Agreement to the contrary, Voyager Know-How shall not include any Know-How to the extent Controlled by any Person that acquires all or any part of Voyager or an Affiliate of Voyager, or any affiliates of such Person, in each case (x) which

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is Controlled by such Person immediately prior to the effective date of the acquisition (and such Control was not acquired through acquisition or license from Voyager or any Affiliate of Voyager in existence prior to the effective date of such acquisition) or (y) which is Controlled by such Person on or after the effective date of acquisition but is not Controlled by Voyager or an Affiliate of Voyager (excluding for purposes of this provision, such Person and Affiliates of Voyager that are such Affiliates by virtue of controlling, being controlled by or under common control with such Person and were not Affiliates of Voyager prior to the acquisition) and was developed, invented or obtained without the direct or indirect use of any non-public Voyager Know-How.

1.112 "Voyager Licensed Patent Rights" means (a) all Patent Rights Controlled by Voyager or any of its Affiliates as of the Effective Date or during the Term, that claim or Cover any Collaboration Product; and (b) Voyager's interest in the Joint Patent Rights. Notwithstanding anything in this Agreement to the contrary, Voyager Licensed Patent Rights shall not include any Patents to the extent owned or Controlled by any Person that acquires all or any part of Voyager or an Affiliate of Voyager, or any affiliates of such Person, in each case (x) which is Controlled by such Person immediately prior to the effective date of the acquisition (and such Control was not acquired through acquisition or license from Voyager or any Affiliate of Voyager in existence prior to the effective date of such acquisition) or (y) which is Controlled by such Person on or after the effective date of acquisition but is not Controlled by Voyager or an Affiliate of Voyager (excluding for purposes of this provision, such Person and Affiliates of Voyager that are such Affiliates by virtue of controlling, being controlled by or under common control with such Person and were not Affiliates of Voyager prior to the acquisition) and was developed, invented, or obtained without the direct or indirect use of any non-public Voyager Know-How. Notwithstanding the foregoing, the Voyager Licensed Patent Rights exclude any Patent Rights licensed to Voyager under that certain License Agreement between Voyager and ReGenX Biosciences, LLC, dated May 28, 2014 (the "ReGenX Agreement"), which will not be considered an Existing In-License Agreement unless and until Neurocrine requests in writing that the ReGenX Agreement becomes an Existing In-License Agreement. Notwithstanding the foregoing, the Voyager Licensed Patent Rights exclude any Patent Rights licensed to Voyager under the [...***...] License Agreement, which Patent Rights will not be considered sublicensed hereunder unless and until Neurocrine requests in writing that such Patent Rights be so sublicensed following the naming of a Development Candidate with respect to the FA Program or either Discovery Program. Notwithstanding the foregoing, the Voyager Licensed Patent Rights exclude any Patent Rights licensed to Voyager under the [...***...] Agreement, which Patent Rights will not be considered sublicensed hereunder unless and until [...***...] consents to the sublicense of such Patent Rights, at which time such Patent Rights shall be considered sublicensed hereunder without any further action by either Party.

1.113 "Voyager Licensed Platform Patent Rights" means all Voyager Licensed Patent Rights that are not Voyager Target-Specific Patent Rights.

1.114 "Voyager Target-Specific Patent Rights" means those Voyager Licensed Patent Rights that contain claims (a) directed specifically toward a particular Collaboration Candidate, Collaboration Product, or its formulation, manufacture or use, (b) directed toward a method of treatment or use relating to any Program or (c) that relate to modulation of a Target in a Program, its expression or activity of its gene products.

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1.115 "VY-AADC" means the Gene Therapy Product under Development by Voyager for the treatment of Parkinson's disease prior to the execution of this Agreement that will be utilized initially in the AADC Program as a Development Candidate, as described in IND Nos. [...***...], the Development of which is afforded a right of reference to the Avigen/Genzyme IND, [...***...].

1.116 "VY-FXN01" means the Gene Therapy Product under Development by Voyager for the treatment of FA prior to the execution of this Agreement that will be utilized initially in the FA Program as a Development Candidate.

1.117 Additional Definitions. Each of the following definitions is set forth in the section of this Agreement indicated below:

Definition:	**Section:**
Acquired Affiliate	9.3.1
Acquired Competing Product	9.3.1
Acquired Competing Program	9.3.1
Acquirer	1.16
Acquisition Party	9.3.1
Act	1.52
Agreement	Preamble
Alliance Manager	3.7
Allocation Schedule	8.1.1
Alternative Method	5.2.4
[...***...]	7.3
[...***...]	1.14
[...***...] Indemnitees	13.1.2
Co-Co Agreement	4.1.1
Co-Co Option	4.1.1
Co-Co Product	4.1.1
Co-Co Program	4.1.1
Co-Co Rate	4.1.3
Co-Co Territory	4.1.1
Co-Co Trigger Date	4.1.1
Collaboration	2.1.1
Collaboration IP Working Group	3.3.1(b)
Combination Product	1.72
Committee	3.3.1
Competitive Infringement	10.3.1
Confidential Information	11.1
CPI	1.50
Defense Proceeding	10.2.1(a)(ii)
Delivery Event	5.8
Development Candidate Criteria	1.27

Discovery Program Development Plan	2.1.3(b)
Disclosing Party	11.1
Dispute	15.2

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Execution Date	Preamble
Existing Confidentiality Agreement	11.1
Existing Pivotal Trial	1.3
ICC	15.3.2
Genzyme	1.54
Inbound Licensor	5.2.1
Indemnified Party	13.3
Indemnifying Party	13.3
Initial Fee	8.1.1
Joint CMC Working Group	3.3.1(c)
Joint Invention	10.1.1
Joint R&D Working Group	3.3.1(a)
JRA Exception	15.14
JSC	3.1.1
Losses	13.1
Major Market Countries	4.2.2
Milestone Event	8.2(a)
Milestone Payment	8.2(a)
Neurocrine	Preamble
Neurocrine Plan	4.2.3
Neurocrine Product Marks	10.6
Neurocrine PRV Use	7.3
Parties	Preamble
Party	Preamble
Patent Challenge	14.5
Payee	8.7.1
Payor	8.7.1
Potential Target List	2.1.2
PRV	7.3
PRV Sale	7.3
rAAV	1.106
Rate-Shifting Fee	4.1.3
Receiving Party	11.1
Redacted Version	11.3.2
ReGenX Agreement	1.112
Royalty Term	8.4

Secondary Market Countries	4.2.2(b)
Selling Party	1.72
Stock Purchase Agreement	8.1.2
Subcommittee	3.1.1
Sublicense	5.5
Sublicensee	5.5
Supplemental Ingredient(s)	1.72
Target Nomination Period	2.1.2
Term	14.1
Title 11	5.8

Third Party Claims	13.1
Transition Plan	4.3
Voyager	Preamble
Withholding Tax Action	8.11.3
Working Group	3.3.1

ARTICLE 2
COLLABORATION; PRE-TRANSITION DEVELOPMENT

2.1 Collaboration and Programs.

2.1.1 Collaboration. The Parties agree to collaborate on the conduct of four (4) Programs under this Agreement: the AADC Program, the FA Program and two (2) Discovery Programs. The Development, Manufacturing and Commercialization activities for Collaboration Candidates and Collaboration Products conducted pursuant to this Agreement under all four Programs, as well as any such activities conducted pursuant to any Co-Co Agreement, together, shall constitute the "Collaboration".

2.1.2 Selection of Targets for Discovery Programs. Within [...***...] after the Effective Date, the Parties shall agree to a list of up to eight (8) Targets (the "Potential Target List") from which Neurocrine will have the right, after consultation with Voyager, to nominate Targets for the two (2) Discovery Programs by written notice to the JSC, which nomination shall occur within [...***...] after the Parties' designation of the Potential Target List (the "Target Nomination Period"). Promptly following each such nomination by Neurocrine, Voyager shall provide Neurocrine with an analysis of such proposed Target, including technological feasibility, intellectual property protection, whether any In-License Agreement would be applicable to such Discovery Program, preliminary development timelines and a preliminary budget. Promptly thereafter, the JSC shall hold a meeting to discuss each proposed Target and determine whether to approve such proposed Target as a Discovery Target. Each Discovery Target must be approved by consensus of the JSC (or, if applicable, consensus of the Executive Officers), and upon approval by the JSC or Executive Officers of a Target nominated by Neurocrine, such Target will become a Discovery Target. Promptly thereafter, Voyager shall update Schedule 1.37 to include any Existing In-License Agreements applicable to such Discovery Program. Voyager may not withhold approval of any proposed Discovery Target selected from the Potential Target List unless Voyager has a bona fide technical reason or other substantial concern that the proposed Discovery Target is not suitable for conducting a Discovery Program. If Voyager withholds its approval of any Target from the Potential Target List proposed by Neurocrine as a Discovery Target, then (a) Voyager shall concurrently provide a written description of its technical reason or other substantial concern to Neurocrine and (b) Voyager shall not, during the [...***...] period after the end of the Target Nomination Period, conduct any activities, itself or with or through a Third Party, or grant a Third Party a license or otherwise enable a Third Party to conduct any activities, related to the development or commercialization of a Gene Therapy Product directed to such Target. If following the JSC's approval of any Discovery Target, the JSC fails to approve an initial Development Plan therefor, such Discovery Target will no longer be a Discovery Target, the restriction in the preceding clause (b) will apply thereto, and Neurocrine shall within [...***...] nominate an additional Target from the Potential Target List as a Discovery Target pursuant

to this Section 2.1.2. Until the JSC's approval of two (2) Discovery Targets and Development Plans therefor, Voyager shall not conduct any activities, itself or with or through a Third Party, or grant a Third Party a license or otherwise enable a Third Party to conduct any activities, related to the development or commercialization of a Gene Therapy Product directed to a Target on the Potential Target List. The foregoing restriction shall terminate upon the JSC's approval of the second Discovery Target and Development Plan therefor.

2.1.3 Conduct of Programs.

(a) Existing Programs. Voyager shall conduct each Existing Program pursuant to the applicable Existing Program Development Plan. The JSC shall, prior to the end of each Calendar Year prior to the applicable Transition Date, review the Existing Program Development Plans and determine whether to update such plans, including to prepare a detailed budget for the subsequent Calendar Year. A Party may also develop and submit to the JSC from time to time proposed substantive amendments to the AADC Program Development Plan or the FA Program Development Plan. The JSC shall review such proposed amendments and may approve such proposed amendments or any other proposed amendments that the JSC may consider from time to time in its discretion and, upon any such approval by the JSC, the AADC Program Development Plan or FA Program Development Plan, as applicable, shall be amended accordingly.

(b) Discovery Programs. Each Discovery Program shall be conducted pursuant to a research plan and associated budget (each such research plan, including the associated budget, a "Discovery Program Development Plan"). Each Discovery Program Development Plan shall set forth the activities to be conducted with respect to the applicable Discovery Program prior to the applicable Transition Date, and, subject to any mutually agreed contributions from Neurocrine pursuant to Section 2.1.7, shall assign to Voyager responsibility for all Development and associated Manufacturing activities with respect to such Discovery Program until filing by Neurocrine of the IND with respect to such Discovery Program. Following the JSC's approval of a Target as a Discovery Target, Voyager shall prepare the initial draft of the applicable Discovery Program Development Plan and submit it to the JSC for review and approval. The JSC shall approve each initial Discovery Program Development Plan with respect to each Discovery Program in accordance with Section 3.1.2(d). The JSC shall, prior to the end of each Calendar Year prior to the applicable Transition Date, review and update, as appropriate, each Discovery Program Development Plan, including preparing a detailed budget for the subsequent Calendar Year. A Party may also develop and submit to the JSC from time to time proposed substantive amendments to any Discovery Program Development Plan. The JSC shall review such proposed amendments and may approve such proposed amendments or any other proposed amendments that the JSC may consider from time to time in its discretion and, upon any such approval by the JSC, the applicable Discovery Program Development Plan shall be amended accordingly.

2.1.4 Voyager Program Responsibilities. Except as otherwise provided in this Agreement or the applicable Development Plan, Voyager shall have sole responsibility for the conduct of each Program (including any Clinical Trials and Manufacture of Collaboration Candidates and Collaboration Products) until the Transition Date with respect to such Program (and responsibility for any post-Transition Date activities that the Parties mutually agree in accordance with this Agreement). Subject to the terms and conditions of this Agreement, until the

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earlier of (i) the Transition Date or (ii) termination of the applicable Program by the JSC or by a Party pursuant to Article 14, Voyager shall use Commercially Reasonable Efforts to Develop VY-AADC, VY-FXN01 and each other Development Candidate and to identify Development Candidates in the Discovery Programs and FA Program, and shall conduct all Development of Collaboration Candidates, including Development Candidates, in accordance with the applicable Development Plan. There shall be no more than two (2) Development Candidates per Program in each of the FA Program and each Discovery Program, unless otherwise mutually agreed by the Parties. Voyager shall conduct all activities allocated to it under the Development Plans and shall use Commercially Reasonable Efforts to comply with the timelines and budgets therein.

2.1.5 Voyager Development Breach. If Voyager materially breaches its obligations with respect to the conduct of activities under the Development Plan for a Discovery Program and fails to cure such breach within [...***...] after written notice of such breach from Neurocrine, then Neurocrine shall have the right, but not the obligation, to assume the conduct of the applicable Program, itself or through an Affiliate or Third Party contractor (other than a competitor of Voyager), by written notice to Voyager. If Neurocrine elects to assume the conduct of any Program, then Voyager shall conduct all activities and provide all assistance reasonably necessary to transition the Program to Neurocrine or its permitted designee, including the transfer of Voyager Know-How and the provision of materials. Notwithstanding anything the contrary herein, in such event, Neurocrine shall not be responsible to reimburse any Development Costs incurred by Voyager to conduct any activities that were not properly conducted by Voyager or whose conduct Neurocrine has assumed.

2.1.6 Voyager Reporting Obligations. On a Calendar Quarterly basis until all four Transition Events have occurred, in advance of each regularly-scheduled JSC meeting, Voyager shall provide Neurocrine with a reasonably detailed report describing the activities undertaken and accomplishments achieved under each Development Plan, setting forth the Development Costs incurred to conduct such activities and including a copy of all results generated by Voyager in the performance of such Development Plan, in each case since the last such report. Voyager shall promptly respond to Neurocrine's reasonable requests for more information with respect to each such Calendar Quarterly report with respect to any Program. In addition, at Neurocrine's request in between such quarterly reports, Voyager shall provide all information reasonably requested by Neurocrine, including results and Development Costs incurred.

2.1.7 Neurocrine Program Responsibilities. On a Program-by-Program basis with regard to each Program, prior to the Transition Date with respect to such Program, Neurocrine shall, at Neurocrine's cost and expense, (a) contribute Development expertise to such Program as determined by the JSC and (b) provide reasonable Development assistance to Voyager during the conduct of such Program, where such assistance is reasonably requested by Voyager and approved by the JSC based on particular Neurocrine expertise.

2.1.8 Neurocrine Reporting Obligations. On a Calendar Quarterly basis for the AADC Program and the FA Program and on an annual basis for the Discovery Programs, following the Transition Event on a Program-by-Program basis, in advance of the regularly-scheduled JSC meeting, Neurocrine shall provide Voyager with a reasonably detailed report describing the activities undertaken and accomplishments achieved under each Program, including a summary of all results generated by Neurocrine under each Program, in each case since the last such report. In

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addition, prior to the Transition Event on a Program-by-Program basis, to the extent Neurocrine has conducted any activities under a Development Plan since the preceding JSC meeting, Neurocrine shall provide Voyager with a reasonably detailed report describing all activities undertaken and accomplishments achieved under each Development Plan, including a copy of all results generated by Neurocrine in the performance of such Development Plan, in each case since the last such report. Neurocrine shall promptly respond to Voyager's reasonable requests for more information with respect to each such Calendar Quarterly or annual report with respect to any Program.

2.1.9 Development Candidates.

(a) On a Program-by-Program basis with respect to the FA Program and each Discovery Program, prior to the applicable Transition Date, Voyager shall notify Neurocrine of potential Development Candidates that are Developed by or on behalf of Voyager under such Program. Based upon the Development Candidate Criteria and the results of Development activities with respect to the FA Program or any Discovery Program, either Party may nominate a development candidate for such Program by providing written notification thereof to the JSC.

(b) Following nomination of a development candidate by either Party, the JSC shall determine whether such nominated development candidate meets the Development Candidate Criteria. Voyager shall respond to reasonable requests from the JSC for additional information regarding each nominated development candidate. If the JSC agrees that a nominated development candidate meets the Development Candidate Criteria, or if the JSC otherwise decides to designate a Collaboration Candidate as a Development Candidate notwithstanding its failure to achieve the Development Candidate Criteria, then such nominated development candidate shall thereafter be deemed to be a Development Candidate hereunder.

2.2 Development Costs.

2.2.1 In General. Neurocrine shall be responsible for all Development Costs incurred by Voyager in connection with Voyager's performance under each applicable Development Plan in accordance with the terms of this Agreement, provided that such Development Costs are in accordance with the budget set forth in such Development Plan, subject to Section 2.2.2.

2.2.2 Payment. Within [...***...] following the end of each Calendar Quarter in which Voyager conducts activities under a Development Plan, Voyager shall provide Neurocrine with a preliminary report detailing, on a Program-by-Program basis, all Development Costs actually incurred by Voyager in such Calendar Quarter to conduct its activities under each Development Plan in accordance with the budget in such Development Plan. Within [...***...] following the end of each Calendar Quarter in which Voyager conducts activities under a Development Plan, Voyager shall provide Neurocrine with an invoice detailing, on a Program-by-Program basis, all Development Costs actually incurred by Voyager in such Calendar Quarter to conduct its activities under each Development Plan in accordance with the budget in such Development Plan. Voyager shall include with each invoice documentation for any individual Out-of-Pocket Costs in excess of [...***...] Dollars ($[...***...]). To the extent that the invoiced amounts for each activity are less than or equal to [...***...] percent ([...***...]%) of the corresponding amounts set forth in the budget in the applicable Development Plan, Neurocrine

shall pay each such invoice, unless subject to a bona fide dispute, within [...***...] after receipt thereof. Neurocrine shall have the right to conduct an audit of Voyager's books and records to verify the amount of Development Costs pursuant to Section 8.7. Such audit shall not be performed more frequently than [...***...] period. If Voyager anticipates that the FTE Costs or Out-of-Pocket Costs it incurs to conduct any activity under a Development Plan will exceed, or if any such costs do exceed, the amount set forth in the applicable budget for such activity by more than [...***...] percent ([...***...]%), Voyager shall promptly notify the JSC, and the JSC shall discuss in good faith and decide whether to increase such budget.

2.3 Records of Activities. Each Party shall maintain complete, current and accurate records of all Development activities conducted by it under the Collaboration, and all data and other information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of such Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-clinical studies and clinical trials for Programs in formal written study records according to applicable Laws, including national and international guidelines such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, GCP, GLP and cGMP. Neurocrine shall have the right to review and copy such records maintained by Voyager at reasonable times, as reasonably requested by Neurocrine.

2.4 No Representation. No Party makes any representation, warranty or guarantee that the Collaboration will be successful, or that any other particular results will be achieved with respect to the Collaboration, any Program or any Collaboration Product.

2.5 Subcontracting. Subject to the terms of this Agreement, each Party shall have the right to engage Affiliates or Third-Party subcontractors (including contract manufacturing organizations) to perform its Development or Manufacturing obligations under this Agreement. Any such Affiliate or subcontractor shall meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity and perform such work consistent with the terms of this Agreement; provided, however, that a Party engaging an Affiliate or subcontractor hereunder shall remain fully responsible and obligated for all activities performed by such Affiliate or subcontractor. Unless otherwise agreed by the Parties, each Party will obligate each of its Third-Party subcontractors hereunder to agree in writing to assign to such Party ownership of, or, solely after using reasonable efforts to obtain such an assignment and being unable to obtain such an assignment, grant to such Party an exclusive, royalty-free, worldwide, perpetual and irrevocable license (with the right to freely grant sublicenses through multiple tiers) to, any inventions arising under its agreement with such Third Party to the extent related to or resulting from the Development, Manufacture or Commercialization of Collaboration Products; and such Party shall structure such assignment or exclusive license so as to enable such Party to license or sublicense such Third Party inventions to the other Party pursuant to the applicable provisions of this Agreement (including permitting such other Party to grant further sublicenses in accordance with this Agreement).

2.6 Academic Collaborators. If any Party collaborates with an academic institution or one or more individuals at an academic institution to Develop Collaboration Products, such Party shall be required to obligate such academic collaborator to agree in writing to grant the same rights specified in Section 2.5 with respect to ownership or licenses to inventions; it being understood

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and agreed that, solely in the case of academic collaborations to Develop Collaboration Products which are not reasonably expected by the applicable Party to result in inventions related to composition of matter or methods of use, in lieu of the rights specified in Section 2.5, it shall be sufficient for such Party to obtain a non-exclusive, worldwide, royalty-free, perpetual license (with the right to freely grant sublicenses through multiple tiers) to, and a right to negotiate for an exclusive license, with the right to grant sublicenses to, any such inventions, which sublicensing rights must permit sublicensing to the other Party pursuant to the applicable provisions of this Agreement (including permitting such other Party to grant further sublicenses in accordance with this Agreement).

ARTICLE 3
MANAGEMENT OF THE COLLABORATION

3.1 Joint Steering Committee and Subcommittees.

3.1.1 The Parties hereby establish the Joint Steering Committee (the "JSC") to serve as the oversight and decision-making body for the activities to be conducted by the Parties pursuant to this Agreement, as more fully described in this Article 3. The Parties anticipate that the JSC will not be involved in day-to-day implementation of the activities under this Agreement but shall have the responsibilities and decision-making authority set forth herein or as mutually agreed by the Parties in writing from time to time. The JSC may establish subcommittees as set forth in Section 3.2 (each a "Subcommittee").

3.1.2 Responsibilities. The JSC shall perform the following functions with respect to the Collaboration, subject to the final decision-making authority of the respective Parties as set forth in Section 3.6:

(a) serve as an information transfer vehicle, from time to time, to facilitate discussions regarding the Development of Collaboration Products;

(b) review and determine whether to update the Existing Program Development Plans or Discovery Program Development Plans (including related budgets) at the end of each Calendar Year in accordance with Sections 2.1.3(a);

(c) discuss and approve as a Discovery Target any Target proposed by Neurocrine under Section 2.1.2;

(d) within [...***...] after submission by Voyager pursuant to Section 2.1.3(b), review, provide comments on and approve each Discovery Program Development Plan;

(e) review and approve any substantive amendments to a Development Plan proposed by a Party, including any amendments to the budget therein;

(f) establish the Development Candidate Criteria for the FA Program promptly after the Effective Date and for each Discovery Program promptly after approval of the Development Plan therefor;

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(g) review and approve the designation of each Development Candidate in accordance with Section 2.1.9(b);

(h) discuss and determine what CMC and Development expertise, if any, Neurocrine shall contribute to each Program in accordance with Section 2.1.7;

(i) review and discuss progress reports on the Development activities submitted by each Party, including the reports submitted by Voyager under Section 2.1.6 and by Neurocrine under Section 2.1.8;

(j) address any issues or disputes arising from the conduct of the Development activities hereunder;

(k) determine whether Proof of Mechanism has been established for the FA Program and for each Discovery Program;

(l) on a Program-by-Program basis for those Programs for which Voyager has exercised the Co-Co Option, review and approve plans for co-Development and co-Commercialization in accordance with the Co-Co Agreements to be entered into by the Parties;

(m) on a Program-by-Program basis for the Discovery Programs and those Programs for which Voyager has a Co-Co Option but has not exercised such Co-Co Option (i) review and, to the extent related to Development of Collaboration Products, approve the Neurocrine Plan, (ii) review and approve any amendments to the Neurocrine Plan to the extent related to the Development of Collaboration Products, and (iii) review (but not approve) any amendments to the Neurocrine Plan related to the Commercialization of Collaboration Products;

(n) if Voyager exercises its Co-Co Option with respect to the AADC Program, review and approve branding decisions with respect to the Co-Co Products thereunder;

(o) resolve disputes between the Parties with respect to the Co-Co Programs;

(p) review the progress reports on the Development and Commercialization activities submitted by Neurocrine in accordance with Section 4.2.4;

(q) determine that successful Development under a Development Plan is not commercially or scientifically viable, and terminate such Program, thereby deeming such program a Terminated Program;

(r) review and discuss Collaboration Product formulation and formulation optimization;

(s) periodically review and provide comments on the Development and post-approval status of each Collaboration Product;

(t) review and discuss manufacturing scale-up, validation and Collaboration Product supply;

(u) review and discuss any potential Future In-License Agreements and reports or recommendations of the JSC;

(v) discuss patent term extensions in accordance with Section 10.2.7;

(w) review and discuss any reports or recommendations of the Joint R&D Working Group;

(x) review and discuss any reports or recommendations of the Collaboration IP Working Group;

(y) review and discuss any reports or recommendations of the Joint CMC Working Group;

(z) review and resolve any disputes of the Joint R&D Working Group, the Collaboration IP Working Group, the Joint CMC Working Group or any other Subcommittee or Working Group;

(aa) form such Subcommittees and additional Working Groups as it deems necessary to achieve the objectives and intent of this Agreement;

(bb) assign responsibilities that may fall within the purview of more than one Subcommittee to a particular Subcommittee or more than one Working Group to a particular Working Group; and

(cc) perform such other responsibilities as may be assigned to the JSC pursuant to this Agreement or as may be mutually agreed upon by the Parties in writing from time to time.

Except with respect to Co-Co Products in the Co-Co Territory as set forth in Section 4.1.2(a), the JSC will not have any decision-making authority with respect to Commercialization of Collaboration Products, including the content of the Neurocrine Plans to the extent related to Commercialization. For clarity, the JSC shall not have any authority beyond the specific matters set forth in this Section 3.1.2, and in particular shall not have any power to amend or modify the terms of this Agreement or waive a Party's compliance with this Agreement.

3.2 Formation and Dissolution of Subcommittee(s). The JSC may, in its discretion, establish Subcommittees from time to time to handle specific matters within the scope of the JSC's area of authority and responsibility, and no Subcommittee's authority and responsibility may be greater than that of the JSC itself. Each Subcommittee shall have such authority and responsibility as determined by the JSC from time to time, and decisions and recommendations of any Subcommittee shall be made in accordance with Section 3.6. The JSC shall determine when each Subcommittee it forms shall be dissolved.

3.3 Working Groups.

3.3.1 Formation of Working Groups. From time to time, the Parties, the JSC or any Subcommittee (each, a "Committee") may establish a working group (each, a "Working

Group") to oversee particular projects or activities. Each Working Group shall undertake the activities allocated to it herein or delegated to it by the Committee to which it reports. During the process of establishing a Working Group, such Working Group and the Committee to which it reports shall agree regarding which matters such Working Group will resolve on its own and which matters such Working Group will advise the Committee regarding (and with respect to which such advice-specific matters the Committee will resolve); provided that the Parties acknowledge and agree that each Working Group is intended to function primarily in a supporting role providing advice to the Committee to which it reports, but that each Working Group will be best positioned to provide expedited guidance and decisions regarding certain operational matters as determined by the Committee to which such Working Group reports.

(a) Joint R&D Working Group. The Parties shall establish a joint research and development working group (the "Joint R&D Working Group") within [...***...] following the Effective Date. The Joint R&D Working Group will be responsible for the oversight of the day-to-day implementation of (i) the Development activities conducted prior to the applicable Transition Event under this Agreement and (ii) providing the JSC with all relevant information and any recommendations necessary for the JSC to exercise its decision-making authority set forth in Section 3.6 with respect to such Development activities. The Joint R&D Working Group will report to the JSC.

(b) Collaboration IP Working Group. The Parties shall establish an intellectual property working group (the "Collaboration IP Working Group") within [...***...] following the Effective Date. The Collaboration IP Working Group will be responsible for providing the JSC and the Parties with guidance with respect to matters relating to (i) the preparation, filing, prosecution and maintenance of Voyager Licensed Patent Rights and Joint Patent Rights, (ii) freedom-to-operate matters, (iii) discussing any challenges to any Third Party's Patent Rights that may Cover any Collaboration Products, and (iv) advising the JSC regarding which of the Existing In-License Agreements are relevant to any Collaboration Products. The Collaboration IP Working Group will report to the JSC.

(c) Joint CMC Working Group. The Parties shall establish a joint Manufacturing working group (the "Joint CMC Working Group") within [...***...] following the Effective Date. The Joint CMC Working Group will be responsible for providing the JSC and the Parties with guidance with respect to matters relating to the generation and maintenance of chemistry, manufacturing and controls (CMC) data required by applicable Law to be included or referenced in, or otherwise support, an IND or Regulatory Approval Application and coordinating the sharing and exchange of such data between Voyager and Neurocrine. The Joint CMC Working Group will report to the JSC.

3.4 Membership. Each Committee shall be composed of an equal number of representatives appointed by each of Voyager and Neurocrine. The JSC shall be comprised of [...***...] representatives of each Party, and each other Committee shall be comprised of such number of representatives of each Party as is agreed upon by the Parties. Each Party shall appoint at least one (1) representative to each Working Group and shall have the right, but not the obligation, to appoint the same number of representatives to any Working Group as are appointed by the other Party to such Working Group. Each individual appointed by a Party as a representative to the JSC shall be an employee of such Party. Each individual appointed by a Party as a

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representative to any Subcommittee or Working Group shall be an employee of such Party, an employee of such Party's Affiliate or, upon the other Party's approval, a contractor to such Party or its Affiliate; provided that, with respect to the Collaboration IP Working Group, either Party may appoint outside intellectual property counsel as a representative. Each Party may replace any of its Committee or Working Group representatives at any time upon written notice to the other Party, which notice may be given by e-mail sent to the other Party's co-chairperson of such Committee and, with respect to a change of representatives to any Working Group, to the other Party's co-chairperson of the Committee to which such Working Group reports. Each Committee and Working Group shall be co-chaired by one designated representative of each Party. Any member of a Committee or Working Group may designate a substitute who is an employee of the applicable Party to attend and perform the functions of that member at any meeting of such Committee, as applicable. Notwithstanding the foregoing, each Party shall ensure at all times during the existence of a Committee or Working Group that its representatives (including any replacements or substitutes therefor) on such Committee or Working Group are appropriate in terms of seniority, experience, expertise and decision-making authority and are subject to obligations of confidentiality and non-use with respect to the other Party's Confidential Information that are no less stringent than those set forth in Article 11.

3.5 Meetings.

3.5.1 The co-chairpersons shall be responsible, with respect to their Committee or Working Group, as applicable, for (a) calling meetings; (b) preparing and circulating an agenda in advance of each meeting; provided that the co-chairpersons shall include any agenda items proposed by either Party on such agenda; (c) ensuring that all decision-making is carried out in accordance with the voting and dispute resolution mechanisms set forth in this Agreement; and (d) preparing and issuing minutes of each meeting within [...***...] (or such shorter time as is agreed by the relevant Committee or Working Group) thereafter. The location of regularly scheduled meetings shall alternate between Voyager's offices located in Cambridge, Massachusetts and Neurocrine's offices located in San Diego, California, unless otherwise agreed by such Committee or Working Group. Such Committee or Working Group may also determine that a meeting will instead be held telephonically, by video conference or by any other media; provided, however, that the JSC shall hold at least one (1) meeting in person each Calendar Year. For the avoidance of doubt, each Party may designate the same individual as a representative on more than one Committee or Working Group. Each Party will bear all expenses it incurs in regard to participating in all meetings of each Subcommittee and Working Group, including all travel and living expenses.

3.5.2 The JSC shall meet at least once each Calendar Quarter prior to the time of First Commercial Sale of a Collaboration Product from all Programs, and annually thereafter, or more or less frequently as the Parties mutually deem appropriate, on such dates and at such places and times as provided herein or as the Parties shall agree.

3.6 Decision-Making.

3.6.1 Escalation to JSC. Except as otherwise provided herein, all decisions of each Committee and each Working Group shall be made by consensus, with all of a Party's voting members collectively having one (1) vote. If a Committee or Working Group other than the JSC

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is incapable of reaching unanimous agreement on a matter before it within [...***...] after first attempting to decide such matter, the matter shall be referred to the JSC for resolution. If the JSC is incapable of reaching unanimous agreement on a matter before it within [...***...] after first attempting to decide such matter and after having at least [...***...], unless agreed otherwise in writing by the Parties, such agreement not to be unreasonably withheld, conditioned or delayed, the matter shall be resolved in accordance with Section 3.6.2.

3.6.2 Escalation to the Executive Officers. If the JSC cannot agree on a matter within [...***...] after it has first attempted to reach such decision and, unless agreed otherwise pursuant to Section 3.6.1, after having at least [...***...], then either Party may, by written notice to the other, have such issue referred to the Executive Officers for resolution. The Parties' respective Executive Officers shall meet within [...***...] after such matter is referred to them, after having at least [...***...], unless agreed otherwise in writing by the Parties, and shall negotiate in good faith to resolve the matter.

3.6.3 Escalation to the Parties. If the Executive Officers are unable to resolve the matter within [...***...] after the matter is referred to them, then:

(a) Existing Programs. With respect to each Existing Program:

(i) Prior to the exercise by Voyager of its Co-Co Option for such Program, Neurocrine shall have the right to decide such unresolved matter;

(ii) From and after the timely exercise by Voyager of its Co-Co Option for such Program, (A) to the extent the unresolved matter relates to the Development or Manufacturing prior to commercial launch in the Co-Co Territory of Collaboration Products in such Program, neither Party shall have the right to decide such unresolved matter and such unresolved matter shall be deadlocked until resolved by mutual agreement of the Parties or the JSC, (B) to the extent the unresolved matter relates to the Manufacturing or Commercialization in the Co-Co Territory of the Collaboration Products in such Program, Neurocrine shall have the right to decide such unresolved matter; and (C) to the extent the unresolved matter relates to the Development, Manufacturing following commercial launch or Commercialization outside of the Co-Co Territory of Collaboration Products in such Program, Neurocrine shall have the right to decide such unresolved matter; and

(iii) If Voyager does not timely exercise its Co-Co Option with respect to such Program, then Neurocrine shall have the right to decide such unresolved matter.

Notwithstanding the foregoing, in no event shall any Committee or Working Group, without Voyager's explicit agreement, or Neurocrine alone have the power or authority to (1) cause Voyager to deviate from its hiring plan for the AADC Program through completion of the Existing Pivotal Trial as it pertains to work through the Transition Date for the AADC Program, (2) cause Voyager to deviate from its hiring plan for the FA Program through completion of the first Phase 1 Clinical Trial for the FA Program as it pertains to work through the Transition Date for the FA Program, or (3) cause Voyager to reallocate or realign its existing personnel as of the Effective Date in relation to any Existing Program.

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(b) Discovery Programs. Neurocrine shall have the right to resolve all unresolved matters relating to the Discovery Programs, provided that Neurocrine shall not have the right to approve (i) any proposed Target as a Discovery Target, (ii) the initial Discovery Program Development Plan for each Discovery Program or (iii) any Development Plan or amendment thereto that would require Voyager to conduct any activities thereunder for which Voyager does not have, and is not able to obtain with the exercise of Commercially Reasonable Efforts, sufficient personnel or resources, or to conduct any activities that are not included in the budget in such Development Plan;

provided, however, that in no event shall any Committee, Working Group or any Party alone have the power or authority to (1) amend this Agreement, (2) determine whether a Party has fulfilled or breached its obligations under this Agreement, (3) impose any requirements on either Party to undertake obligations beyond those for which it is responsible, or to forgo any of its rights, under this Agreement, (4) make a decision that is expressly stated under this Section 3.6.3 to require the mutual agreement of the Parties or of the JSC, (5) make a decision that could reasonably be expected to cause Voyager to breach an In-License Agreement or give rise to the right of the applicable Inbound Licensor to take any action under such In-License Agreement, or (6) require any Party to perform any act that it reasonably believes to be inconsistent with any Law. Any decision made by the Executive Officers in accordance with Section 3.6.2 or by a Party in accordance with this Section 3.6.3 shall be considered a decision made by the JSC.

3.7 Alliance Managers. Promptly after the Effective Date, each Party shall appoint an individual (who may not be a then-current member of the JSC) to act as alliance manager for such Party (each, an "Alliance Manager"). Each Alliance Manager shall thereafter be permitted to attend meetings of the JSC as a nonvoting observer, subject to the confidentiality provisions of Article 11. The Alliance Managers shall be the primary point of contact for the Parties regarding the activities contemplated by this Agreement. The Alliance Managers shall also be responsible for assisting the JSC in performing its oversight responsibilities. The name and contact information for each Party's Alliance Manager, as well as any replacement chosen by such Party, in its sole discretion, from time to time, shall be promptly provided to the other Party in accordance with Section 15.8.

3.8 Authority. Each Party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion will be delegated to or vested in the JSC or any other Subcommittee or any Working Group unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing.

ARTICLE 4
POST-TRANSITION ACTIVITIES

4.1 Co-Development and Co-Commercialization.

4.1.1 Voyager's Opt-In Right. On an Existing Program-by-Existing Program basis, Voyager shall have the right to elect to co-develop and co-commercialize Collaboration Products that are the subject of such Existing Program in the United States (the "Co-Co Option") by providing Neurocrine with written notice of such election within [...***...] following the applicable Co-Co Trigger Date. Upon such exercise, the Parties shall negotiate in good faith and

enter into an agreement, which shall be based on terms and conditions substantially the same as those set forth in this Section 4.1 and otherwise consistent with this Agreement (each such agreement, a "Co-Co Agreement"), pursuant to which the Parties will jointly Develop and Commercialize and share in the Development Costs, Commercialization costs and profit or loss resulting from the Development and Commercialization of such Collaboration Products in the United States (the "Co-Co Territory"). Once Voyager exercises the Co-Co Option with respect to an Existing Program, each Collaboration Product in such Existing Program shall be designated a "Co-Co Product" hereunder and such Existing Program shall be designated a "Co-Co Program" hereunder, and the Parties will share Development Costs incurred thereafter. The "Co-Co Trigger Date" shall mean (a) with respect to the AADC Program, Voyager's receipt of topline data with respect to the Existing Pivotal Trial, which data Voyager shall submit to Neurocrine promptly after availability thereof and (b) with respect to the FA Program, the date upon which the JSC determines that Proof of Mechanism has been achieved.

4.1.2 Co-Co Agreement General Principles. It is the intent of the Parties that Development and Commercialization of each Co-Co Product in the Co-Co Territory under the applicable Co-Co Agreement will be conducted in accordance with the following principles, except as otherwise mutually agreed by the Parties in writing. The Parties shall take into account and attempt to implement the following principles in their decision-making, including preparation, review and approval of any updates to and amendments of the Development plan and Commercialization plan under such Co-Co Agreement:

(a) Development and Commercialization of each Co-Co Product in and for the Co-Co Territory shall be conducted according to a mutually agreed Development plan and Commercialization plan, respectively, prepared and updated periodically by Neurocrine, in consultation with Voyager, and submitted to the JSC for review and approval. Such plans shall (i) set forth the Development activities and Commercialization activities, respectively, to be undertaken by the Parties with respect to the applicable Co-Co Product in and for the Co-Co Territory in the subsequent [...***...], (ii) be updated at least [...***...] and (iii) include a related detailed budget. Either Party may propose amendments to a Development plan or Commercialization plan to the JSC for review and approval. No Development or Commercialization activities shall be delegated to a Party in the Development plan or Commercialization plan (or any amendment thereto) without such Party's prior agreement. Each Party will use Commercially Reasonable Efforts to perform the Development and Commercialization activities delegated to such Party in the Development plan and Commercialization plan, as applicable. Each Party's Development Costs for the Co-Co Program shall be calculated in a manner consistent with Development Costs calculation under this Agreement (including related definitions). FTE Costs with respect to Commercialization costs for the Co-Co Program shall be calculated in a manner consistent with this Agreement. Notwithstanding the foregoing, the terms of the Co-Co Agreement (i) shall not require any realignment or decrease in the size of the then Neurocrine field forces, and (ii) shall be reasonably directed to maximize sales of the Co-Co Product.

(b) The Development plan and the Commercialization plan under the Co-Co Agreement shall each include an allocation of responsibilities between the Parties reasonably and equitably determined after taking into consideration each Party's expertise, capabilities, staffing and available resources to take on such activities. Notwithstanding the

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foregoing, but subject to the last sentence of Section 4.1.2(a), the Development plan and the Commercialization plan under the Co-Co Agreement shall include meaningful participation in Development activities, Commercialization activities (including participation in field sales and detailing), preparation for Commercialization, and medical affairs activities by Voyager (unless otherwise agreed by Voyager), provided that in all cases Neurocrine will be responsible for booking sales of Collaboration Products.

(c) The Parties shall share Development and Commercialization costs incurred by either Party or its Affiliates in accordance with the applicable budgets in conducting activities for the Co-Co Territory in accordance with the applicable Co-Co Rate pursuant to the Development plan and Commercialization plan under the Co-Co Agreement. The Co-Co Agreement shall provide that (i) if either Party incurs Development Costs or Commercialization costs in excess of [...***...] percent ([...***...]%) of the Development Costs or Commercialization costs, as applicable, budgeted for activities assigned to such Party in the budget of the then-current version of the Development plan or Commercialization plan, as applicable, then such Party shall be solely responsible for such excess costs unless such Party has received the other Party's written approval to share such excess costs and (ii) global Development Costs incurred for Development activities that support Regulatory Approval in the Co-Co Territory and in other countries of the Territory shall be reasonably and equitably allocated to the Co-Co Program in accordance with the reasonably expected proportion of Co-Co Product sales in the Co-Co Territory as compared with other countries in the Territory, as mutually agreed by the Parties.

(d) All profit or loss (which shall be defined in the Co-Co Agreement in a customary manner) and any amounts due to any Inbound Licensor under an In-License Agreement from and after the exercise of the Co-Co Option (including royalty, milestone, and sublicense income payments) with respect to the Co-Co Products shall be shared between the Parties at the Co-Co Rate, to the extent such amounts are allocable to the Co-Co Territory. Proceeds of the sale of any PRV granted to Neurocrine in connection with the approval of the BLA for a Co-Co Product shall be considered Net Sales for the Co-Co Program and costs and expenses associated with any Third Party engaged to facilitate such sale shall be considered a cost for the Co-Co Program, but only if Voyager approves of the engagement of such Third Party prior to such sale. Notwithstanding Sections 13.1.1(c) or 13.2.3, and regardless of the Parties' respective insurance coverages, any losses incurred by either Party arising from Third Party Claims related to Exploitation of the Co-Co Products in or for the Co-Co Territory, including Third Party Claims based on intellectual property infringement, product liability or personal injury, shall be shared between the Parties at the Co-Co Rate, except to the extent resulting from the gross negligence, recklessness or intentional misconduct of a Party or any of its Affiliates or its or their respective directors, officers, employees, agents or representations or a Party's breach of this Agreement.

(e) Neurocrine's obligation to pay the royalty set forth in Sections 8.3.1(a) and 8.3.2(a) shall terminate, and Neurocrine's obligation to make milestone payments with respect to such Co-Co Products shall be modified as set forth in Section 8.2(b).

(f) Regardless of the specific division of responsibility between the Parties for particular activities at any particular time, the JSC shall serve as a conduit for sharing information, knowledge and expertise relating to the Development and Commercialization of each Co-Co Product.

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(g) The Co-Co Agreement shall specify that the mutual consent of both Parties shall be required to Develop and Commercialize each Co-Co Product with any Third Party in the Co-Co Territory, including the sale, licensing or divestiture of marketing rights or product assets as to such Co-Co Product in the Co-Co Territory.

(h) The dispute resolution provisions in the Co-Co Agreement shall mirror Sections 15.2 and 15.3 of this Agreement and the Parties shall agree that any arbitration brought under a Co-Co Agreement may be consolidated with an arbitration brought under another Co-Co Agreement or this Agreement.

4.1.3 Co-Co Rate. Each Party shall receive (in the case of profits) or pay (in the case of losses), as applicable, its allocable share of profit and losses with respect to each Co-Co Product in the Co-Co Territory. The rate at which the Parties shall share in such profit and losses is referred to herein as the "Co-Co Rate". The Co-Co Rate for the FA Program shall be 60% for Neurocrine and 40% for Voyager, and the Co-Co Rate for the AADC Program shall initially be 50% for each of Neurocrine and Voyager; provided that, Neurocrine may elect, by delivery of written notice and payment to Voyager of the Rate-Shifting Fee within [...***...] of BLA acceptance for filing by the FDA with respect to the Co-Co Product for the AADC Program, to change the Co-Co Rate for the AADC Program to 55% for Neurocrine and 45% for Voyager. The "Rate-Shifting Fee" shall be Thirty-Five Million Dollars ($35,000,000). If Neurocrine so elects, the Co-Co Rate shall be adjusted effective as of the first day of the month following Neurocrine's election, and there shall be no credit or accounting for profit and losses shared by the Parties prior to such date. If Neurocrine does not notify Voyager of its election and pay the Rate-Shifting Fee within such [...***...] period, then the Co-Co Rate for Co-Co Products in the AADC Program shall remain 50% for each of Neurocrine and Voyager for the term of the applicable Co-Co Agreement.

4.1.4 Termination of Co-Co Agreement.

(a) Voyager shall have the right to terminate any Co-Co Agreement for any or no reason on [...***...] prior written notice. For the avoidance of doubt, following termination of a Co-Co Agreement as set forth in this subsection (a), Voyager shall not be entitled to any refund or credit for amounts that it may have paid under such Co-Co Agreement prior to termination (other than amounts that may be payable or creditable to Voyager as a final reconciliation of its share of profits and losses through termination).

(b) Neurocrine shall have the right to terminate any Co-Co Agreement upon a Change of Control of Voyager if the Acquirer is Developing or Commercializing a branded product that directly competes with a product being Developed or Commercialized by Neurocrine. In such event, the Parties will negotiate in good faith a reasonable royalty to Voyager (in excess of the applicable royalties in Section 8.3) that would approximate Voyager's share (at the Co-Co Rate) of profit under the Co-Co Agreement, and if the Parties fail to agree on such share, the dispute will be submitted to an independent mutually agreed expert for determination, whose decision will be final and binding on the Parties.

(c) If a Co-Co Agreement is terminated, as set forth above in this Section 4.1.4 or in accordance with the terms of such Co-Co Agreement, then (i) the Co-Co

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Products from such Co-Co Program shall be deemed Collaboration Products (and not Co-Co Products) hereunder for the remainder of the Term, (ii) the Parties shall cease to share profit and loss with respect to such Collaboration Products and Neurocrine's obligation to pay the royalties set forth in Sections 8.3.1(a) and 8.3.2(a), as applicable, shall be reinstated from and after the effective date of termination and (iii) Neurocrine's obligations to make milestone payments with respect to such Collaboration Products shall thereafter be as set forth in Section 8.2(b) for Collaboration Products that are not Co-Co Products; provided, that Neurocrine shall not have any obligation to make milestone payments with respect to milestones that occurred prior to the effective date of termination of the Co-Co Agreement.

4.2 Neurocrine Development and Commercialization.

4.2.1 Neurocrine Responsibilities. From and after the Transition Date with respect to a Program that is not a Co-Co Program, Neurocrine shall be solely responsible at Neurocrine's cost and expense for all Development, Manufacturing and Commercialization activities in connection with the Collaboration Products that are the subject of such Program in the Field in the Territory, which activities shall be conducted in accordance with the Neurocrine Plan and this Agreement; provided that Voyager shall provide reasonable Development assistance to Neurocrine as reasonably requested by Neurocrine and reasonably agreed by Neurocrine in connection with activities for which Voyager has expertise. Neurocrine shall reimburse Voyager for all Development Costs incurred by Voyager under this Section 4.2.1 within [...***...] of Voyager's submission of an invoice therefor.

4.2.2 Neurocrine Diligence.

(a) Major Market Countries. Neurocrine shall use Commercially Reasonable Efforts (i) to Develop, seek Regulatory Approval for and Commercialize at least one (1) Collaboration Product in each Program in each of [...***...] (collectively, the "Major Market Countries") and (ii) to Commercialize at least one (1) Collaboration Product in each Program in each Major Market Country in which it receives Regulatory Approval and, if applicable, pricing and reimbursement approval for such Collaboration Product.

(b) Secondary Market Countries. Neurocrine shall use Commercially Reasonable Efforts (i) to Develop, seek Regulatory Approval for and Commercialize Collaboration Products in [...***...] (collectively, the "Secondary Market Countries") and (ii) to Commercialize such Collaboration Products in the Secondary Market Countries for which it receives Regulatory Approval and, if applicable, pricing and reimbursement approval for such Collaboration Products to the extent sufficient commercial opportunities exist in such countries and such activities do not impede Development or Commercialization of Collaboration Products in any Major Market Countries.

Notwithstanding the foregoing or any other provision under this Agreement, it will be consistent with the exercise of Commercially Reasonable Efforts for Neurocrine to prioritize one Program over all other Programs at any given time, and it will not be consistent with the exercise of Commercially Reasonable Efforts for Neurocrine to prioritize another Program over the AADC

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Program, and Neurocrine may not give priority to another Program over the AADC Program without Voyager's written agreement.

4.2.3 Neurocrine Plan. Within [...***...] after the Transition Date with respect to a Program, Neurocrine shall submit a written plan, prepared in good faith, (such plan, as each may be amended from time to time in accordance with this Agreement, the "Neurocrine Plan") to the JSC for review and approval (to the extent set forth in Section 3.1.2(m)), which Neurocrine Plan shall include a description and overall summary of the Development, Manufacturing and Commercialization activities that Neurocrine intends to conduct in order to obtain Regulatory Approval for each Collaboration Product that is the subject of such Program in the Territory, which shall specifically include such activities in each of the [...***...]. Neurocrine shall use Commercially Reasonable Efforts to execute the activities specified in the Neurocrine Plan. Neurocrine may submit to the JSC proposed amendments to the Neurocrine Plan from time to time during the term of this Agreement. All amendments to the Neurocrine Plan shall be reviewed and, to the extent provided in Section 3.1.2, approved by the JSC.

4.2.4 Neurocrine Reports. Neurocrine shall, within [...***...] after the end of each of the first and second halves of each Calendar Year prior to First Commercial Sale of a Collaboration Product in all Programs, and annually thereafter, provide Voyager with written progress reports on the status of the Development and Commercialization activities under the applicable Neurocrine Plan with respect to each Collaboration Product in such Calendar Year. Notwithstanding the foregoing, Neurocrine agrees that to the extent that an In-License Agreement applicable to a given Program requires more thorough or more frequent reporting or requires that reports be provided on a different timeline than that set forth in this Section 4.2.4, Voyager shall notify Neurocrine of the deadline and content of such reports, and Neurocrine shall provide such reports to Voyager as requested by Voyager no less than [...***...] prior to the date that Voyager is required to submit such report pursuant to the applicable In-License Agreement.

4.3 Program Transition. On a Program-by-Program basis, no later than [...***...] before the reasonably anticipated Transition Date with respect to such Program, the Parties shall commence preparing in good faith and prior to such Transition Date shall agree to a plan to transfer to Neurocrine (or its designee (other than a competitor of Voyager who is developing or commercializing a gene therapy, gene editing or anti-sense oligonucleotide product)) all Development and Manufacturing activities relating to Collaboration Product(s) in such Program then being undertaken by Voyager (the "Transition Plan"). Voyager shall transition all such activities to Neurocrine, at Neurocrine's cost and expense, and shall conduct all transition activities in accordance with the Transition Plan as soon as reasonably practicable. As part of each such Transition Plan, Voyager shall provide to Neurocrine all Voyager Know-How relevant to the applicable Program and not previously provided to Neurocrine.

4.3.1 Reimbursement. To the extent that Neurocrine is required to reimburse Voyager hereunder for any costs incurred by Voyager or pursuant to the activities under the Transition Plan, Voyager shall submit an invoice itemizing such costs and expenses Voyager has incurred, on a Calendar Quarter basis, together with any written evidence of such costs. Neurocrine shall pay such invoice, unless subject to a bona fide dispute, within [...***...] of

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receipt. For the avoidance of doubt, any such costs shall be calculated by Voyager as Development Costs.

4.4 Transition Activities. In connection with the transition of each Program to Neurocrine, and as further detailed in the Transition Plan, Voyager shall conduct the following activities for no additional consideration:

4.4.1 Voyager shall provide all assistance reasonably necessary for Neurocrine or its designees to continue the Manufacture and Development of all Collaboration Products in such Program;

4.4.2 Upon Neurocrine's request, Voyager shall assign to Neurocrine any agreements (including any agreement with any Third Party manufacturer with respect to a Collaboration Candidate or Collaboration Product) solely relating to the Development or Manufacture of any Collaboration Candidate or Collaboration Product to which Voyager or any of its Affiliates is a party; provided that if any such agreement is not assignable to Neurocrine (because consent is required or because it relates to products that are not Collaboration Products), Voyager shall take all actions reasonably requested by Neurocrine so that Neurocrine may receive the benefits of such agreement applicable to Collaboration Candidates and Collaboration Products, which may include assigning a statement of work or work order to Neurocrine and facilitating a discussion of the terms of a services agreement between Neurocrine and the applicable counterparty;

4.4.3 Voyager shall transfer to Neurocrine copies of all data, reports, records, materials and other information arising out of the applicable Program, including all non-clinical and clinical data relating to any Collaboration Candidate or Collaboration Product, and all adverse event or other safety data resulting from such Program, as well as any chemistry, manufacturing and controls (CMC) or other Manufacturing data generated in connection with such Program; and

4.4.4 Voyager shall provide Neurocrine with a written summary of its inventory of Collaboration Candidates and Collaboration Products, and Voyager shall, at Neurocrine's election, promptly destroy such inventory or deliver such inventory to Neurocrine. Voyager represents and warrants that, at the time of delivery, all clinical supply of Collaboration Candidates and Collaboration Products (a) will have been Manufactured in accordance with applicable Law, including cGMP, (b) will not be adulterated or misbranded under the Act and may be introduced into interstate commerce pursuant to the Act, (c) will comply with the specifications therefor, and (d) will comply with the quality agreement to be entered into between the Parties. In the event that Voyager cannot make such representations with respect to any such inventory, Voyager shall destroy such inventory and certify such destruction to Neurocrine, unless requested otherwise by Neurocrine; provided that if any such non-compliance results from either (i) Voyager's gross negligence or willful misconduct in the Manufacture of such inventory or (ii) Voyager's negligence or willful misconduct in the oversight of any Third Party's Manufacture of such inventory, Voyager shall reimburse the amounts paid by Neurocrine under the Development Plan for the Manufacture of such inventory.

ARTICLE 5
GRANT OF LICENSES

5.1 License Grant. Subject to the terms and conditions of this Agreement, Voyager hereby grants to Neurocrine, and Neurocrine accepts, an exclusive, royalty-bearing, non-transferable (except in accordance with Section 15.4), sublicenseable (subject to Section 5.5) license under the Voyager IP to Develop, Commercialize, Manufacture, have Manufactured and use Collaboration Candidates and Collaboration Products in the Field in the Territory during the Term; provided, however, that, such license shall be subject to Voyager's retained rights under the Voyager IP to conduct the activities allocated to Voyager under any Development Plan or Co-Co Agreement or otherwise under this Agreement. The license granted under this Section 5.1 shall automatically convert to a fully paid-up, non-royalty bearing, perpetual, irrevocable, exclusive license on a country-by-country and Collaboration Product-by-Collaboration Product basis upon the expiration of the Royalty Term applicable to such Collaboration Product in such country (but not upon an earlier termination of this Agreement with respect thereto).

5.2 In-License Agreements.

5.2.1 Neurocrine acknowledges that the license granted by Voyager to Neurocrine in Section 5.1 includes sublicenses under certain Voyager IP that is licensed to Voyager pursuant to In-License Agreements, and that such sublicenses are subject to the applicable terms of the In-License Agreements, the scope of the licenses granted to Voyager or the applicable Affiliate thereunder and the rights granted to or retained by the Third Party counterparties and any other Third Parties (including Governmental Authorities) (each, an "Inbound Licensor") set forth therein. To the extent Patent Rights under the In-License Agreements are sublicensed to Neurocrine hereunder, Neurocrine covenants to comply with, and to cause its sublicensed Affiliates and to require its Sublicensees to comply with, the In-License Agreements, pursuant to their terms, including Sections 5.1, 5.2, 8.1, 10.1, 10.2, 12.5, and 13.7-13.9 of the [...***...] Agreement the text of which Sections are set forth on Schedule 5.2.1 in compliance with Section 4.2 of the [...***...] Agreement and if the Patent Rights under the [...***...] Agreement are sublicensed to Neurocrine hereunder, Section 2.3 of the [...***...] Agreement. To the extent there is a conflict between any of the terms of any In-License Agreement and the rights granted to Neurocrine hereunder (including with respect to any sublicensing rights, Prosecution and Maintenance, enforcement and defense rights) the terms of such In-License Agreement shall control with respect to the Know-How and Patent Rights licensed to Voyager under such In-License Agreement.

5.2.2 If either Party becomes aware of any Third Party's Know-How that would be necessary or reasonably useful for the Development, Manufacturing or Commercialization of a Collaboration Product or any Third Party's Patent Right that Covers in the Territory any Collaboration Product, such Party shall promptly notify the other Party, and the Parties shall discuss whether to seek a license under such Know-How or Patent Rights. Voyager shall have the first right to enter into Third Party licenses related to Know-How, Patent Rights, or other intellectual property rights related to any Vectorization Technology, in Voyager's sole discretion. If Voyager determines to enter into such a license, then prior to doing so Voyager shall provide written notice to Neurocrine and, if Neurocrine expresses a desire to obtain a sublicense to such license pursuant to Section 5.2.3, Voyager shall thereafter provide Neurocrine with a reasonable opportunity to review and comment on the proposed terms of such license that are applicable to

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Neurocrine as a sublicensee thereunder. Voyager shall use reasonable efforts to negotiate the terms of such license accordingly. Neurocrine shall have the first right to seek any other Third Party license related to Know-How, Patent Rights, or other intellectual property rights. If Neurocrine elects not to seek any other such license, and if Voyager seeks such license, and if Neurocrine expresses a desire to obtain a sublicense to such license pursuant to Section 5.2.3, Voyager shall thereafter provide Neurocrine with a reasonable opportunity to review and comment on the proposed terms of such license that are applicable to Neurocrine as a sublicensee thereunder. Voyager shall use reasonable efforts to negotiate the terms of such license accordingly. For the avoidance of doubt, nothing contained in this Section 5.2.2 creates an obligation for Voyager to obtain any Third Party license.

5.2.3 If, after the Effective Date, subject to Section 5.2.2, Voyager or any of its Affiliates enters into a Future In-License Agreement with a Third Party pursuant to which Voyager (or, subject to the last sentence of this Section 5.2.3, any of its Affiliates) obtains Control over a Third Party's Know-How that is necessary or reasonably useful for the Development, Manufacturing or Commercialization of a Collaboration Product or any Patent Right that Covers in the Territory any Collaboration Product, Voyager shall promptly provide such Future In-License Agreement to Neurocrine and provide any information reasonably requested by Neurocrine with respect thereto, and such Third Party's Know-How and Patent Rights shall be included in the license granted to Neurocrine under Section 5.1 and considered Voyager IP hereunder, only if Neurocrine agrees in writing to pay the share of the payments due to Inbound Licensors applicable to the Collaboration Product(s), as well as a reasonably allocable share of any other payments due to Inbound Licensors not specific to a compound or product, as set forth in Section 5.2.4.

5.2.4 As between the Parties, the amounts payable under all In-License Agreements shall be allocated as follows:

(a) With respect to an Existing Program (unless and until such Existing Program becomes a Co-Co Program), (i) Voyager shall be responsible for any payment required under applicable Existing In-License Agreements and (ii) each of Voyager and Neurocrine shall be responsible for fifty percent (50%) of all payments under any applicable Future In-License Agreement that are specifically related to a Collaboration Product, it being agreed that if Voyager's fifty percent (50%) share of royalties payable under the Future In-License Agreement exceed the royalties payable by Neurocrine to Voyager with respect to the applicable Collaboration Product in the applicable country in the applicable Calendar Quarter, then Neurocrine shall bear such excess. Notwithstanding the foregoing, Voyager shall be solely responsible for all payments under any potential In-License Agreements for intellectual property referenced on Schedule 5.2.4(a) for Existing Programs.

(b) With respect to the Discovery Programs, (i) each of Voyager and Neurocrine shall be responsible for fifty percent (50%) of all payments under any Existing In-License Agreement and Future In-License Agreement that are specifically related to Vectorization Technology, it being agreed that if Voyager's fifty percent (50%) share of royalties payable under the Existing In-License Agreement or Future In-License Agreement exceed the royalties payable by Neurocrine to Voyager with respect to the applicable Collaboration Product in the applicable country in the applicable Calendar Quarter, then Neurocrine shall bear such excess and (ii)

Neurocrine shall be responsible for 100% of all payments under any Future In-License Agreement that are not specifically related to Vectorization Technology.

(c) With respect to any Co-Co Program, from and after the exercise of the Co-Co Option, pursuant to Section 4.1.2(d), any amounts due to any Inbound Licensor under an In-License Agreement (including royalty, milestone and sublicense income payments) with respect to the Co-Co Products shall be shared between the Parties at the Co-Co Rate, to the extent such amounts are allocable to the Co-Co Product in the Co-Co Territory.

Notwithstanding the fact that Voyager has obtained a license related to Know-How, Patent Rights or other intellectual property rights Covering Vectorization Technology and that such intellectual property rights may be included within Neurocrine's license to Existing In-License Agreements or that Neurocrine may elect, under Section 5.2.3 to take a sublicense to Know-How, Patent Rights or other intellectual property rights Covering Vectorization Technology under a Future In-License Agreement, to the extent that Voyager demonstrates that an alternative methodology or approach that is not Covered by such licensed intellectual property rights (an "Alternative Method") yields results that are of materially equivalent or superior quality, and Voyager proposes to Neurocrine that such Alternative Method be deployed in a Collaboration Program on a timeline that is practicable and does not introduce unreasonable risk to the success of a Program, then Neurocrine shall reasonably consider deploying such Alternative Method for the relevant Collaboration Program; provided that if, notwithstanding Voyager's proposal for the use of the Alternative Method, Neurocrine exercises its final-decision making authority pursuant to Section 3.6 to decline the use of the Alternative Method, then any payments under the Existing Licensed Agreement or Future In-License Agreement implicated by Neurocrine's refusal to adopt the Alternative Method shall be allocated between the Parties as set forth in Section 5.2.4(a) (without giving effect to the last sentence thereof).

5.2.5 Neurocrine shall prepare and deliver to Voyager any additional reports required under the applicable In-License Agreements of Voyager, in each case to the extent requested by Voyager, and, provided that Voyager has notified Neurocrine reasonably sufficiently in advance of the applicable deadline, to enable Voyager to comply with its obligations under the applicable In-License Agreements.

5.3 Obligations Under In-Licenses.

5.3.1 Voyager shall not take (or fail to take) any action, including failure to pay any amounts when due (except that any such failure to pay that was caused by Neurocrine's failure to make a payment required to be made by Neurocrine under Section 5.2.4 will not be considered an action or failure to take action by Voyager for purposes of this Section 5.3.1), that constitutes a material breach under any In-License Agreement. Voyager will not, without the consent of Neurocrine (a) take any action with respect to any In-License Agreement (including amending, terminating or otherwise modifying) that diminishes the rights granted to Neurocrine under this Agreement; or (b) fail to take any action with respect to an In-License Agreement that is reasonably necessary to avoid diminishing the rights granted to Neurocrine under this Agreement.

5.3.2 Voyager shall reasonably enforce, or otherwise take all actions necessary to enable Neurocrine to enforce, at Voyager's expense, Voyager's rights and benefits and the

obligations of the counterparty under each In-License Agreement that may affect the rights, benefits and obligations of Neurocrine hereunder, including taking such actions as Neurocrine may request, and will inform Neurocrine of any action it takes under any In-License Agreement to the extent such action may affect Neurocrine's rights under this Agreement.

5.3.3 Voyager shall not (and shall cause its Affiliates not to) assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 15.4) any In-License Agreement without the prior written consent of Neurocrine.

5.3.4 Voyager shall (and shall cause its Affiliates to) provide Neurocrine with prompt notice of any claim of a breach under any In-License Agreement or notice of termination of any In-License Agreement, made by any of Voyager, its Affiliate or the Inbound Licensor, and shall promptly send to Neurocrine (or cause its Affiliates promptly to send to Neurocrine) copies of all material correspondence regarding each In-License Agreement, to the extent relevant to the rights or obligations of Neurocrine under this Agreement.

5.3.5 In the event that Voyager or its Affiliate receives written notice of an alleged breach by Voyager or its Affiliate under any In-License Agreement, where termination of such In-License Agreement or any diminishment of the licenses granted to Neurocrine under the Voyager IP is being or could be sought by the Inbound Licensor, then Voyager will promptly, but in no event less than [...***...] thereafter, provide written notice thereof to Neurocrine and grant Neurocrine the right (but not the obligation) to cure such alleged breach, and if Neurocrine elects to and does cure such breach, then Neurocrine may offset any Out-of-Pocket Costs and expenses incurred by or on behalf of Neurocrine or any of its Affiliates in connection with curing such breach against Neurocrine's future payment obligations to Voyager under this Agreement. Each Party shall notify the other Party if it intends to cure such breach and again promptly after curing such breach.

5.3.6 Neurocrine acknowledges and agrees that, if any license granted to Voyager under an In-License Agreement is terminated then Neurocrine's sublicense under such terminated license shall automatically terminate, subject to Neurocrine's right to receive a direct license from any Inbound Licensor of such In-License Agreement to the extent specified in the applicable In-License Agreement. In the event that any In-License Agreement is terminated by the applicable Inbound Licensor, and such In-License Agreement does not permit the sublicense to survive (or Neurocrine to receive a direct license), then Voyager will take all reasonable actions requested by Neurocrine to facilitate Neurocrine's entry into a direct license agreement with the applicable Inbound Licensor. In the event that any In-License Agreement is terminated by the applicable Inbound Licensor, and such In-License Agreement permits the sublicense to survive (or Neurocrine to receive a direct license), Neurocrine will have the right, at Neurocrine's election, to convert the applicable sublicenses granted under this Agreement by Voyager to a direct license from the applicable Inbound Licensor to Neurocrine on the terms and conditions contained in such In-License Agreement, or such other terms and conditions as may be negotiated by Neurocrine and the applicable Inbound Licensor, and Voyager will reasonably cooperate with Neurocrine and its Affiliates to effectuate such direct license and assist Neurocrine in discussions with Inbound Licensors to accomplish such direct license. In the event Neurocrine enters into any such direct license with an Inbound Licensor, Neurocrine may offset any Out-of-Pocket Costs and expenses incurred by or on behalf of Neurocrine or any of its Affiliates or Sublicensees in connection with

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entering into and exercising its rights or performing under such direct license, against Neurocrine's future payment obligations to Voyager under this Agreement.

5.4 Genzyme Agreement. Voyager shall notify Neurocrine within [...***...] after Genzyme's rights to the FA Program outside the United States expire and shall provide written confirmation thereof from Genzyme. Upon such expiration, the Territory with respect to the FA Program will automatically expand to include all countries in the world. If instead Genzyme exercises its option with respect to the FA Program, then promptly thereafter Voyager will use Commercially Reasonable Efforts to facilitate negotiation of a cooperation agreement among Genzyme, Neurocrine and Voyager including provisions related to data sharing, license grants and coordination of development activities for Collaboration Candidates and Collaboration Products in the FA Program.

5.5 Neurocrine's Sublicensing Rights. Neurocrine shall have the right to grant and authorize sublicenses under the rights granted to it under Section 5.1 to any of its Affiliates and Third Parties through multiple tiers (each such Third Party, a "Sublicensee"). Neurocrine shall provide Voyager with a fully-executed copy of any agreement (redacted as necessary to protect confidential or commercially sensitive information that is not necessary for Voyager to determine Neurocrine's compliance with this Agreement or for Voyager to comply with any applicable In-License Agreement) reflecting any such sublicense to a Third Party promptly after the execution thereof (a "Sublicense"). If Neurocrine or any Affiliate or Sublicensee grants a sublicense, the terms and conditions of this Agreement that are applicable to Sublicensees shall apply to such Sublicensee to the same extent as they apply to Neurocrine. Neurocrine will itself pay and account to Voyager for all payments due under this Agreement by reason of operation of any such sublicense. Each Sublicense must be consistent with, and require the Sublicensee to meet, all applicable obligations and requirements of the In-License Agreements. Notwithstanding the foregoing, unless and until the receipt of written agreement by the applicable Inbound Licensor to permit further sublicensing to a Third Party, Neurocrine shall not have the right to grant any sublicenses to the extent not permitted under the applicable In-License Agreement; provided that upon Neurocrine's request, Voyager will use Commercially Reasonable Efforts to obtain the right for Neurocrine to grant sublicenses to the extent not already permitted by an In-License Agreement.

5.6 Licenses to Voyager.

5.6.1 Development License. Subject to the terms and conditions of this Agreement, Neurocrine hereby grants to Voyager, and Voyager accepts, a non-exclusive, royalty-free, non-transferable (except in accordance with Section 15.4), sublicenseable (only to its permitted subcontractors under Section 2.5) license under the Neurocrine IP to conduct the Development and Manufacturing activities allocated to Voyager under the Development Plans in the Field in the Territory in accordance with this Agreement.

5.6.2 Co-Co License. Subject to the terms and conditions of this Agreement and each applicable Co-Co Agreement, on a Program-by-Program basis, upon Voyager's exercise of the Co-Co Option with respect to such Program in accordance with Section 4.1.1, Neurocrine grants to Voyager, and Voyager accepts, a non-exclusive, non-transferable (except in accordance with Section 15.4), sublicenseable (solely as set forth in the applicable Co-Co Agreement) license

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under the Neurocrine IP to conduct those Development, Commercialization and Manufacturing activities that are allocated to Voyager under such Co-Co Agreement with respect to Co-Co Products in such Program in the Field in and for the Co-Co Territory during the term of such Co-Co Agreement.

5.7 No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances shall a Party, as a result of this Agreement, obtain any ownership interest, license right or other right in any Know-How, Patent Rights or other intellectual property rights of the other Party or any of its Affiliates, including items owned, controlled, developed or acquired by the other Party or any of its Affiliates, or provided by the other Party to the first Party at any time pursuant to this Agreement.

5.8 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to this Agreement by a Party to the other, including those set forth in Sections 5.1 and 5.6, are and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the U.S. Bankruptcy Code ("Title 11"), licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code and any foreign counterpart thereto. Without limiting the Parties' rights under Section 365(n) of Title 11, if a case under Title 11 is commenced by or against either Party, the other Party shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the possession of such other Party, shall be promptly delivered to it (a) before this Agreement is rejected by or on behalf of such Party, within [...***...] after such other Party's written request, unless such Party, or its trustee or receiver, elects within [...***...] to continue to perform all of its obligations under this Agreement, or (b) after any rejection of this Agreement by or on behalf of such Party, if not previously delivered as provided under clause (a) above (any such event described in clause (a) or (b) above, and occurring while such Title 11 case is pending, being a "Delivery Event"). All rights of the Parties under this Section 5.8 and under Section 365(n) of Title 11 are in addition to and not in substitution of any and all other rights, powers, and remedies that each Party may have under this Agreement, Title 11, and any other applicable Laws. The Parties agree that they intend the foregoing rights to extend to the maximum extent permitted by Law and any provisions of applicable contracts with Third Parties, including for purposes of Title 11, (i) the right of access to any intellectual property (including all embodiments thereof) of Voyager or Neurocrine, as applicable, or any Third Party with whom Voyager or Neurocrine contracts to perform an obligation of Voyager or Neurocrine under this Agreement, and, in the case of the Third Party, that is necessary for the Development and Manufacture of Collaboration Products and (ii) the right to contract directly with any Third Party described in clause (i) in this sentence to complete the contracted work, provided however, that in each case such rights shall be subject to the confidentiality obligations contemplated by this Agreement. If a bankruptcy proceeding is commenced by or against Voyager, notwithstanding anything to the contrary in Article 10, Neurocrine may, to the maximum extent permitted by Law, take appropriate actions in connection with the filing, prosecution, maintenance and enforcement of any Voyager Licensed Patent Rights licensed to Neurocrine under this Agreement to the extent that Voyager is required or has the right to take such actions under this Agreement and to the extent that Voyager fails to take such actions following at least [...***...] prior written notice from Neurocrine.

ARTICLE 6
MANUFACTURING

6.1 Manufacturing Responsibilities Prior to Transition Date. Prior to the Transition Date for a Program, Voyager shall be responsible for the Manufacture of Collaboration Products from such Program, subject to Section 2.1.7 or unless otherwise agreed by the Parties in writing.

6.2 Manufacturing After Transition Date. No later than [...***...] prior to the anticipated Transition Date for a Program, the Parties shall discuss in good faith the allocation of Manufacturing and supply responsibilities between the Parties with regard to the Collaboration Product(s) from such Program in connection with Neurocrine's and, to the extent applicable, Voyager's Development and Commercialization activities hereunder. The Parties may negotiate in good faith either or both a clinical supply agreement and/or a commercial supply agreement for Voyager to supply Neurocrine with any Collaboration Product.

ARTICLE 7
GENERAL PROVISIONS RELATING TO ACTIVITIES

7.1 Compliance. All Development, Manufacturing and Commercialization activities to be conducted by a Party under this Agreement shall be conducted in compliance with applicable Laws, including all applicable cGMP, GLP and GCP requirements.

7.2 Regulatory Activities.

7.2.1 INDs and Related Communications.

(a) Subject to the terms of any applicable Co-Co Agreement, from and after the applicable Transition Date, Neurocrine shall, as between the Parties, have the sole right to prepare, obtain and maintain all INDs, Regulatory Approval Applications (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals, pricing and reimbursement approvals and other submissions and to conduct communications with the Regulatory Authorities and Governmental Authorities in the Territory for the applicable Collaboration Products. Neurocrine will be the regulatory sponsor for all Clinical Trials commenced on Collaboration Products from and after the Effective Date. Upon Neurocrine's request, Voyager shall provide reasonable assistance to Neurocrine in connection with the regulatory activities for Collaboration Products, including the preparation of the IND for the FA Program and other relevant Regulatory Filings.

(b) With regard to the Existing Programs, subject to the terms of any applicable Co-Co Agreement, Neurocrine shall provide drafts of each such IND, Regulatory Approval Application or other material submission or communication described in Section 7.2.1(a) to Voyager for Voyager's review and comment a reasonable period of time prior to such submission of such IND, Regulatory Approval Applications or other material submission or communications to the applicable Regulatory Authority. Neurocrine shall, and shall cause its Affiliates to, reasonably incorporate any comments of Voyager into such IND, Regulatory Approval Applications and other material submissions and communications if received by Neurocrine within [...***...] after Neurocrine has provided access to Voyager.

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(c) With regard to the Existing Programs, subject to the terms of any applicable Co-Co Agreement, Neurocrine shall provide Voyager with prior written notice, to the extent Neurocrine has advance knowledge, of any scheduled meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority in the Territory relating to any substantive matter with respect to any Collaboration Product in such Existing Program, within [...***...] after Neurocrine or its Affiliate first receives notice of the scheduling of such meeting, conference, or discussion (or within such shorter period as may be necessary in order to give Voyager a reasonable opportunity to attend such meeting, conference, or discussion). Voyager shall have the right to have one (1) or, to the extent reasonable, more of its employees or agents attend and participate in all such meetings, conferences, and discussions.

(d) For clarity, this Section 7.2.1 shall not in any way prohibit Neurocrine from complying with its reporting requirements pursuant to applicable Law, including with respect to adverse event reporting.

7.2.2 Ownership and Assignment of Regulatory Filings. All Regulatory Filings (including all Regulatory Approvals) and pricing and reimbursement approvals in the Territory with respect to the applicable Collaboration Products shall be owned by, and shall be the sole property and held in the name of, Neurocrine or its designated Affiliate, Sublicensee or designee.Voyager shall and hereby does assign to Neurocrine all of its right, title and interest in and to all Regulatory Filings (including INDs) relating to each Collaboration Product, and Voyager shall deliver such Regulatory Filings (and any documentation or correspondence, including conversation logs, relating to or supporting such Regulatory Filings) to Neurocrine within [...***...] after the Effective Date. No later than [...***...] after the Effective Date, Voyager shall submit to the FDA a letter transferring sponsorship of IND Nos. [...***...] to Neurocrine, and Neurocrine shall submit to the FDA a letter accepting transfer of sponsorship of IND Nos. [...***...] from Voyager. Each Party shall notify the other Party concurrently with its submission of its respective letter to the FDA, such notification to include a copy of such letter.

7.3 Sale of Priority Review Voucher. If the FDA grants to Neurocrine a priority review voucher in connection with the approval of the BLA for a Collaboration Product (a "PRV"), Neurocrine may (a) sell the PRV to a Third Party in an arm's-length transaction (a "PRV Sale"), (b) keep the PRV for its own use or use by any of its Affiliates for any product other than a Collaboration Product (a "Neurocrine PRV Use") or (c) use the PRV for a Collaboration Product (in which event (c) no payments will be due to Voyager under this Section 7.3). In the event of a PRV Sale: (1) if the PRV was for a Collaboration Product in an Existing Program and the Co-Co Option for such Existing Program was either previously exercised or had not expired or been waived by Voyager, Neurocrine shall pay Voyager an amount equal to the [...***...]; and (2) with respect to the PRV for any other Collaboration Product from an Existing Program or a Discovery Program, Neurocrine shall pay Voyager an amount equal to the [...***...]. In the Event of a Neurocrine PRV Use: (1) if the PRV was for a Collaboration Product in an Existing Program and the Co-Co-Option for such Existing Program was either previously exercised or had not expired or been waived by Voyager, Neurocrine shall pay Voyager an amount equal to [...***...]

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[...***...]; and (2) with respect to the PRV for any other Collaboration Product from an Existing Program or a Discovery Program, Neurocrine shall pay Voyager an amount equal to the [...***...]. All payments under this Section 7.3 shall be made within [...***...] after the closing of the PRV Sale or the effective date of Neurocrine PRV Use, as applicable.

7.4 Records and Audits. Each Party shall, and shall require its Affiliates and permitted subcontractors to, maintain materially complete, current and accurate hard and electronic (as applicable) copies of records of all work conducted pursuant to its Development, Manufacturing and Commercialization activities under this Agreement, and all results, data, developments and Know-How made in conducting such activities. Such records shall accurately reflect all such work done and results achieved in sufficient detail and in good scientific manner appropriate for applicable patent and regulatory purposes. Neurocrine shall have the right to receive and retain a copy of all such records of Voyager at reasonable times, upon reasonable prior written notice to Voyager, after the applicable Transition Date with regard to all such records relating to the Development or Manufacturing activities conducted by Voyager with respect to the applicable Collaboration Product(s). Neurocrine agrees that to the extent that an In-License Agreement applicable to a given Program requires records to be retained for a period longer than the period set forth in this Section 7.4, Neurocrine shall retain applicable records for such time period as required by the applicable In-License Agreement.

ARTICLE 8
INITIAL FEE; MILESTONES AND ROYALTIES; PAYMENTS

8.1 Initial Consideration.

8.1.1 Upfront Fee. In partial consideration for the rights granted to Neurocrine hereunder, Neurocrine shall pay Voyager a one-time, non-refundable, non-creditable upfront payment of One Hundred Fifteen Million Dollars ($115,000,000) **(**the "Initial Fee") within five (5) Business Days after the Effective Date. The Initial Fee shall be allocated as set forth on Schedule 8.1 (the "Allocation Schedule").

8.1.2 Equity Purchase. In partial consideration of the rights granted hereunder, Voyager shall issue and sell to Neurocrine, and Neurocrine shall purchase from Voyager, shares of Voyager common stock, par value $0.001 per share, pursuant to the terms of the stock purchase agreement attached as Exhibit A (the "Stock Purchase Agreement") and executed by the Parties concurrently with this Agreement.

8.2 Milestone Payments.

(a) Each event described in Sections 8.2.1, 8.2.2, 8.2.3 and 8.2.4 is referred to as a "Milestone Event." In partial consideration for the rights and licenses granted to Neurocrine hereunder, (i) within [...***...] after (A) in the case of Milestone Events (a), (b) and (c) (but only if [...***...]) under Section 8.2.2 and Milestone Event (a) under Section 8.2.3, Neurocrine's receipt of written

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notice from Voyager following Voyager's achievement of the applicable Milestone Event or the JSC's determination that such Milestone Event was achieved and (B) in all other cases under Sections 8.2.1, 8.2.2 and 8.2.3, the first achievement of a Milestone Event set forth below by or on behalf of Neurocrine, any of its Affiliates or any Sublicensee, and (ii) in the case of Section 8.2.4, within [...***...] after the end of the Calendar Quarter in which achievement of the applicable Commercial Milestone first occurs, Neurocrine shall make a one-time (except as provided below), non-refundable, non-creditable milestone payment to Voyager in the amount below corresponding to such Milestone Event (each, a "Milestone Payment").

(b) If Voyager does not timely exercise its Co-Co Option with respect to an Existing Program, then the tables in Section 8.2.1 (for Development Milestones), Section 8.2.2 (for Development Milestones), and Section 8.2.4 (for Commercial Milestones) shall apply in their entirety with respect to such Existing Program. If Voyager exercises its Co-Co Option with respect to an Existing Program, then Voyager shall be entitled to receive Milestone Payments only with respect to any Milestone Event that relates to the Territory outside the Co-Co Territory for so long as such Existing Program remains a Co-Co Program, as further provided below. If a Co-Co Agreement is terminated and the applicable Program is no longer a Co-Co Program, then the tables in Section 8.2.1 (for Development Milestones), Section 8.2.2 (for Development Milestones), and Section 8.2.4 (for Commercial Milestones) shall thereafter apply with respect to such Existing Program in the United States, but only with respect to Milestone Events achieved after termination of the Co-Co Program.

(c) Except as expressly set forth below, each Milestone Payment shall be deemed earned as of the achievement of the corresponding Milestone Event.

8.2.1 Development Milestone Payments for Collaboration Products under AADC Program.

	Milestone Event	**Milestone Payment ($)**
(a)	[...***...]	[...***...] ($[...***...])*
(b)	[...***...]	[...***...] ($[...***...])*
(c)	[...***...]	[...***...] ($[...***...])*
(d)	[...***...]	[...***...] ($[...***...])
(e)	[...***...]	[...***...] ($[...***...])

*subject to adjustment as set forth below

All Milestone Payments above may be paid only one (1) time. The Milestone Payment for Milestone Event (a), if achieved, will not be payable unless and until Voyager's Co-Co Option for the AADC Program expires unexercised or at such time as Voyager provides a signed written notice of its decision not to exercise such Co-Co Option. If the Development Milestone described

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in Section 8.2.1(a) is not achieved with respect to the [...***...], then the Milestone Payment associated with Section 8.2.1(a) shall become due and payable upon commencement of a [...***...]. In the event that Voyager exercises its Co-Co Option with respect to the AADC Program, the Milestone Payments for the Milestone Events described in Sections 8.2.1(a) through (c) will not be due. In the event that a Development Milestone described in either Sections 8.2.1(b) or (c) occurs as a result of the [...***...], the payment of the amount of the Milestone Payment with respect to Section 8.2.1(b) shall be increased to [...***...] Dollars ($[...***...]) and the payment of the amount of the Milestone Payment with respect to Section 8.2.1(c) shall be increased to [...***...] Dollars ($[...***...]).

8.2.2 Development Milestone Payments for Collaboration Products under FA Program.

	Milestone Event	**Milestone Payment ($)**
(a)	[...***...]	[...***...] ($[...***...])
(b)	[...***...]	[...***...] ($[...***...])
(c)	[...***...]	[...***...] ($[...***...])*
(d)	[...***...]	[...***...] ($[...***...])*
(e)	[...***...]	[...***...] ($[...***...])
(f)	[...***...]	[...***...] ($[...***...])
(g)	[...***...]	[...***...] ($[...***...])
(h)	[...***...]	[...***...] ($[...***...])

*subject to adjustment as set forth below

The Milestone Payment described in Section 8.2.2(a) may be paid for up to two (2) Development Candidates under the FA Program. All other Milestone Payments above may be paid only one (1) time for the FA Program. In the event the Development Milestone described in Section 8.2.2(f) occurs with respect to a Collaboration Product but the Milestone Event described in Section 8.2.2(e) has not occurred and the corresponding Milestone Payment has not been paid, then the Milestone Payment associated with the Milestone Event described in Section 8.2.2(e) shall be due and payable with the payment associated with the Development Milestone described in Section 8.2.2(f). In the event that Voyager exercises its Co-Co Option with respect to the FA Program, the Milestone Payments for the Milestone Events described in Sections 8.2.2(c) through (g) shall not be due. If Voyager does not timely exercise its Co-Co Option with respect to the FA

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Program and the Development Milestones described in Sections 8.2.2(c) and (d) occur as a result of the same study, the Milestone Payment associated with Section 8.2.2(c) shall not be payable upon achievement of the Milestone Event in Section 8.2.2(c) and instead will become due and payable (if applicable) upon occurrence of the Development Milestone described in Section 8.2.2(e), provided that if the Milestone Event described in Section 8.2.2(e) has not occurred when the Milestone Event described Section 8.2.2(f) occurs, then the Milestone Payment associated with Section 8.2.2(c) shall become due and payable upon occurrence of the Development Milestone described in Section 8.2.2(f). If the Development Milestone described in Section 8.2.2(d) has not occurred when the Milestone Event described in Section 8.2.2(e) occurs, then the Milestone Payment associated with Section 8.2.2(d) shall become due and payable upon occurrence of the Development Milestone described in Section 8.2.2(e). In the event the Development Milestone described in Section 8.2.2(g) occurs with respect to a Collaboration Product, all prior such Development Milestones that have not occurred shall be deemed to have occurred, and any Milestone Payment(s) associated with such prior Development Milestones that have not previously been paid shall be due and payable with the Milestone Payment associated with the Milestone Event described in Section 8.2.2(g). The Milestone Payment described in Section 8.2.2(h) shall only become payable if, as of the relevant time, the Territory has expanded to include countries outside the United States with respect to the FA Program in accordance with Section 5.4.

8.2.3 Development Milestone Payments for Collaboration Products under Discovery Programs.

	Milestone Event	**Milestone Payment ($)**
(a)	[...***...]	[...***...] ($[...***...])
(b)	[...***...]	[...***...] ($[...***...])
(c)	[...***...]	[...***...] ($[...***...])
(d)	[...***...]	[...***...] ($[...***...])
(e)	[...***...]	[...***...] ($[...***...])
(f)	[...***...]	[...***...] ($[...***...])
(g)	[...***...]	[...***...] ($[...***...])
(h)	[...***...]	[...***...] ($[...***...])
(i)	[...***...]	[...***...] ($[...***...])

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The Milestone Payment described in Section 8.2.3(a) may be paid for up to two (2) Development Candidates in each Discovery Program. All other Milestone Payments above may be paid only one (1) time per Discovery Program. In the event the Development Milestone described in Section 8.2.3(f) occurs with respect to a Collaboration Product but the Milestone Event described in Section 8.2.3(e) has not occurred and the corresponding Milestone Payment has not been paid, then the Milestone Payment associated with the Milestone Event described in Section 8.2.3(e) shall be due and payable with the payment associated with the Development Milestone described in Section 8.2.3(f). If the Development Milestones described in Sections 8.2.3(c) and (d) occur as a result of the same study, the Milestone Payment associated with Section 8.2.3(c) shall not be payable upon achievement of the Milestone Event in Section 8.2.3(c) and instead will become due and payable upon occurrence of the Development Milestone described in Section 8.2.3(e), provided that if the Milestone Event described in Section 8.2.3(e) has not occurred when the Milestone Event described in Section 8.2.3(f) occurs, then the Milestone Payment associated with Section 8.2.3(c) shall become due and payable upon occurrence of the Development Milestone described in Section 8.2.3(f). If the Development Milestone described in Section 8.2.3(d) has not occurred when the Milestone Event described in Section 8.2.3(e) occurs, then the Milestone Payment associated with Section 8.2.3(d) shall become due and payable upon occurrence of the Development Milestone described in Section 8.2.3(e). In the event the Development Milestone described in Section 8.2.3(g) occurs with respect to a Collaboration Product, all prior such Development Milestones that have not occurred shall be deemed to have occurred, and any Milestone Payment(s) associated with such prior Development Milestones that have not previously been paid shall be due and payable with the Milestone Payment associated with the Milestone Event described in Section 8.2.3(g).

8.2.4 Commercial Milestones for Collaboration Products.

	Milestone Event	**$ in Millions**
(a)	Aggregate Territory-wide (except as provided below) Net Sales of such Collaboration Product greater than or equal to $[...***...]	[...***...] ($[...***...])
(b)	Aggregate Territory-wide (except as provided below) Net Sales of such Collaboration Product greater than or equal to $[...***...]	[...***...] ($[...***...])
(c)	Aggregate Territory-wide (except as provided below) Net Sales of such Collaboration Product greater than or equal to $[...***...]	[...***...] ($[...***...])
(d)	Aggregate Territory-wide (except as provided below) Net Sales of such Collaboration Product greater than or equal to $[...***...]	[...***...] ($[...***...])
	Total per Collaboration Product	**Two Hundred and Seventy-Five Million ($275,000,000)**

The Milestone Payments above will be payable one time for each Collaboration Product to achieve the corresponding Milestone Event (subject to the aggregate cap below). With respect to Co-Co Products, Net Sales in the Co-Co Territory will not be included in aggregate Net Sales for purposes of determining whether the Commercial Milestones above have been achieved.

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The aggregate amount payable under this Section 8.2.4 will not exceed one billion one hundred million dollars ($1,100,000,000).

8.3 Royalties. Subject to the adjustments under Section 8.5, Neurocrine will make royalty payments, during the applicable Royalty Terms, as set forth in this Section 8.3.

8.3.1 Royalties on Collaboration Products under AADC Program.

(a) Annual Net Sales in the United States. In further consideration for the licenses and other rights granted to Neurocrine with respect to the AADC Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under the AADC Program that are not Co-Co Products.

	Annual Net Sales in the United States of the Collaboration Product	**Tiered Royalty Rate**
(a)	Annual Net Sales in the United States less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(b)	Annual Net Sales in the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(c)	Annual Net Sales in the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(d)	Annual Net Sales in the United States greater than or equal to [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)

(b) Annual Net Sales outside of the United States. In further consideration for the licenses and other rights granted to Neurocrine with respect to the AADC Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the Territory outside the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under the AADC Program.

	Annual Net Sales outside the United States of the Collaboration Product	**Tiered Royalty Rate**
(a)	Annual Net Sales outside the United States less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(b)	Annual Net Sales outside the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(c)	Annual Net Sales outside the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)

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	Annual Net Sales outside the United States of the Collaboration Product	Tiered Royalty Rate
(d)	Annual Net Sales outside the United States greater than or equal to [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)

8.3.2 Royalties on Collaboration Products under FA Program.

(a) Annual Net Sales in the United States. In further consideration of the licenses and other rights granted to Neurocrine with respect to the FA Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under the FA Program that are not Co-Co Products.

	Annual Net Sales in the United States of the Collaboration Product	Tiered Royalty Rate
(a)	Annual Net Sales in the United States less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(b)	Annual Net Sales in the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(c)	Annual Net Sales in the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(d)	Annual Net Sales in the United States greater than or equal to [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)

(b) Annual Net Sales outside of the United States. In further consideration of the licenses and other rights granted to Neurocrine with respect to the FA Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the Territory outside the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under the FA Program. Such royalty payments shall become payable only if the Territory expands to include countries outside the United States with respect to the FA Program.

	Annual Net Sales outside the United States of the Collaboration Product	Tiered Royalty Rate
(a)	Annual Net Sales outside the United States less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(b)	Annual Net Sales outside the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)

	Annual Net Sales outside the United States of the Collaboration Product	Tiered Royalty Rate
(c)	Annual Net Sales outside the United States greater than or equal to [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)

8.3.3 Royalties on Collaboration Products under Discovery Programs

(a) Annual Net Sales in the United States. In further consideration of the licenses and other rights granted to Neurocrine with respect to each Discovery Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under each Discovery Program.

	Annual Net Sales in the United States of the Collaboration Product	Tiered Royalty Rate
(a)	Annual Net Sales in the United States less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(b)	Annual Net Sales in the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(c)	Annual Net Sales in the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(d)	Annual Net Sales in the United States greater than or equal to [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)

(b) Annual Net Sales outside of the United States. In further consideration of the licenses and other rights granted to Neurocrine with respect to each Discovery Program, Neurocrine shall make tiered royalty payments to Voyager in respect of Annual Net Sales in the Territory outside the United States, on a Collaboration Product-by-Collaboration Product basis, of Collaboration Products under each Discovery Program.

	Annual Net Sales outside the United States of the Collaboration Product	Tiered Royalty Rate
(a)	Annual Net Sales outside the United States less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(b)	Annual Net Sales outside the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)
(c)	Annual Net Sales outside the United States greater than or equal to [...***...] Dollars ($[...***...]) but less than [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)

	Annual Net Sales outside the United States of the Collaboration Product	Tiered Royalty Rate
(d)	Annual Net Sales outside the United States greater than or equal to [...***...] Dollars ($[...***...])	[...***...] Percent ([...***...]%)

8.3.4 Calculation of Royalties. Royalties on aggregate Net Sales of Collaboration Products in a Calendar Year shall be paid at the rate applicable to the portion of Net Sales within each of the Annual Net Sales tiers during such Calendar Year. For example, if, during a Calendar Year, Annual Net Sales of Collaboration Products under the AADC Program in the United States are equal to $[...***...], then the royalties payable by Neurocrine would be calculated by adding [...***...], to equal total royalties of $[...***...].

8.4 Royalty Period. On a country-by-country and Collaboration Product-by-Collaboration Product basis, royalty payments in the Territory shall commence on the First Commercial Sale of such Collaboration Product in such country and terminate upon the latest of: (a) the expiration, invalidation or abandonment date of the last Valid Claim of the Voyager Licensed Patent Rights or Joint Patent Rights that claims the composition of matter or method of use (for an indication for which such Collaboration Product received Regulatory Approval in such country) of such Collaboration Product in such country; (b) ten (10) years from First Commercial Sale of such Collaboration Product in such country; and (c) expiration of Regulatory Exclusivity for such Collaboration Product in such country (the applicable "Royalty Term").

8.5 Royalty Adjustments.

8.5.1 Valid Claim Expiration. If, with respect to a Collaboration Product in any country in the Territory, at any time in the Royalty Term for such Collaboration Product and country there is no Valid Claim within the Voyager Licensed Patent Rights or the Joint Patent Rights that claims the composition of matter or method of use (for an indication for which such Collaboration Product received Regulatory Approval in such country) of such Collaboration Product in such country, then the royalties payable for such Collaboration Product in such country shall be reduced by fifty percent (50%) from the royalties otherwise due for such Collaboration Product in such country under Section 8.3. If such royalty reduction applies to any country other than the United States, it will be calculated by determining the portion of total Net Sales in the Territory outside the United States of the relevant Collaboration Product in a Calendar Quarter that is attributable to the country in which such reduction applies, and by determining the total royalties for the Territory outside the United States without reduction, and then reducing by fifty percent

(50%) the applicable portion (based on Net Sales) of the total royalties attributable to the country in which such reduction applies.

8.5.2 Biosimilar Reduction. If, in any country in the Territory during the Royalty Term in such country for a Collaboration Product, a Biosimilar Product with respect to such Collaboration Product is launched in such country, then, for any Calendar Quarter in which such Biosimilar Product(s) comprise greater than or equal to [...***...] percent ([...***...]%) of the total units of such Collaboration Product and Biosimilar Product(s) sold in such country (based on sales of units of such Collaboration Product and Biosimilar Product(s) as reported by IQVIA, or, if such data are not available, such other reliable data source as reasonably determined by Voyager and Neurocrine) the royalties payable for such Collaboration Product with respect to such country for such Calendar Quarter shall be reduced by fifty percent (50%) from the royalties otherwise due for such Collaboration Product in such country under Section 8.3. Such reduction shall be calculated as described in the last sentence of Section 8.5.1.

8.5.3 Stacking. If Neurocrine or any of its Affiliates determines in good faith that it is reasonably necessary to (a) obtain a license from a Third Party under one or more Valid Claims licensable by such Third Party Covering a Collaboration Product or under Know-How licensable by such Third Party in order for Neurocrine, its Affiliates and Sublicensees to Exploit such Collaboration Product in the Field in a country in the Territory and (b) make payments under such license, and Neurocrine or any of its Affiliates actually enters into any such license, then the amount of Neurocrine's royalty payments under Section 8.3 for such Collaboration Product in such country in a Calendar Quarter may be reduced by fifty percent (50%) of the royalties and other amounts actually paid by Neurocrine or any of its Affiliates to such Third Party to the extent applicable to such Collaboration Product in such country during such Calendar Quarter; provided, however, that neither Neurocrine nor any of its Affiliates shall be entitled to make reductions hereunder for any amounts payable by Neurocrine or any of its Affiliates relating to any Neurocrine IP existing as of the Effective Date.

8.5.4 Limits on Deductions. On a Collaboration Product-by-Collaboration Product basis, in no event shall the cumulative effect of the adjustments in Sections 8.5.1, 8.5.2 or 8.5.3 reduce the royalties payable to Voyager pursuant to Section 8.3 below fifty percent (50%) of the amounts that would otherwise have been payable with respect to the applicable Collaboration Product in the applicable country in the applicable Calendar Quarter, as determined pursuant to Section 8.3.4. Neurocrine may carry forward to subsequent Calendar Quarters any amounts it could not deduct as a result of the application of the preceding sentence.

8.6 Reports; Payment of Royalty.

8.6.1 Reports. During the Term, following the First Commercial Sale of any Collaboration Product in any country in the Territory (excluding the First Commercial Sale in the United States of a Co-Co Product for which reporting shall be addressed in the applicable Co-Co Agreement), Neurocrine shall furnish to Voyager a written report within [...***...] after the end of each Calendar Quarter showing, on a Collaboration Product-by-Collaboration Product and country-by-country basis, the Net Sales of each Collaboration Product in each country of the Territory and the royalties payable under this Agreement. Royalties with respect to Net Sales of Collaboration Products shall be due and payable on the date such royalty report is due.

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8.6.2 Compliance with In-License Agreements. Neurocrine and its Affiliates and Sublicensees shall provide any information reasonably requested by Voyager to enable Voyager to comply with any applicable reporting requirements under the In-License Agreements. Provided that Voyager timely notifies Neurocrine of such reporting requirement, Neurocrine shall ensure that all applicable and necessary information is received by Voyager from Neurocrine, whether generated by Neurocrine, any of its Affiliates or any Sublicensee, sufficiently in advance (no fewer than [...***...] in advance) of the date(s) on which such information is due to the relevant Inbound Licensor under an In-License Agreement to avoid a breach of such In-License Agreement. All payments owed by Voyager under the In-License Agreements, including license fees, royalties and milestones, shall be allocated between the Parties as set forth in Section 5.2.4 and such payment shall be remitted to the applicable Inbound Licensor by Voyager. Notwithstanding anything to the contrary in this Agreement, unless otherwise agreed by the applicable counterparty, the provisions regarding currency conversion, international payments and late payments, and other relevant definitions and provisions, of the relevant In-License Agreements shall apply to calculate the payments due under the relevant In-License Agreements (but not the payments due under this Agreement).

8.7 Accounting; Audit.

8.7.1 Each Party (the "Payor") agrees to keep, and to require its Affiliates and Sublicensees to keep, full, clear and accurate records for a minimum period of [...***...] after the relevant payment is owed pursuant to this Agreement, setting forth as applicable the sales and other disposition of Collaboration Products sold or otherwise disposed of, the Development and Commercialization activities with respect to Collaboration Products, and the Development Costs incurred therewith, in sufficient detail to enable royalties and compensation payable to, or the Development Costs payable by, the other Party (the "Payee") hereunder to be determined.

8.7.2 Neurocrine agrees, upon not less than [...***...] prior written notice, to permit, and to require its Affiliates to permit, such books and records relating to such Collaboration Products to be examined by an independent accounting firm selected by Voyager and reasonably acceptable to Neurocrine for the purpose of verifying reports provided (or required to be provided) by Neurocrine under this Article 8 or under the Co-Co Agreements. Voyager agrees, upon not less than [...***...] prior written notice, to permit, and to require its Affiliates to permit, such books and records relating to Development Costs and other costs under the Co-Co Agreements to be examined by an independent accounting firm selected by Voyager and reasonably acceptable to Neurocrine for the purpose of verifying reports provided (or required to be provided) by Voyager under Section 2.2.2 or under the Co-Co Agreements. Any such audit shall not be performed more frequently than [...***...] period, shall not audit any previously audited records, and shall be conducted under appropriate confidentiality provisions, for the sole purpose of verifying the accuracy and completeness of all financial, accounting and numerical information and calculations provided under this Agreement or under the Co-Co Agreements. The independent accounting firm shall only share the results of the audit, not the underlying records, with the auditing party.

8.7.3 Any audit conducted by Voyager is to be made at the expense of Voyager, except if the results of the audit reveal an underpayment of royalties, milestones or other payments to Voyager under this Agreement or under the Co-Co Agreements of [...***...] percent ([...***...]%) or more in

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the audited period, in which case (a) Neurocrine shall promptly remit to Voyager the amount of such underpayment and (b) the reasonable fees and expenses for such audit shall be paid by Neurocrine. Any audit conducted by Neurocrine is to be made at the expense of Neurocrine, except if the results of the audit reveal an overpayment of Development Costs or other payments to Voyager under this Agreement or under the Co-Co Agreements of [...***...] percent ([...***...]%) or more in the audited period, in which case (x) Voyager shall promptly remit to Neurocrine the amount of such overpayment and (y) the reasonable fees and expenses for such audit shall be paid by Voyager. For clarity, any audit that reveals an underpayment or overpayment, as the case may be, of less than [...***...] percent ([...***...]%) in the audited period, shall be made at the expense of the Party conducting the audit.

8.8 Currency Conversion. When calculating Net Sales, the amount of such sales or costs in foreign currencies shall be converted into Dollars using the standard methodologies employed by Neurocrine generally for consolidation purposes. Neurocrine shall provide reasonable documentation of the calculation and reconciliation of the conversion figures on a Collaboration Product-by-Collaboration Product and country-by-country basis as part of its report of Net Sales for the period covered under the report.

8.9 Books and Records. Any books and records to be maintained under this Agreement by a Party or its Affiliates or Sublicensees shall be maintained in accordance with Accounting Standards.

8.10 Methods of Payments. All payments due from one Party to the other Party under this Agreement shall be paid in Dollars by wire transfer to a bank in the United States designated in writing by the Payee.

8.11 Taxes.

8.11.1 Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement.

8.11.2 In the event that Neurocrine is required to withhold any tax to be paid to, or held for the benefit of, the tax or revenue authorities in any country in the Territory regarding any payment to Voyager, such amount shall be deducted from the payment to be made by Neurocrine; provided that Neurocrine shall take reasonable and lawful actions to avoid and minimize such withholding and promptly notify Voyager so that Voyager may take lawful actions to avoid and minimize such withholding. Neurocrine shall promptly furnish Voyager with copies of any tax certificate or other documentation evidencing such withholding, as necessary, to enable Voyager to support a claim, if permissible, for income tax credit in respect of any amount so withheld. Each Party shall cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty in effect from time to time. The Parties shall use commercially reasonable efforts to reduce or eliminate such withholding, including providing any reasonable documentation to reduce or eliminate such withholding.

8.11.3 If a withholding or deduction obligation arises as a result of any action by Neurocrine (including any assignment, sublicense, change of place of incorporation, or failure to

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comply with applicable Laws or filing or record retention requirements) (a "Withholding Tax Action"), then the sum payable by Neurocrine (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Voyager receives a sum equal to the sum which it would have received had no such Withholding Tax Action occurred.

8.12 Late Payments. Any undisputed amount owed by Neurocrine to Voyager under this Agreement that is not paid on or before the date such payment is due shall bear simple interest at a rate per annum equal to the lesser of (a) the greater of (i) the prime or equivalent rate per annum quoted by *The Wall Street Journal* on the first Business Day after such payment is due, plus [...***...], or (ii) [...***...] percent ([...***...]%) per month, or (b) the highest rate permitted by applicable Law, calculated on the number of days such payments are paid after such payments are due.

ARTICLE 9
EXCLUSIVITY

9.1 Exclusivity.

9.1.1 Voyager.

(a) During the Term of this Agreement, neither Voyager nor any of its Affiliates shall, except as otherwise permitted in this Article 9, either alone or with or for any Third Party, Develop, Manufacture or Commercialize any Competitive Product or grant any Affiliate or Third Party a license or sublicense to enable any Third Party to do so.

(b) Notwithstanding the foregoing, (i) Voyager shall have no restriction under this Section 9.1.1 with respect to the Development, Manufacture or Commercialization of Gene Therapy Products directed to any Target that was the subject of a Terminated Program and is not the subject of any other Program, provided, however, that, Voyager may not utilize any Neurocrine IP or Confidential Information of Neurocrine in such Development, Manufacture or Commercialization, and (ii) nothing in this Section 9.1.1 shall preclude Voyager from complying with its obligations to grant rights to Genzyme under and in accordance with the Genzyme Agreement (as such agreement exists as of the Effective Date) if Genzyme exercises the option granted to it thereunder.

9.1.2 Neurocrine.

(a) During the Term of this Agreement, neither Neurocrine nor any of its Affiliates shall, except as otherwise permitted in this Article 9, either alone or with or for any Third Party, Develop, Manufacture or Commercialize any Competitive Product or grant any Affiliate or Third Party a license or sublicense to do so.

(b) Notwithstanding the foregoing, Neurocrine shall have no restriction under this Section 9.1.2 with respect to the Development, Manufacture or Commercialization of Gene Therapy Products directed to any Target that was the subject of a Terminated Program and is not the subject of any other Program; provided, however, that Neurocrine may not utilize any

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Voyager IP or Confidential Information of Voyager in such Development, Manufacture or Commercialization.

9.2 Exception for Basic Research. Notwithstanding Section 9.1, Neurocrine and Voyager shall be free during the Term, either alone or with or for an Affiliate or a Third Party, to conduct basic scientific, non-clinical and pre-clinical Development with respect to the biological mechanism of action, pharmacology, structure-activity relationship (SAR) or the like for any Gene Therapy Product; provided, however, that neither Party shall conduct any basic scientific, non-clinical and pre-clinical Development with respect to a Collaboration Product, other than under a Development Plan, Neurocrine Plan or Co-Co Agreement, without the prior written approval of the Joint R&D Working Group, and the conduct of such non-clinical and pre-clinical Development shall be subject to the supervision and oversight of the Joint R&D Working Group.

9.3 Acquisitions.

9.3.1 If, during the term of the exclusivity covenant in Section 9.1, a Party or any of its Affiliates (such Party, the "Acquisition Party") acquires or is acquired by a Third Party (an "Acquired Affiliate") (whether such acquisition occurs by way of a purchase of assets, merger, consolidation, change of control or otherwise) that is, at the time of such acquisition, engaging in any activities that would violate Section 9.1.1 or 9.1.2, as applicable, if conducted by such Acquisition Party (such activities, an "Acquired Competing Program" and any product Developed, Commercialized or otherwise Exploited thereunder, an "Acquired Competing Product"), then the Acquisition Party or its Acquired Affiliate shall, no later than [...***...] following the date of consummation of the relevant acquisition, notify the other Party in writing that the Acquisition Party or such Acquired Affiliate shall:

(a) divest, whether by license or otherwise, its interest in the Acquired Competing Program to a Third Party, to the extent necessary to be in compliance with Section 9.1, with no rights in such Acquired Competing Program retained by the Acquisition Party or any of its Affiliates; or

(b) terminate Research, Development, Manufacture and Commercialization under the Acquired Competing Program, to the extent necessary to be in compliance with Section 9.1.

9.3.2 If the Acquisition Party or its Acquired Affiliate notifies the other Party in writing that it intends to divest such Acquired Competing Program or terminate Development, Manufacture and Commercialization under the Acquired Competing Program as provided in Section 9.3.1(a) or 9.3.1(b), then the Acquisition Party or Acquired Affiliate, as applicable, shall effect the consummation of such divestiture within [...***...] or effect such termination within [...***...] after the consummation of the relevant acquisition, subject to compliance with applicable Law, and shall confirm to the other Party in writing when such divestiture or termination has been completed. The Acquisition Party shall keep the other Party reasonably informed of its and its Affiliates' efforts and progress in effecting such divestiture or termination until it is completed. Until such divestiture or termination occurs, the Acquisition Party shall keep its and its Affiliates' activities with respect to such Acquired Competing Program separate from their activities under this Agreement or any Co-Co Agreement.

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9.3.3 Subject to the Acquisition Party's compliance with this Section 9.3, the activities of such Acquisition Party or its Acquired Affiliate with respect to any Competing Acquirer Program shall not be a breach of this Agreement.

ARTICLE 10
INTELLECTUAL PROPERTY RIGHTS

10.1 Ownership of Inventions; Disclosure.

10.1.1 Ownership. Subject to Section 10.1.2, (a) title to all Inventions made solely by employees or agents of Voyager in the course of activities conducted pursuant to this Agreement shall be owned by Voyager; (b) title to all Inventions made solely by employees or agents of Neurocrine in the course of activities conducted pursuant to this Agreement shall be owned by Neurocrine; and (c) title to all Inventions made jointly by employees or agents of Neurocrine and employees or agents of Voyager in the course of activities conducted pursuant to this Agreement (each, a "Joint Invention") shall be owned jointly by Neurocrine and Voyager. For purposes of determining ownership hereunder, inventorship of Inventions made pursuant to this Agreement shall be determined in accordance with the patent laws of the United States. Except as expressly provided in this Agreement, each Party may (subject to the licenses and exclusivity provisions of this Agreement) practice the Joint IP, but neither Party may grant licenses or otherwise encumber its ownership interest in any Joint IP without the prior written consent of the other Party.

10.1.2 Exceptions. Notwithstanding Section 10.1.1 and anything to the contrary set forth in this Agreement, Voyager shall exclusively own all Vectorization IP made in the course of the Collaboration, regardless of which Party or its employees or agents conceived or reduced to practice such Invention or whether such Invention was jointly developed by the Parties. Neurocrine, on behalf of itself and its Affiliates, hereby assigns, and to the extent such present assignment is not possible, agrees to assign, to Voyager all of Neurocrine's right, title and interest in and to such Vectorization IP, and all intellectual property rights therein, and, thereafter, such Vectorization IP and any intellectual property rights therein shall not be considered Neurocrine IP or Joint IP, but shall be considered Voyager IP, to the extent applicable.

10.1.3 Disclosure of Inventions.

(a) During the Term, the Parties shall promptly disclose to each other any Inventions relating to any Collaboration Candidate, Development Candidate or Collaboration Product.

(b) During the Term, Neurocrine shall promptly disclose to Voyager any Vectorization Know-How made solely by Neurocrine or jointly by the Parties.

10.1.4 Background IP. Each Party shall retain ownership of intellectual property rights, including Patent Rights and Know-How, existing as of the Effective Date, and nothing in this Agreement shall assign any ownership to the other Party with respect to such intellectual property rights.

10.2 Patent Prosecution and Maintenance.

10.2.1 Voyager Licensed Platform Patent Rights.

(a) Subject to the terms of any applicable In-License Agreement and Co-Co Agreement:

(i) Subject to the remainder of this Section 10.2.1(a), Voyager shall have the sole right, at its sole cost and cost and expense, for Prosecuting and Maintaining the Vectorization Patent Rights and for conducting and defending any Defense Proceeding relating thereto.

(ii) Subject to Section 10.2.2, Voyager shall have the first right, at its sole cost and expense, for Prosecuting and Maintaining the Voyager Licensed Platform Patent Rights and for conducting and defending any opposition, reexamination request, nullity action, interference, or other post-grant proceeding involving an attack upon the validity, title or enforceability thereof relating thereto, and for initiating any interference, including in each case any appeals therefrom (each, a "Defense Proceeding") (except that in connection with any actions subject to Section 10.3, the Party with responsibility for such action pursuant to Section 10.3 shall have responsibility for any related Defense Proceedings). Upon request by Neurocrine, the Parties shall coordinate and use reasonable efforts, in connection with Voyager's Prosecution and Maintenance of the Voyager Licensed Platform Patent Rights, to enable Neurocrine to file patent applications, including divisionals, continuations or other patent applications for Voyager Target-Specific Patent Rights.

(iii) Voyager shall keep Neurocrine fully informed with respect to (A) the issuance of a Voyager Licensed Platform Patent Right being Prosecuted and Maintained by Voyager pursuant to this Section 10.2.1(a), and (B) the abandonment of any Voyager Licensed Platform Patent Right.

(iv) Without limiting the foregoing, Voyager shall (A) provide Neurocrine with copies of the text of the applications for any Voyager Licensed Platform Patent Right as soon as practicable but at least [...***...] before filing, except for urgent filings, in which case Voyager shall provide copies as soon as practicable before, simultaneously with or immediately after filing; (B) provide Neurocrine with a copy of each submission made to and material or substantive document received from a patent authority, court or other tribunal regarding any Voyager Licensed Platform Patent Right reasonably promptly after making such filing or receiving such document, including a copy of each application as filed together with notice of its filing date and application number; (C) keep Neurocrine advised of the status of all substantive communications, actual and prospective filings or submissions regarding any Voyager Licensed Platform Patent Right, and give Neurocrine copies of any such communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (D) consider in good faith and reasonably incorporate Neurocrine's comments on such communications, filings and submissions for any Voyager Licensed Platform Patent Right (including particular countries in which Neurocrine desires Voyager to file a particular Voyager Licensed Platform Patent Right, provided, however, that Neurocrine shall reimburse Voyager for all expenses incurred in Prosecuting and Maintaining Patent Rights in countries requested by Neurocrine in which a

company similarly situated to Voyager may not file patent applications in accordance with commercially reasonable business practices), unless incorporating such comments would reasonably be expected to have a material adverse effect on the scope of any Voyager Licensed Platform Patent Right that covers products being developed or commercialized by Voyager that are not Collaboration Products. Neurocrine's rights pursuant to this Section 10.2.1(a)(iv) shall terminate with respect to Voyager Licensed Platform Patent Rights that are relevant to one Program only at such time as such Program is terminated pursuant to the terms of this Agreement.

(b) Voyager shall notify Neurocrine as to any decision to abandon, to cease Prosecution and Maintenance of, or not to continue to pay the expenses of Prosecution and Maintenance of, any Voyager Licensed Platform Patent Right in any country in which it was filed. Voyager will provide such notices at least [...***...] prior to any filing or payment due date, or any other due date that requires action, in connection with such Voyager Licensed Platform Patent Right. Thereafter, Neurocrine may, upon written notice to Voyager, in Voyager's name and at Neurocrine's sole cost and expense, control the Prosecution and Maintenance of such Voyager Licensed Platform Patent Right, and Neurocrine shall keep Voyager informed of the status of such Voyager Licensed Platform Patent Right in accordance with Sections 10.2.1(a)(iii) and (iv), *mutatis mutandis*.

10.2.2 Voyager Target-Specific Patent Rights.

(a) Subject to the terms of any applicable In-License Agreement and Co-Co Agreement:

(i) Neurocrine shall have the first right, at its sole cost and expense, for Prosecuting and Maintaining the Voyager Target-Specific Patent Rights and for conducting any Defense Proceeding relating thereto (except that in connection with any counterclaims brought in actions subject to Section 10.3, the Party with responsibility for such action pursuant to Section 10.3 shall have responsibility for such Defense Proceedings); provided, however, that with regard to patent applications within Voyager Target-Specific Patent Rights that were filed prior to the Effective Date and patent applications claiming priority thereto, Voyager shall continue to Prosecute and Maintain, at Neurocrine's expense, such patent applications until [...***...], or earlier as the Parties agree in writing; and provided further that the provisions of Section 10.2.1(a)(iv) shall apply to Voyager's Prosecution and Maintenance of such patent applications within the Voyager Target-Specific Rights.

(ii) Neurocrine shall keep Voyager fully informed with respect to (A) the issuance of a Voyager Target-Specific Patent Right being Prosecuted and Maintained by Neurocrine pursuant to this Section 10.2.2(a), and (B) the abandonment of any Voyager Target-Specific Patent Right Prosecuted and Maintained by Neurocrine pursuant to this Section 10.2.2(a); provided, however, that if Voyager continues to Prosecute and Maintain Voyager Target-Specific Patent Rights pursuant to Section 10.2.2(a)(i), Voyager shall not be permitted to abandon such Patent Rights without Neurocrine's written consent.

(iii) Without limiting the foregoing, Neurocrine shall (A) provide Voyager with copies of the text of the applications for any Voyager Target-Specific Patent Right it Prosecutes or Maintains as soon as practicable but at least [...***...] before filing, except

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for urgent filings, in which case Neurocrine shall provide copies as soon as practicable before, simultaneously with or immediately after filing; (B) provide Voyager with a copy of each submission made to and material or substantive document received from a patent authority, court or other tribunal regarding any Voyager Target-Specific Patent Right reasonably promptly after making such filing or receiving such document, including a copy of each application as filed together with notice of its filing date and application number; (C) keep Voyager advised of the status of all substantive communications, actual and prospective filings or submissions regarding any Voyager Target-Specific Patent Right, and give Voyager copies of any such communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (D) consider in good faith Voyager's comments on such communications, filings and submissions for any such Voyager Target-Specific Patent Right and shall reasonably incorporate such comments unless their incorporation would reasonably be expected to have a material adverse effect on the scope of any Voyager Target-Specific Patent Right.

(b) Neurocrine shall notify Voyager as to any decision to abandon, to cease Prosecution and Maintenance of, or not to continue to pay the expenses of Prosecution and Maintenance of, any Voyager Target-Specific Patent Right in any country in which it was filed. Neurocrine will provide such notices at least [...***...] prior to any filing or payment due date, or any other due date that requires action, in connection with such Voyager Target-Specific Patent Right. Thereafter, Voyager may, upon written notice to Neurocrine, in Voyager's name and at Voyager's sole cost and expense, control the Prosecution and Maintenance of such Voyager Target-Specific Patent Right, and Neurocrine will have the rights thereto as set forth in Sections 10.2.1(a)(i) and (ii) with respect to such Voyager Target-Specific Patent Right.

10.2.3 Neurocrine Patent Rights. Neurocrine shall be responsible, at its sole cost and expense, and shall have the exclusive right, but not the obligation, for Prosecuting and Maintaining the Neurocrine Patent Rights and for conducting Defense Proceedings relating thereto.

10.2.4 Joint Patent Rights.

(a) Subject to the terms of any applicable Co-Co Agreement:

(i) Subject to Section 10.2.4(b), Neurocrine shall have the first right, at its sole cost and expense, for Prosecuting and Maintaining in both Parties' names the Joint Patent Rights specifically excluding any Vectorization Patent Rights Covering Vectorization Know-How that was jointly developed by the Parties and assigned to Voyager pursuant to Section 10.1.2). Voyager shall execute any powers of attorney necessary for Neurocrine's counsel to conduct such activities.

(ii) Neurocrine shall keep Voyager fully informed with respect to (A) the issuance of any Joint Patent Right being Prosecuted and Maintained by Neurocrine pursuant to this Section 10.2.4(a), and (B) the abandonment of any Joint Patent Right being Prosecuted and Maintained by Neurocrine pursuant to this Section 10.2.4(a).

(iii) Without limiting the foregoing, Neurocrine shall (A) provide Voyager with copies of the text of the applications for any such Joint Patent Right as soon as

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practicable but at least [...***...] before filing, except for urgent filings, in which case Neurocrine shall provide copies as soon as practicable before, simultaneously with or immediately after filing; (B) provide Voyager with a copy of each submission made to and material or substantive document received from a patent authority, court or other tribunal regarding any such Joint Patent Right reasonably promptly after making such filing or receiving such material document, including a copy of each application as filed together with notice of its filing date and application number; (C) keep Voyager advised of the status of all substantive communications, actual and prospective filings or submissions regarding any such Joint Patent Right, and shall give Voyager copies of any such communications, filings and submissions proposed to be sent to any patent authority or judicial body; and (D) consider in good faith Voyager's comments on such communications, filings and submissions for any such Joint Patent Right.

(b) Neurocrine shall notify Voyager as to any decision to abandon, to cease Prosecution and Maintenance of, or not to continue to pay the expenses of Prosecution and Maintenance of, any such Joint Patent Right in any country in which it was filed. Neurocrine shall provide such notices at least [...***...] prior to any filing or payment due date, or any other due date that requires action, in connection with such Joint Patent Right. Thereafter, Voyager may, upon written notice to Neurocrine, in both Parties' names and at Voyager's sole cost and expense, control the Prosecution and Maintenance of such Joint Patent Right, and Voyager shall keep Neurocrine reasonably informed of the status of such Joint Patent Right in accordance with Sections 10.2.4(a)(ii) and (iii), *mutatis mutandis*.

10.2.5 The Parties shall undertake reasonable efforts and cooperate to ensure to the fullest extent practicable and not prejudicial that Joint Patent Rights are Prosecuted and Maintained in a manner that separates the claims pertaining to one Program and the Collaboration Products arising therefrom, on the one hand, from other Programs and the Collaboration Products arising therefrom, on the other hand, into distinct patent applications and ultimately separate issued patents.

10.2.6 Cooperation. Each Party shall reasonably cooperate with and assist the other Party in connection with the activities of such Party under Section 10.2 upon the reasonable request of the other Party, including by making scientists and scientific records reasonably available and the execution of all such documents and instruments and the performance of such acts as may be reasonably necessary in order to permit the other Party to continue any Prosecution or Maintenance of the applicable Patent Rights.

10.2.7 Patent Term Extension. Notwithstanding anything to the contrary in Section 10.2.1, 10.2.2 or 10.2.4, the JSC shall discuss all decisions regarding patent term extensions in the Territory, including in the United States with respect to extensions pursuant to 35 U.S.C. § 156 *et. seq.* and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for Voyager Licensed Patent Rights and the Joint Patent Rights, in each case including whether or not to so apply and which Party shall so apply; provided that Neurocrine shall have the right to make all decisions with respect to any such extension of a Voyager Patent Right or Joint Patent Right Covering any Collaboration Product; provided that Neurocrine shall not have the right to extent any Voyager Licensed Platform Patent Right that Voyager intends to extend with respect to a different product for which there is no other Patent

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Right reasonably available to extend. Each Party shall provide prompt and reasonable assistance, as requested by the other Party, including by taking such action as is required under any applicable Law to obtain such extension or supplementary protection certificate.

10.3 Enforcement and Defense. Subject to the terms of any applicable In-License Agreement and any applicable Co-Co Agreement:

10.3.1 Notice. Each Party shall promptly notify the other of any knowledge it acquires of any (a) actual or potential infringement by a Third Party of any Voyager Patent Right, Neurocrine Patent Right or Joint Patent Right that is or would be competitive with a Collaboration Product or (b) submission to a Party or a Regulatory Authority of an application for a product (including an application under Section 351(k) of the PHSA) that references a Product ("Competitive Infringement").

10.3.2 Actions.

(a) If any Neurocrine Patent Right is infringed by a Third Party in any country in the Territory, then Neurocrine shall have the sole right, but not the obligation, to institute and control any action or proceeding with respect to such infringement of such Patent Right, by counsel of its own choice.

(b) If any Vectorization Patent Right that is not a Voyager Patent Right is infringed by a Third Party in any country in the Territory, then Voyager shall have the sole right, but not the obligation, to institute and control any action or proceeding with respect to such infringement of such Patent Right, by counsel of its own choice. If, in any such proceeding brought by Voyager, Neurocrine is required to join for standing purposes or in order for Voyager to commence or continue such proceeding, then Neurocrine shall join such proceeding, at Voyager's expense, and shall be represented in such proceeding by counsel of Voyager's choice at Voyager's expense, unless Neurocrine elects to be represented by counsel of its own chose at Neurocrine's expense.

(c) Voyager shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to Competitive Infringement of any Voyager Licensed Platform Patent Right, by counsel of its own choice, provided that Voyager shall not unreasonably refuse to accept input from Neurocrine with respect to such proceeding. If in any such proceeding brought by Voyager, Neurocrine is required to join for standing purposes or in order for Voyager to commence or continue any such proceeding, then Neurocrine shall join such proceeding, at Voyager's expense, and shall be represented in such proceeding by counsel of Neurocrine's choice at Neurocrine's expense. If Voyager does not bring an infringement action pursuant to this Section 10.3.2(c) within [...***...] after receipt of notice of the existence of an infringement (or in cases where there is a relevant statutory period during which an infringement action must be commenced or in which any material rights may be lost that would expire prior to the expiration of such [...***...] period and of which Neurocrine has notified Voyager promptly after it becomes aware, [...***...] prior to the expiration of such relevant statutory period), Voyager and Neurocrine shall meet and discuss Voyager's reasons for not initiating a lawsuit or otherwise making or prosecuting a claim. If following such discussions Neurocrine desires to initiate a lawsuit or otherwise make or prosecute a claim with

respect to the Competitive Infringement and so notifies Voyager in writing, then upon receiving Voyager's prior written consent, which consent shall not be unreasonably withheld, Neurocrine may institute, prosecute, and control such action; provided that, if, under the terms of an applicable In-License Agreement, Voyager has an applicable enforcement right that it cannot delegate to Neurocrine then, at Neurocrine's request and expense, Voyager shall exercise such rights in such infringement action as directed by Neurocrine. If in any such proceeding Voyager is required to join for standing purposes or in order for Neurocrine (or an Inbound Licensor) to commence or continue any such proceeding, then Voyager shall join such proceeding, at Neurocrine's expense, and shall be represented in such proceeding by counsel of Voyager's choice at Voyager's expense.

(d) Neurocrine shall have the primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to Competitive Infringement of any Voyager Target-Specific Patent Right or Joint Patent Right, by counsel of its own choice, provided that Neurocrine shall not unreasonably refuse to accept input from Voyager with respect to such proceeding. If in any such proceeding brought by Neurocrine, Voyager is required to join for standing purposes or in order for Neurocrine to commence or continue any such proceeding, then Voyager shall join such proceeding, at Neurocrine's expense, and shall be represented in such proceeding by counsel of Voyager's choice at Voyager's expense. The exercise by Neurocrine of the right to bring an infringement action shall be subject to and consistent with the terms of all applicable In-License Agreements; provided that, if, under the terms of an applicable In-License Agreement, Voyager has an applicable enforcement right that it cannot delegate to Neurocrine then, at Neurocrine's request and expense, Voyager shall exercise such rights in such infringement action as directed by Neurocrine. If Neurocrine does not bring an infringement action pursuant to this Section 10.3.2(d) within [...***...] after receipt of notice of the existence of an infringement (or in cases where there is a relevant statutory period during which an infringement action must be commenced or in which any material rights may be lost that would expire prior to the expiration of such [...***...] period and of which Voyager has notified Neurocrine promptly after it becomes aware, [...***...] prior to the expiration of such relevant statutory period), Voyager and Neurocrine shall meet and discuss Neurocrine's reasons for not initiating a lawsuit or otherwise making or prosecuting a claim. If following such discussions Voyager desires to initiate a lawsuit or otherwise make or prosecute a claim with respect to the Competitive Infringement and so notifies Neurocrine in writing, then upon receiving Neurocrine's prior written consent, which consent shall not be unreasonably withheld, Voyager may institute, prosecute, and control such action. If in any such proceeding Neurocrine is required to join for standing purposes or in order for Voyager (or an Inbound Licensor) to commence or continue any such proceeding, then Neurocrine shall join such proceeding, at Voyager's expense, and shall be represented in such proceeding by counsel of Neurocrine's choice at Neurocrine's expense. The Party initiating the suit shall have the sole and exclusive right to elect counsel for any suit initiated by it pursuant to Section 10.3.2(a), (c) or (d); provided that, with respect to a Voyager Target-Specific Patent Right or Joint Patent Right, such counsel is reasonably acceptable to the other Party.

(e) Each Party agrees to cooperate fully in any action under this Section 10.3.2 that is controlled by the other Party, including executing legal papers and cooperating in the prosecution as may be reasonably requested by the controlling Party, all at the controlling Party's expense.

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(f) Unless otherwise agreed by the Parties in writing, and subject to the terms of the Co-Co Agreements, the amount of any recovery from a proceeding brought under this Section 10.3.2 shall first be applied to the Out-of-Pocket Cost of such action incurred by the Party prosecuting the applicable action, and any remaining recovery amount shall be applied to the Out-of-Pocket Cost of such action incurred by the other Party (if any), and then, of the remaining amount, (i) any recovery for a proceeding brought by Neurocrine with respect to a Voyager Target-Specific Patent Right, Voyager Licensed Platform Patent Right or Joint Patent Right or a proceeding brought by Voyager with respect to a Voyager Licensed Platform Patent Right shall be retained by Neurocrine, but shall be deemed Net Sales of the applicable Collaboration Product in the applicable country and subject to royalty payments under Section 8.3 or, with respect to Co-Co Products, shared between the Parties at the Co-Co Rate, (ii) any recovery for a proceeding brought by Voyager with respect to a Voyager Target-Specific Patent Right shall be allocated [...***...] percent ([...***...]%) to Voyager and [...***...] percent ([...***...]%) to Neurocrine and (iii) any recovery for a proceeding brought with respect to a Neurocrine Patent Right shall be retained by Neurocrine. If, in connection with a proceeding brought under this Section 10.3.2 with respect to a Voyager Target-Specific Patent Right, an Inbound Licensor is entitled to a portion of any recovery that is greater than the portion of the recovery payable, after costs, to Voyager, the Parties will meet and agree in good faith on an alternative sharing of such recovery to that set forth in the immediately preceding sentence that takes into account the amounts payable to the applicable Inbound Licensor and results in an equitable allocation of the remaining amounts to Neurocrine and Voyager after payment of such amounts to the applicable Inbound Licensor.

10.3.3 Defense. With respect to any defense or declaratory judgment actions relating to, or other attack upon, validity or enforceability of a Voyager Patent Right, Neurocrine Patent Right or Joint Patent Right that is not a Defense Proceeding, the Party with responsibility for the Prosecution and Maintenance of such Patent Right shall have the first right, but not the obligation, to assume the defense thereof at its sole cost and expense, except that if such action is in connection with a Competitive Infringement, Section 10.3.2 will apply to such action (as if it were enforcement against a Competitive Infringement).

10.4 Infringement Claimed by Third Parties.

10.4.1 If a Third Party commences, or threatens to commence, any proceeding against a Party alleging infringement of such Third Party's intellectual property by the Exploitation by a Party, its Affiliates, subcontractors or Sublicensees of any Collaboration Candidate or any Collaboration Product, the Party against whom such proceeding is threatened or commenced shall give prompt notice to the other Party.

10.4.2 Unless the Party against whom such proceeding is filed seeks indemnification for a claim covered pursuant to Article 13, such Party shall, as between the Parties, have the sole right to control the defense and settlement of any such proceeding under Section 10.4.1 at its own cost.

10.5 Marking. Neurocrine and its Affiliates and Sublicensees shall mark each Collaboration Product in such a manner to conform with the patent laws and practice of any country in which such Collaboration Product is Manufactured or sold or to which such

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Collaboration Product is shipped to ensure maximum enforceability of Patent Rights in such country.

10.6 Trademarks. Except for Collaboration Products arising from the AADC Program if Voyager exercises its Co-Co Option for such Program, Neurocrine shall have the right to brand Collaboration Products in the Territory using Neurocrine-related trademarks and any other trademarks and trade names it determines appropriate, which may vary by country or within a country ("Neurocrine Product Marks"). Neurocrine shall own all rights in the Neurocrine Product Marks and, as between the Parties, shall have the sole right to register, maintain, enforce and defend the Neurocrine Product Marks, at its sole expense, provided that Neurocrine will provide Voyager appropriate licenses to the Neurocrine Product Marks under any applicable Co-Co Agreement to undertake activities assigned to Voyager thereunder so requiring such licenses. If Voyager exercises its Co-Co Option for the AADC Program, branding of Co-Co Products arising from the AADC Program shall be governed by the applicable provisions of the applicable Co-Co Agreement and subject to final review and approval of the JSC.

ARTICLE 11
CONFIDENTIALITY

11.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement, or as otherwise agreed in writing, the Parties agree that the receiving Party (the "Receiving Party") (a) shall keep confidential and shall not publish or otherwise disclose and (b) shall not use for any purpose other than as provided for in this Agreement (which purpose includes exercising its rights and performing its obligations under this Agreement), in each case (a) and (b) any Know-How or other confidential and proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) that is disclosed to it by the other Party (the "Disclosing Party"), including trade secrets, Know-How, inventions or discoveries, proprietary information, formulae, processes, techniques and information relating to the Disclosing Party's past, present or future marketing, financial, or Exploitation activities of any product or potential product or useful technology of the Disclosing Party or the pricing thereof (collectively, "Confidential Information" of the Disclosing Party), except that "Confidential Information" shall exclude information to the extent that it can be established by the Receiving Party that such information:

11.1.1 was in the lawful knowledge and possession of the Receiving Party prior to the time it was first disclosed to the Receiving Party by the Disclosing Party, or was otherwise developed independently by the Receiving Party without reference to any of the Disclosing Party's Confidential Information, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party;

11.1.2 was generally available to the public or otherwise part of the public domain at the time of its first disclosure to the Receiving Party by the Disclosing Party;

11.1.3 became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party by the Disclosing Party and other than through any act or omission of the Receiving Party in breach of this Agreement or the Existing Confidentiality Agreement; or

11.1.4 was lawfully disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others.

For the avoidance of doubt, any information disclosed by a Party to the other Party prior to the Execution Date pursuant to the Confidential Disclosure Agreement between Voyager and Neurocrine dated August 28, 2018 (as amended from time to time, the "Existing Confidentiality Agreement"), that was considered Confidential Information (as defined in the Existing Confidentiality Agreement) of a Party shall be Confidential Information of such Party hereunder, subject to the provisions of Sections 11.1.1, 11.1.2, 11.1.3 and 11.1.4. Notwithstanding the foregoing, any Inventions within the Vectorization Know-How shall be considered the Confidential Information of Voyager, with Voyager considered the Disclosing Party and Neurocrine considered the Receiving Party, and Neurocrine may not rely on Section 11.1.1 with respect to any such Inventions developed by Neurocrine under this Agreement and assigned to Voyager.

11.2 Authorized Disclosure. Except as expressly provided otherwise in this Agreement, a Receiving Party may disclose Confidential Information of the Disclosing Party as follows: (a) to the extent required to those of its employees, agents and representatives who reasonably need to know such Confidential Information in order to advise or assist the Receiving Party in connection with the performance of its obligations or exercise of its rights granted or reserved in this Agreement and under appropriate written (or legal or ethical such as in the case of attorneys) confidentiality and non-use obligations no less protective of the Disclosing Party than those set forth in this Agreement; (b) as required by applicable Law; provided, however, that if a Receiving Party is required by Law to make any such disclosure of a Disclosing Party's Confidential Information it will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure requirement, limit disclosure to only the Confidential Information requested to be disclosed and, if requested by the Disclosing Party, cooperate with the Disclosing Party to secure confidential treatment of such Confidential Information required to be disclosed; (c) in communication with existing or bona fide prospective investors, lenders, professional advisors, acquirers, merger partners, subcontractors, licensees or Inbound Licensors on a need to know basis, in each case under appropriate written (or legal or ethical such as in the case of attorneys) confidentiality and non-use obligations substantially equivalent to those of this Agreement, except that the term of such obligations may be shorter, and with respect to any disclosure to an Inbound Licensor under an Existing In-License Agreement, Neurocrine acknowledges that the relevant Inbound Licensor is obligated to retain any information provided to it in confidence only as required pursuant to the terms of the applicable Existing In-License Agreement; (d) to the extent mutually agreed to in writing by the Parties; (e) to a patent authority in connection with Prosecution and Maintenance, Defense Proceedings and enforcement of Patent Rights in accordance with Article 10; and (f) in the case of Neurocrine as Receiving Party, in Regulatory Filings for Collaboration Products and, in each case under appropriate written confidentiality and non-use obligations substantially equivalent to those of this Agreement, to Third Party contractors in connection with its Development, Manufacture and Commercialization of Collaboration Products. The confidentiality and non-use obligations set forth under this Agreement shall survive the termination or expiration of this Agreement for a period of [...***...].

11.3 Press Release; Disclosure of Agreement.

11.3.1 On or promptly after the Effective Date, the Parties shall jointly issue a public announcement of the execution of this Agreement. Subject to Sections 11.3.2, 11.3.3 and 11.4, neither Party may issue any subsequent press release or other public disclosure regarding this Agreement or its terms or the Parties' activities hereunder, or any results or data arising hereunder, except (a) with the other Party's prior written consent, (b) for any disclosure that is reasonably necessary to comply with applicable securities exchange listing requirements or other applicable Laws, provided that the Party making such disclosure provides the other Party a copy of the proposed disclosure as soon as reasonably practicable and reasonably considers any comments thereto provided by the other Party within [...***...] after the receipt of such proposed disclosure or such shorter period required to comply with applicable Laws, (c) in the case of Voyager, to announce the exercise of the Co-Co Option, provided that Voyager first provides Neurocrine a copy of the proposed disclosure and reasonably considers any timely comments thereto provided by Neurocrine, or (d) in the case of Neurocrine, disclosure of any information relating to the Development, Manufacture or Commercialization of any Collaboration Product that does not include Confidential Information of Voyager, provided that Neurocrine first provides Voyager a copy of the proposed disclosure and reasonably considers any timely comments thereto provided by Voyager. Notwithstanding the foregoing, to the extent information regarding this Agreement has already been publicly disclosed, each Party (other than a Party that had caused such information to become publicly disclosed in breach of this Article 11, if applicable) may subsequently disclose the same information to the public without the consent of the other Party, as long as it remains accurate at the time of subsequent disclosure.

11.3.2 Notwithstanding Section 11.3.1, each Party shall be permitted to disclose the existence and terms of this Agreement to the extent required to comply with applicable Laws or legal process, including the rules or regulations of the U.S. Securities and Exchange Commission, or similar agency in any country other than the United States, or of any stock exchange, including Nasdaq. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof, the Parties will coordinate in advance with each other in connection with the redaction of certain provisions of this Agreement with respect to any filings with the U.S. Securities and Exchange Commission or similar agency in any country other than the United States, or of any stock exchange, including Nasdaq, on which securities issued by a Party or a Party's Affiliate are traded (the "Redacted Version"), and each Party will use commercially reasonable efforts to seek confidential treatment for such terms as may be reasonably requested by the other Party; provided that the Parties will use commercially reasonable efforts to file redacted versions with any governing bodies that are consistent with the Redacted Version.

11.3.3 Each Party shall be permitted to disclose the terms of this Agreement, in each case under appropriate confidentiality obligations substantially equivalent to those of this Agreement (except that the term of the obligations may be shorter as consistent with the applicable Party's ordinary business practices with regard to the protection of its confidential information), to any existing or bona fide prospective investors, lenders, professional advisors, acquirers, merger partners, licensees or Inbound Licensors, except that, with respect to any disclosure to an Inbound Licensor under an Existing In-License Agreement, Neurocrine acknowledges that the relevant Inbound Licensor is obligated to retain any information provided to it in confidence only as required pursuant to the terms of the applicable Existing In-License Agreement.

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11.4 Publications. The Parties recognize that it may be useful or required to publish or publicly disclose the results of Exploitation activities conducted hereunder, and each Party (and its Affiliates and Sublicensees) shall be free to publish or publicly disclose such results, including on its clinical trials registry or on a government-sponsored database such as www.clinicaltrials.gov, subject to the prior review by the other Party for patentability and protection of its Confidential Information as described in this Section 11.4; provided that any publication by Voyager of any data or results obtained under activities conducted under the subject matter of this Agreement shall be subject to approval by the JSC. The Party that desires to publish such results shall provide the other Party with a copy of such proposed abstract, manuscript, or presentation no less than [...***...] in the case of abstracts) prior to its intended submission for publication. The reviewing Party shall respond in writing promptly and in no event later than [...***...] in the case of abstracts) after receipt of the proposed material, with one or more of the following: (a) comments on the proposed material, which the publishing Party shall consider in good faith, (b) a specific statement of concern, based upon the need to seek patent protection or to block publication if the reviewing Party determines that the proposed disclosure contains or describes intellectual property that should be maintained as a trade secret to protect a Collaboration Product or any Exploitation activities conducted under this Agreement, and/or (c) an identification of the reviewing Party's Confidential Information that is contained in the material reviewed. In the event of concern over patent protection or whether maintaining a trade secret would be a priority, the publishing Party agrees not to submit such publication or to make such presentation that contains such information until the reviewing Party is given a reasonable period of time, and in no event more than [...***...], unless otherwise agreed by the Parties, to seek patent protection for any material in such publication or presentation which it believes is patentable or to resolve any other issues; provided, however, that the publishing Party shall abandon such proposed publication or presentation if the reviewing Party reasonably determines in good faith that maintaining such information as a trade secret is a commercially reasonable priority. Any Confidential Information of the reviewing Party shall, if requested by the reviewing Party, be removed. Furthermore, with respect to any proposed abstracts, manuscripts or summaries of presentations by Clinical Trial investigators, such materials shall be subject to review under this Section 11.4 to the extent that Neurocrine or Voyager (as the case may be) has the right to do so. Voyager shall not grant any other Third Party any rights to publish results generated under this Agreement without approval by an appropriate Committee.

11.5 Remedies. Each Party shall be entitled to seek, in addition to any other right or remedy it may have, at Law or in equity, a temporary injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Article 11.

11.6 [...***...] Agreement. Pursuant to Section 14.8 of the [...***...] Agreement, Neurocrine agrees that it shall not make any form of representation or statement which would constitute an express or implied endorsement by [...***...] of any Licensed Products (as defined in the [...***...] Agreement), and that it shall not authorize others to do so, without first having obtained written approval from [...***...], except as may be required by governmental law, rule or regulation.

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ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 Representations and Warranties of Both Parties. Each Party hereby represents and warrants to the other Party, as of the Execution Date and as of the Effective Date, that:

12.1.1 such Party is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

12.1.2 such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

12.1.3 this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof;

12.1.4 the execution, delivery and performance of this Agreement by such Party do not conflict with or result in a breach of any agreement or any provision thereof, or any instrument or understanding, oral or written, to which it is a party or by which it is bound, or any provision of the organization documents of such Party, nor violate any Laws of any court, governmental body or administrative or other agency having jurisdiction over such Party; and

12.1.5 no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable Laws currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements, except as may be required to obtain clearance of this Agreement under the HSR Act, to conduct Clinical Trials, to Manufacture Collaboration Products, or to seek or obtain Regulatory Approvals.

12.2 Representations, Warranties and Covenants, as applicable, of Voyager. Voyager hereby represents, warrants, and covenants to Neurocrine, as of the Execution Date and, except as set forth below, with respect to each Discovery Program, as of the date the JSC approves the applicable Discovery Target (subject to any disclosures in the Schedule of Exceptions attached hereto as Exhibit C, which disclosures shall be deemed to be exceptions to such representations and warranties) that:

12.2.1 Voyager has the right to grant all rights and licenses it purports to grant to Neurocrine under this Agreement;

12.2.2 Voyager has not granted, and will not during the Term grant, any right or license to any Third Party that would conflict with the rights or licenses granted to Neurocrine hereunder;

12.2.3 Exhibit B sets forth a true and complete list, as of the Execution Date, of all Voyager Licensed Patent Rights, indicating the assignee(s) of each such Patent Right; and Voyager

is the sole and exclusive owner of, or otherwise Controls via an exclusive license, the Voyager Licensed Patent Rights, free and clear of any claims, liens, charges or encumbrances other than licenses granted by Voyager that do not conflict with the licenses granted to Neurocrine under this Agreement;

12.2.4 The inventions claimed by the Voyager Licensed Patent Rights (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof and (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e) and (c) are not otherwise subject to 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated thereunder;

12.2.5 No claim or litigation has been brought or threatened in writing against Voyager or, to its Knowledge, any Third Party by any Person alleging that the Voyager IP or Vectorization Technology is infringing or, if practiced or commercialized, will infringe the rights of any Third Party, or that the development of the Voyager IP or Vectorization Technology infringed or misappropriated the intellectual property rights of any Third Party, and to Voyager's Knowledge there is no basis for any such claim;

12.2.6 To Voyager's Knowledge, the conduct of the Development Plans have not, do not and will not infringe any Patent Rights or misappropriate any materials, Know-How or other intellectual property of any Third Party;

12.2.7 There are no judgments, orders, decrees or settlements against or owed by Voyager or any of its Affiliates, and, there is no written claim, written demand, suit, proceeding, arbitration, and to Voyager's Knowledge, other claim, demand, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to the Knowledge of Voyager, threatened against Voyager or any of its Affiliates, in each case relating to the Voyager IP, the Programs and Collaboration Products or the transactions contemplated by this Agreement;

12.2.8 To Voyager's Knowledge, no Person is infringing or threatening to infringe, or misappropriating or threatening to misappropriate, the Voyager IP, and no Person has challenged or threatened to challenge the inventorship, ownership, Voyager's right to use, scope, validity or enforceability of, or Voyager's or any Inbound Licensor's rights in or to, any Voyager Licensed Patent Rights (including through the institution or threat of institution of interference, derivation, post-grant review, opposition, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous Governmental Authority);

12.2.9 To Voyager's Knowledge, the Voyager Licensed Patent Rights are valid and enforceable, or in the case of pending patent applications, will be valid and enforceable upon issuance, the inventorship of each Voyager Patent Right is properly identified on each patent and patent application, and Voyager has complied (and, to its Knowledge, its Inbound Licensors have complied) with, all applicable Laws and duties of candor with respect to the filing, prosecution and maintenance of the Voyager Licensed Patent Rights. Voyager has paid, with respect to all Voyager Licensed Patent Rights to which Voyager has prosecution and maintenance rights, and, to Voyager's Knowledge, its Inbound Licensors have paid all maintenance and annuity fees with respect to the Voyager Licensed Patent Rights due as of the Execution Date;

12.2.10 All of its employees, officers, and consultants have executed agreements or have existing obligations under applicable Laws requiring assignment to Voyager of all inventions made during the course of and as the result of their association with Voyager and obligating the individual to maintain as confidential Voyager's Confidential Information as well as confidential information of other Persons (including Neurocrine and its Affiliates) which such individual may receive, in each case to the extent required to support Voyager's obligations under this Agreement;

12.2.11 (i) Neither Voyager nor, to Voyager's Knowledge, any Third Party, is in breach of any In-License Agreement in any material respect and, to Voyager's Knowledge, each In-License Voyager Agreement is in full force and effect, and neither Voyager nor any of its Affiliates has received any written notice of breach of any In-License Agreements; (ii) there are no agreements between Voyager (or any of its Affiliates), on the one hand, and a Third Party, on the other hand, pursuant to which Voyager or any of its Affiliates has Control of any Voyager IP as of the Execution Date other than those listed on Schedule 1.37, (iii) none of the Existing In-License Agreements includes any obligations that restrict or conflict with the practice of the licenses granted by Neurocrine hereunder; and (iv) true, correct and complete copies of each Existing In-License Agreement have been provided to Neurocrine.

12.2.12 Except for any contract granting only a non-exclusive license to (a) a Third Party to provide services or products to Voyager in a fee-for-service arrangement that does not convey to any Third Party or allow any Third Party to retain any rights in any Voyager Licensed Patent Rights or Voyager Know-How or (b) Inbound Licensors for non-commercial research and educational purposes, there are no agreements pursuant to which Voyager or any of its Affiliates has granted any right or license to practice any Voyager Licensed Patent Rights or Voyager Know-How that would be inconsistent or in conflict with the rights granted pursuant to this Agreement;

12.2.13 Voyager has taken reasonable precautions to preserve the confidentiality of the Voyager Know-How, including requiring each Person having access to the Voyager Know-How to be subject to confidentiality, non-use and non-disclosure obligations protecting the Voyager Know-How as the confidential, proprietary materials and information of Voyager;

12.2.14 Voyager has made available to Neurocrine (a) all Regulatory Filings relating to Collaboration Candidates, (b) all information in Voyager's or its Affiliates' Control related to the safety or efficacy of any Collaboration Candidate or Collaboration Product and (c) all other information in Voyager's Control requested by Neurocrine.

12.2.15 Voyager and its Affiliates have generated, prepared, maintained and retained all Regulatory Filings for Collaboration Candidates and Collaboration Products in accordance with GLP, GCP and all other applicable Laws, and all such information is complete and accurate;

12.2.16 Voyager and its Affiliates have conducted, and its and their respective contractors and consultants have conducted, all Development of Collaboration Candidates and Collaboration Products in accordance with GLP, GCP and all other applicable Laws;

12.2.17 Neither Voyager nor any of its Affiliates, nor, to Voyager's Knowledge, any of its or their respective officers, employees or agents, has (a) committed an act, (b) made a statement or (c) failed to act or make a statement that, in each case (a), (b) and (c), (A) would be or create an untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Authority with respect to the Exploitation of Collaboration Candidates and Collaboration Products or (B) could reasonably be expected to provide a basis for the FDA 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 in the Territory;

12.2.18 Since November 10, 2015, Voyager and its Affiliates have conducted and will conduct their business in compliance with the Foreign Corrupt Practices Act of 1977 and any other applicable anti-corruption Laws. Voyager covenants as follows:

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

(b) Voyager and its Affiliates, and their respective employees and contractors, in connection with the performance of their respective obligations under this Agreement, shall not cause Neurocrine or its respective Affiliates, employees or agents to be in violation of the FCPA or any other applicable Law.

(c) Voyager shall without unreasonable delay notify Neurocrine if Voyager has any credible information or reasonable suspicion that there may be a violation of the FCPA or any other applicable Law in connection with the performance of this Agreement or the Development, Manufacture or Commercialization of any Collaboration Candidate or Collaboration Product.

(d) In connection with the performance of its obligations under this Agreement, Voyager shall comply and shall cause its and its Affiliates' employees and contractors to comply with Voyager's own anti-corruption and anti-bribery policy, a copy of which will be provided to Neurocrine within [...***...] of the Effective Date.

(e) Neurocrine will have the right, upon reasonable prior written notice and during Voyager's regular business hours, to engage an independent Third Party to audit

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Voyager's books and records in the event that a suspected violation of any of the representations, warranties or covenants in this Section 12.2.18 needs to be investigated.

(f) In the event that Voyager has violated or been reasonably suspected of violating any of the representations, warranties or covenants in this Section 12.2.18, Voyager will cause its or its Affiliates' personnel or others working under its direction or control to submit to periodic training that Voyager will provide on anti-corruption law compliance.

(g) Voyager will, at Neurocrine's request, annually certify to Neurocrine in writing Voyager's compliance, in connection with the performance of Voyager's obligations under this Agreement, with the representations, warranties or covenants in this Section 12.2.18.

(h) Neurocrine shall have the right to suspend or terminate this Agreement in its entirety where there is a credible finding, after a reasonable investigation, that Voyager, in connection with performance of its obligations under this Agreement, has violated the FCPA; and

12.2.19 Voyager (a) will promptly notify Neurocrine of any lawsuits, claims, administrative actions, regulatory inquiries or investigations, or other proceedings asserted or commenced against Voyager or its Affiliates or their respective employees or agents involving in any material way the ability of Voyager to deliver the rights, licenses and sublicenses granted herein; and (b) will promptly notify Neurocrine in writing of any facts or circumstances that come to Voyager's attention and that cause, or are reasonably expected to cause, any of the representations and warranties contained in Section 12.1 or 12.2 to be untrue in any material respect at any time during the Term.

12.3 Mutual Covenants. Each Party hereby covenants to the other Party that:

12.3.1 All individuals who are employees or independent contractors of such Party or any of its Affiliates working under this Agreement are and will be under written obligation to assign or, in the case of independent contractors, assign or exclusively license, all right, title and interest in and to all Inventions and other Know-How, and all intellectual property rights therein, developed under this Agreement to such Party or its Affiliate as the sole owner or exclusive licensee thereof;

12.3.2 Such Party will not employ, or use any contractor or consultant that employs or uses, any Person (a) that is debarred by the FDA (or subject to a similar sanction of EMA or any other Governmental Authority) or (b) to such Party's Knowledge, that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or any other Governmental Authority), in each of clauses (a) and (b) in the conduct of its activities under this Agreement;

12.3.3 In performing its obligations or exercising its rights under this Agreement, such Party, its Affiliates, and, with respect to Neurocrine, its Sublicensees, shall comply with all applicable Law, including all anti-corruption Laws; and

12.3.4 Such Party will not grant any license relating to the Voyager IP (if such Party is Voyager) or the Neurocrine IP (if such Party is Neurocrine) that would conflict with the rights or licenses granted or to be granted to the other Party hereunder.

12.4 Disclaimer. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

ARTICLE 13
INDEMNIFICATION; INSURANCE

13.1 Indemnification by Neurocrine. Subject to Section 13.3 and the terms of the Co-Co Agreement, Neurocrine shall indemnify, hold harmless and defend:

13.1.1 Voyager and its Affiliates, and its or their respective directors, officers, employees, agents and representatives, from and against any and all liabilities, damages, losses, costs and expenses, including the reasonable fees of attorneys and other professional advisors (collectively, "Losses"), to the extent arising out of or resulting from any Third Party suits, claims, actions, proceedings or demands ("Third Party Claims") to the extent resulting from:

(a) The gross negligence, recklessness or intentional misconduct of Neurocrine or any of its Affiliates, or its or their respective directors, officers, employees, agents or representatives, in connection with performance by or on behalf of Neurocrine of Neurocrine's obligations or exercise of Neurocrine's rights under this Agreement;

(b) any breach of this Agreement, including any representation or warranty or covenant, by Neurocrine; or

(c) the Exploitation of Collaboration Candidates and Collaboration Products conducted by or on behalf of Neurocrine, any of its Affiliates or any Sublicensee hereunder (excluding Development or Manufacturing carried out by Voyager hereunder), including (a) any product liability, personal injury, property damage or other damage, and (b) infringement of any Patent Rights or other intellectual property rights of any Third Party, except to the extent related to any Vectorization Technology licensed to Neurocrine hereunder; provided, however, that, Losses arising from Exploitation of any Collaboration Product under any Co-Co Agreement shall be shared as Development Costs or profit or loss, as applicable, in accordance with the term of such Co-Co Agreement;

except, in each case ((a)-(c)), to the extent arising from the gross negligence, recklessness or intentional misconduct of Voyager or any of its Affiliates or its or their respective directors, officers, employees, agents or representatives or Voyager's breach of this Agreement, including any representation, warranty or covenant.

13.1.2 [...***...], its trustees, officers, agents and employees (the "[...***...] Indemnitees"), as set forth in Section 9.3 of the [...***...] Agreement, if the Patent Rights under the [...***...] Agreement become sublicensed to Neurocrine hereunder.

13.2 Indemnification by Voyager. Subject to Section 13.3 and the terms of the Co-Co Agreements, Voyager shall indemnify, hold harmless and defend, Neurocrine and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all Losses, to the extent arising out of or resulting from any Third Party Claims to the extent resulting from:

13.2.1 the gross negligence, recklessness or intentional misconduct of Voyager or any of its Affiliates or subcontractors, or its or their respective directors, officers, employees, agents or representatives, in connection with performance by or on behalf of Voyager of Voyager's obligations or exercise of Voyager's rights under this Agreement;

13.2.2 any breach of this Agreement, including any representation or warranty or covenant, by Voyager;

13.2.3 the Exploitation of Collaboration Candidates and Collaboration Products conducted by or on behalf of Voyager or any of its Affiliates, or any of their respective licensees (excluding Development, Manufacturing or Commercialization carried out by Neurocrine hereunder), outside of the Territory or before the Effective Date or after termination of this Agreement, and including (a) any product liability, personal injury, property damage or other damage and (b) infringement of any Patent Rights or other intellectual property rights of any Third Party; provided, however, that, Losses arising from Exploitation of any Collaboration Product under any Co-Co Agreement shall be shared as Development Costs or profit or loss, as applicable, in accordance with the term of such Co-Co Agreement; or

13.2.4 the infringement of any Patent Rights or other intellectual property rights of any Third Party by the Exploitation of any Collaboration Product conducted by or on behalf of Neurocrine or its Affiliates or any Sublicensees, to the extent related to any Vectorization Technology licensed to Neurocrine by Voyager hereunder;

except, in each case (13.2.1 – 13.2.4), to the extent arising from the gross negligence, recklessness or intentional misconduct of Neurocrine or any of its Affiliates or its or their respective directors, officers, employees, agents or representatives or Neurocrine's breach of this Agreement, including any representation, warranty or covenant.

13.3 Procedure. A Person entitled to indemnification under this Article 13 (an "Indemnified Party") shall give prompt written notification to the Person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any Third Party Claim for which indemnification may be sought or, if earlier, upon the assertion of any such Third Party Claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party Claim as provided in this Section 13.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice). Within [...***...] after delivery of such notification, the Indemnifying Party may, upon

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written notice thereof to the Indemnified Party, assume control of the defense of such Third Party Claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all reasonable costs and expenses, including attorney fees, incurred by the Indemnified Party in defending itself within [...***...] after receipt of any reasonably detailed invoice and supporting documentation therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense; provided that, if the Indemnifying Party assumes control of such defense and the Indemnified Party in good faith concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such Third Party Claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party in connection therewith. The Party controlling such defense shall keep the other Party advised of the status of such Third Party Claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such Third Party Claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld, delayed or conditioned, agree to any settlement of such Third Party Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party.

13.4 Insurance. Subject to the terms of any applicable Co-Co Agreement:

13.4.1 Voyager's Insurance Obligations. Voyager shall maintain, at its cost, insurance against liability and other risks associated with its activities and obligations under this Agreement, including its Clinical Trials and its indemnification obligations hereunder, in such amounts, subject to such deductibles and on such terms as are reasonable for a company such as Voyager for the activities to be conducted by it under this Agreement. Voyager shall furnish to Neurocrine evidence of such insurance upon request. If the Patent Rights under the [...***...] Agreement become sublicensed to Neurocrine hereunder, Neurocrine shall name the [...***...] Indemnitees as additional insureds, pursuant to Section 13.1 of the [...***...] Agreement.

13.4.2 Neurocrine's Insurance Obligations. Neurocrine shall maintain, at its cost, insurance against liability and other risks associated with its and its Affiliates' and any Sublicensees' activities and obligations under this Agreement, including Clinical Trials, the Exploitation of Collaboration Products and Neurocrine's indemnification obligations hereunder, in such amounts and on such terms as are reasonable and customary for a company such as Neurocrine for the activities to be conducted by it under this Agreement. Neurocrine shall furnish to Voyager evidence of such insurance upon request.

13.5 Limitation of Liability. EXCEPT FOR A BREACH OF ARTICLE 9 OR ARTICLE 11 OR FOR CLAIMS OF A THIRD PARTY THAT ARE SUBJECT TO INDEMNIFICATION UNDER THIS ARTICLE 13, NEITHER VOYAGER NOR NEUROCRINE, NOR ANY OF THEIR RESPECTIVE AFFILIATES, LICENSORS, LICENSEES OR SUBLICENSEES, WILL BE LIABLE TO THE OTHER PARTY, ITS

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AFFILIATES OR SUBLICENSEES FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES, OR LOST PROFITS, ROYALTIES, DATA OR PROCUREMENT OF SUBSTITUTE GOODS, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), INDEMNITY OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

ARTICLE 14
TERM AND TERMINATION

14.1 Term. This Agreement shall commence as of the Effective Date and, unless terminated earlier, this Agreement shall continue in full force and effect until the later of (a) the expiration of the last to expire Royalty Term with respect to all Collaboration Products in all countries in the Territory or (b) the last expiration or termination of all Co-Co Agreements (the "Term").

14.2 Termination by Neurocrine. Neurocrine may terminate this Agreement in its entirety or on a Program-by-Program and/or country-by-country basis by providing written notice of termination to Voyager, which notice specifies the scope of the termination and includes an effective date of termination at least (a) one hundred eighty (180) days after the date of the notice if such notice is provided prior to First Commercial Sale of any Collaboration Product to which the termination applies or (b) one (1) year after the date of the notice if such notice is provided after First Commercial Sale of any Collaboration Product to which the termination applies.

14.3 Termination for Breach.

14.3.1 This Agreement may be terminated (a) on a Program-by-Program basis, at any time upon written notice by either Party if the other Party is in material breach of this Agreement with respect to such Program or (b) in its entirety, at any time upon written notice by either Party if the other Party is in material breach of this Agreement with respect to all Programs, or if such material breach does not relate specifically to any Program, in either case ((a) or (b)) except if the breaching Party has cured such breach within [...***...] in the case of a payment breach ([...***...] in the case of the Initial Fee), or within [...***...] in the case of all other breaches, after the non-breaching Party has provided written notice to the breaching Party of such breach; provided that if the breach is curable but is not capable of cure within such [...***...] period, then the cure period will be extended for so long as the breaching Party is diligently implementing a cure plan reasonably designed to cure such breach, provided that, such cure period does not exceed [...***...] in total.

14.3.2 Without limiting Section 14.3.1, if the applicable material breach is a material breach by Neurocrine of its obligations under Section 4.2.2 to use Commercially Reasonable Efforts with respect to a Program in one or more, but not all, of the Major Market Countries, then Voyager will not have the right to terminate this Agreement with respect to such Program in all countries but instead may terminate this Agreement with respect to such Program

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only in the Major Market Country(ies) in which there was an uncured material breach by Neurocrine with respect to its obligation to use Commercially Reasonable Efforts.

14.3.3 If the Parties reasonably and in good faith disagree as to whether there has been a material breach, the Party that seeks to dispute that there has been a material breach shall contest the allegation in accordance with Section 15.2 during the applicable cure period. The cure period for any allegation made in good faith as to a material breach under this Agreement will, subject to Sections 14.3.1 and 15.3, including the suspension of such cure period set forth therein, run from the date that written notice of breach was first provided to the breaching Party by the non-breaching Party.

14.4 Termination for Failure to Make Equity Purchase. If Neurocrine fails to purchase from Voyager shares of Voyager common stock pursuant to the terms and within the timeframe specified in the Stock Purchase Agreement (subject to any cure provisions therein), then Voyager shall have the right to terminate this Agreement in its entirety upon written notice to Neurocrine.

14.5 Termination for Patent Challenge. If, during the Term, Neurocrine (a) commences or participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts any claim, challenging or denying the validity or enforceability of any claim of Voyager Licensed Patent Rights, except in the normal course of patent prosecution, or (b) actively assists any other Person in bringing or prosecuting any action or proceeding (including any patent opposition or reexamination proceeding) challenging or denying the validity or enforceability of any claim of Voyager Licensed Patent Rights (each of (a) and (b), a "Patent Challenge"), then, to the extent permitted by applicable Laws, Voyager shall have the right, exercisable within sixty (60) days following receipt of notice regarding such Patent Challenge, in its sole discretion, to terminate this Agreement with respect to such Voyager Patent Right(s), such termination to be effective ninety (90) days following such notice (or such longer period as Voyager may designate in such notice) unless Neurocrine withdraws or causes to be withdrawn all such challenge(s) (or in the case of *ex-parte* proceedings, multi-party proceedings, or other Patent Challenges that Neurocrine does not have the power to unilaterally withdraw or cause to be withdrawn, Neurocrine ceases actively assisting any other party to such Patent Challenge and, to the extent Neurocrine is a party to such Patent Challenge, it withdraws from such Patent Challenge) within such ninety (90)-day period. The foregoing sentence shall not apply (i) with respect to any Voyager Licensed Patent Rights that Voyager first asserts against Neurocrine or any of its Affiliates where the Patent Challenge is made in defense of such assertion, or (ii) with respect to any Patent Challenge commenced by a Third Party that after the Effective Date acquires or is acquired by Neurocrine or its Affiliates or its or their business or assets, whether by stock purchase, merger, asset purchase or otherwise, but only with respect to Patent Challenges commenced prior to the closing of such acquisition. The following will not be considered a Patent Challenge: (A) responding to compulsory discovery, subpoenas or other requests for information in a judicial or arbitration proceeding or (B) complying with any applicable Law or court order.

14.6 Effects of Termination Other than by Neurocrine for Voyager Breach. Without limiting any other legal or equitable remedies that either Party may have, if this Agreement is terminated (in whole or in part) for any reason except by Neurocrine pursuant to Section 14.3 above, then the following shall apply, provided that if termination of this Agreement is limited to

a particular country(ies) or Program(s) then the following shall apply only with respect to such country(ies) or Program(s):

14.6.1 the license grants to Neurocrine in Section 5.1 shall terminate immediately;

14.6.2 Neurocrine shall, and hereby does, effective upon such termination, grant to Voyager a royalty-bearing, sublicenseable (through multiple tiers) license under the Neurocrine IP that has been used with or incorporated into Collaboration Products in such Program as of the effective date of termination to Exploit Collaboration Products in such Program in the terminated country(ies), which license will be non-exclusive or exclusive as requested by Voyager; the Parties shall negotiate in good faith commercially reasonable royalties payable by Voyager to Neurocrine on sales of such Collaboration Products, which shall reflect the value of, and Neurocrine's investment in the development of, such Collaboration Products and the exclusivity of the license, and the terms related to such royalty payments.

14.6.3 if Voyager so requests, and to the extent permitted under the relevant agreement at the time of termination, Neurocrine shall transfer to Voyager any agreements between Neurocrine or any of its Affiliates, on the one hand, and any Affiliate or Third Party, on the other hand, to the extent relating to the Exploitation of any Collaboration Product in the terminated Program(s) and country(ies) to which Neurocrine or any of its Affiliates or any Sublicensees is a party, subject to any required consents of such Third Party, which Neurocrine shall use commercially reasonable efforts to obtain promptly (but shall not be obligated to pay any additional consideration to such Third Party);

14.6.4 if the date of expiration or termination of the Agreement is after any Transition Event, then, with respect to any Collaboration Product that is the subject of a terminated Program:

(a) Neurocrine shall provide to Voyager a fair and accurate description of the status of the Exploitation of any Collaboration Product in such Program in the Field in the terminated country(ies) through the effective date of termination or expiration;

(b) Neurocrine shall as promptly as practicable transfer to Voyager or Voyager's designee (i) possession and ownership of all Regulatory Filings (including any supporting documentation or data therefor), Regulatory Approvals and pricing and reimbursement approvals relating to the Exploitation of such Collaboration Products in the terminated Program(s) and country(ies), (ii) copies of all non-clinical and clinical data relating to any of such Collaboration Products, and all adverse event or other safety data in the possession or Control of Neurocrine, any of its Affiliates or any Sublicensee related to such Collaboration Products; (ii) if this Agreement is terminated in its entirety, all records and materials containing Confidential Information of Voyager. To the extent required to effect the transfer of any Regulatory Filing or Regulatory Approvals in any terminated country(ies), Neurocrine shall appoint, and cause its Affiliates and use Commercially Reasonable Efforts to cause its Sublicensees to appoint, Voyager as the agent for Neurocrine, its Affiliates and, as applicable, the Sublicensees for all matters relating to such Collaboration Products involving Regulatory Authorities in such terminated country(ies) until all Regulatory Approvals and other Regulatory Filings have been transferred to Voyager or its designee;

(c) if the effective date of termination or expiration is after the First Commercial Sale of a Collaboration Product in any country in the Territory, then Neurocrine shall appoint Voyager or its designee as the exclusive distributor of the Collaboration Product in the Territory and grant Voyager the right to appoint sub-distributors, until such time as all Regulatory Approvals and pricing and reimbursement approvals in the Territory have been transferred to Voyager or its designee;

(d) if Neurocrine or any of its Affiliates is Manufacturing such Collaboration Product, then, at Voyager's option, Neurocrine shall supply such Collaboration Product to Voyager in the Territory at Neurocrine's fully burdened manufacturing cost plus [...***...] percent ([...***...]%) thereof (except that such percentage above cost shall not apply if Voyager terminated this Agreement pursuant to Section 14.3 above), until the earlier of (A) such time as all Regulatory Approvals and pricing and reimbursement approvals in the Territory have been transferred to Voyager or its designee, Voyager has obtained all necessary Manufacturing approvals and Voyager has procured or developed its own source of the Collaboration Product supply for the Territory or (B) [...***...] following the effective date of such termination or expiration;

(e) Neurocrine shall promptly transfer and assign to Voyager all of Neurocrine's and its Affiliates' and shall use Commercially Reasonable Efforts to cause its Sublicensees to transfer and assign any Sublicensee's rights, title and interests in and to all Neurocrine Product Marks used in the Commercialization of such Collaboration Products (but not any house marks of such Person or any trademark containing the word "Neurocrine" owned by Neurocrine or any of its Affiliates or, as applicable, any Sublicensee); and

(f) Neurocrine shall, upon Voyager's written request, transfer to Voyager any inventory of such Collaboration Products owned or controlled by Neurocrine or any of its Affiliates and shall use Commercially Reasonable Efforts to cause any Sublicensee to transfer any such inventory of such Collaboration Products owned or controlled by such Sublicensee as of the termination date at the actual price paid by Neurocrine, such Affiliate or, as applicable, such Sublicensee for such supply.

14.6.5 Neurocrine shall provide any other assistance reasonably requested by Voyager for the purpose of allowing Voyager or its designee to proceed expeditiously with the Exploitation of Collaboration Products in the Field in the Territory over a [...***...] period following termination, and Voyager shall pay Neurocrine's FTE Costs and Out-of-Pocket Costs to conduct such assistance (except in the event Voyager terminated this Agreement pursuant to Section 14.3 above);

14.6.6 Neurocrine shall, and shall cause its Affiliates and use Commercially Reasonable Efforts to cause its Sublicensees to, execute all documents as may be reasonably requested by Voyager in order to give effect to the foregoing clauses; and

14.6.7 If this Agreement is terminated in its entirety, Voyager shall return to Neurocrine or destroy, and certify such destruction in writing any Confidential Information of Neurocrine, except for any such Confidential Information that Voyager has the right to use pursuant to the terms of this Agreement.

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14.7 Effects of Termination by Neurocrine for Voyager Breach. If Neurocrine terminates this Agreement with respect to one or more Programs pursuant to Section 14.3, then all rights and obligations under this Agreement with respect to such terminated Programs will terminate, except as expressly provided in Section 14.9, and if such termination is of this Agreement in its entirety, Voyager shall return to Neurocrine or destroy, and certify such destruction in writing, any Confidential Information of Neurocrine. If Neurocrine has the right to terminate this Agreement with respect to one or more Programs for Voyager's material breach pursuant to Section 14.3, then in lieu of termination, and in addition to the remedies provided in Section 2.1.5, Neurocrine shall have the right to keep this Agreement in effect and to elect the following upon written notice to Voyager:

14.7.1 If a Co-Co Agreement is then in effect with respect to the terminated Program(s), then such Co-Co Agreement(s) will terminate, and Voyager will no longer have the right to co-develop and co-commercialize the applicable Collaboration Products with Neurocrine; and

14.7.2 Subject to the applicable terms of any In-License Agreement, Neurocrine shall no longer have any obligations with respect to diligence or to use Commercially Reasonable Efforts with respect to any Collaboration Products resulting from the applicable Programs.

14.8 HSR Filing; Termination Upon HSR Denial.

14.8.1 Except for the Parties' obligations under Article 11, Article 12 and this Section 14.8, which shall be effective as of the Execution Date, this Agreement shall not become effective until the Effective Date.

14.8.2 Each Party will use reasonable efforts to do, or cause to be done, all things necessary, proper and advisable to, as promptly as practicable, take all actions necessary to obtain expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act, including filing with the U.S. Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice, any HSR Filing required of it under the HSR Act with respect to the transactions contemplated hereby within ten (10) Business Days after the Execution Date (or such later time as may be agreed to in writing by the Parties). The Parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing and during the review by the U.S. Federal Trade Commission and/or the Antitrust Division of the U.S. Department of Justice. Each Party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; provided, however, that Neurocrine shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of Voyager) required to be paid in connection with making any such HSR Filing**.** If the Parties make an HSR Filing hereunder, then this Agreement shall terminate (a) at the election of either Party, immediately upon notice to the other Party, if the U.S. Federal Trade Commission or the U.S. Department of Justice seeks a preliminary injunction under the Antitrust Laws against Neurocrine and Voyager to enjoin the transactions contemplated by this Agreement; or (b) at the election of either Party, immediately upon notice to the other Party, in the event that the HSR Clearance Date shall not have occurred on or prior to one hundred eighty (180) days after the effective date of the HSR Filing. In the event of such termination, this Agreement shall be of no further force and effect.

14.9 Accrued Rights; Surviving Provisions of the Agreement.

14.9.1 Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration, including any payment obligations hereunder , and any and all damages or remedies arising from any breach hereunder. Such termination or expiration shall not relieve any Party from obligations which are expressly indicated to survive expiration or termination of this Agreement.

14.9.2 The provisions of Articles 10, 11, 13, and 15 and Sections 2.2.2, 2.3, 2.4, the last sentence of 5.1 (only for those licenses that have become irrevocable prior to termination), 8.7, 8.8, 8.9, 8.10, 8.11, 8.12, 12.4, 14.6, 14.7, 14.9, shall survive the termination of this Agreement in its entirety or expiration of this Agreement for any reason, in accordance with their respective terms and conditions, and for the duration stated, and where no duration is stated, shall survive indefinitely.

ARTICLE 15
MISCELLANEOUS

15.1 Governing Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed in accordance with the Laws of the State of New York without reference to conflicts of laws principles; provided that with respect to matters involving the enforcement of intellectual property rights, the Laws of the applicable country shall apply. The provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement or any subject matter hereof.

15.2 Dispute Resolution. Except for the disputes at the JSC, which matters shall be resolved as provided in Section 3.6, in the event of any dispute arising out of or in connection with this Agreement ("Dispute"), either Party shall refer such Dispute in writing to the Parties' respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such Dispute. If the Dispute is not resolved within [...***...] after it has been referred to the Executive Officers, the Dispute shall be finally settled through binding arbitration pursuant to Section 15.3. Any disputes concerning the propriety of the commencement of arbitration shall be finally settled by the arbitral tribunal.

15.3 Arbitration Request.

15.3.1 No Arbitration of Patent Issues. Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patents Covering the Manufacture, use, importation, offer for sale or sale of Collaboration Products shall be submitted to a court of competent jurisdiction in the country in which such Patents were granted or arose.

15.3.2 Arbitration Procedure. Any Disputes that have not been amicably resolved pursuant to Section 15.2 within the [...***...] time period specified therein shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce (the "ICC") before a tribunal comprised of three arbitrators. Each Party shall nominate one arbitrator and within [...***...] of the second arbitrator's appointment, the two party-nominated arbitrators shall nominate the third arbitrator, who shall serve as president of the tribunal. The arbitrators shall have experience in pharmaceutical licensing disputes. An arbitrator shall be deemed to meet

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this qualification unless a Party objects within [...***...] after the arbitrator is nominated. The seat, or legal place, or will be New York City, New York, United States. The language of the arbitration shall be English. The Parties shall mutually agree on the rules to govern discovery and the rules of evidence for the arbitration within [...***...] after the commencement of the arbitration. If the Parties fail to timely agree to such rules, the United States Federal Rules of Civil Procedure will govern discovery and the United States Federal Rules of Evidence will govern evidence for the arbitration. Subject to Section 13.5, the arbitrators shall be authorized to award compensatory damages, but shall not be authorized to award punitive, special, consequential, or any other similar form of damages, or to reform, modify, or materially change this Agreement. The arbitrators shall also be authorized to grant temporary, preliminary or permanent equitable remedies or relief, including an injunction or order for specific performance. The award of the arbitrators shall be the sole and exclusive remedy of the Parties, except for those remedies that are set forth in this Agreement or which apply to a Party by operation of the applicable provisions of this Agreement, and the Parties hereby expressly agree to waive the right to appeal from the decisions of the arbitrator, and there shall be no appeal to any court or other authority (government or private) from the decision of the arbitrator. Judgment on the award rendered by the arbitrators may be entered in any court of competent jurisdiction.

15.3.3 Costs. During the pendency of the arbitration each Party shall bear its own attorneys' fees, costs, and expenses of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators and the ICC administrative expenses; provided, however, that the arbitrators, in their final award, shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party its costs and expenses of arbitration, including its reasonable attorneys' fees, the fees and costs of the arbitrators and ICC, and other costs and expenses (including, for example, expert witness fees and expenses, transcripts, photocopy charges and travel expenses), as determined by the arbitrators.

15.3.4 Preliminary Injunctions. Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order, preliminary injunction or other interim relief from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the award of the arbitrators on the ultimate merits of any dispute.

15.3.5 Confidentiality. The Parties agree that the arbitration shall be kept confidential. The existence and contents of the arbitration, any non-public information provided in the arbitration, and any submissions, orders or awards made in the arbitration shall be deemed Confidential Information of each of the Parties and subject to Article 11, except that a Party may disclose such information to the arbitrators, the ICC, its counsel, experts, witnesses and any other person to the extent required for the conduct of the arbitration, or as required by applicable Law, to protect or pursue a legal right, or to enforce or challenge an awards in *bona fide* legal

15.3.6 Suspension of Cure Period. From the date the Secretariat of the International Court of Arbitration receives the request for arbitration and until such time as the Dispute has been finally settled, the running of the time periods as to which Party must cure a breach of this Agreement shall be suspended as to any breach that has been referred to arbitration.

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15.3.7 Consolidation. In order to facilitate the comprehensive resolution of related disputes, and upon request of any Party to the arbitration proceeding, the International Court of Arbitration may consolidate the arbitration proceeding with any other arbitration relating to this Agreement to a Co-Co Agreement

15.4 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, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that either Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to (a) an Affiliate; or (b) the Acquirer in the context of a Change of Control. Any purported assignment in violation of this Section 15.4 shall be void.

15.5 Change of Control.

15.5.1 Voyager shall notify Neurocrine in writing within [...***...] after entering into any agreement providing for or intended to result in any Change of Control of Voyager, identifying the parties to such agreement.

15.5.2 Following the effectiveness of such Change of Control: (a) Neurocrine shall have the right to disband the JSC and to require Voyager to adopt reasonable procedures, to be agreed upon in writing with Neurocrine, to limit the dissemination of Neurocrine's Confidential Information to only those personnel having a need to know such Confidential Information in order for Voyager to perform its obligations or to exercise its rights under this Agreement, (b) all unexercised Co-Co Options will terminate, (c) Co-Co-Agreements will terminate to the extent provided in Section 4.1.4(b), and (d) if the Acquirer is Developing or Commercializing a branded product that directly competes with a product being Developed or Commercialized by Neurocrine, Neurocrine will have the rights set forth in Section 2.1.5 (as if Voyager had materially breached its Development obligations and failed to cure such breach).

15.5.3 Voyager covenants that, following a Change of Control of Voyager, (a) there will be no material change in the level or nature of efforts or resources expended by Voyager with respect to, or the qualifications and experience of the personnel assigned to (including with respect to the allocation of their time to), any Program and (b) each employee of Voyager or its Affiliates who worked on any Program during the [...***...] period immediately prior to the Change of Control or who would reasonably be expected to work on any Program thereafter will continue to work on such Program for so long as s/he remains an employee of Voyager or any of its Affiliates.

15.6 Performance by Affiliates and Sublicensees. Each Party hereby acknowledges and agrees that it shall be responsible for the full and timely performance as and when due under, and observance of all applicable covenants, terms, conditions and agreements set forth in this Agreement by its Affiliate(s), licensees and Sublicensees.

15.7 Force Majeure. No Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Agreement for failure or delay in fulfilling or performing any obligation (other than a payment obligation) of this

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Agreement when such failure or delay is due to force majeure. For purposes of this Agreement, force majeure is defined as any cause beyond the reasonable control of the affected Party and without the fault or negligence of such Party, which may include acts of God; material changes in Law; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; labor disturbances; epidemic; and failure of public utilities or common carriers. In such event the Party affected by such force majeure shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled for up to a maximum of ninety (90) days, after which time the Parties shall promptly meet to discuss in good faith how to best proceed in a manner that maintains and abides by the Agreement. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any force majeure.

15.8 Notices. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or reputable overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to Voyager,

addressed to:	Voyager Therapeutics, Inc. 75 Sidney Street Cambridge, MA 02139 Attention: Chief Executive Officer Telephone:857-259-5340 Facsimile:617-621-2971
with a copy to:	Wilmer Cutler Pickering Hale and Dorr LLP 7 World Trade Center 250 Greenwich Street New York, NY 10007 Attention:Brian A. Johnson, Esq. Telephone:212-937-7206 Facsimile:212-230-8888

If to Neurocrine,

addressed to:	Neurocrine Biosciences, Inc. 12780 El Camino Real San Diego, CA 92130 Attention: Chief Legal Officer Telephone:858- 617-7714 Facsimile:858-777-3488
with a copy to:	Cooley LLP 4401 Eastgate Mall

San Diego, CA 92121
Attention: Jason L. Kent, Esq.
Telephone: 858-550-6044
Facsimile: 858 550 6420

or to such other address for such Party as it shall have specified by like notice to the other Party, provided that notices of a change of address shall be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next Business Day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third (3rd) Business Day after such notice or request was deposited with the U.S. Postal Service.

15.9 Export Clause. Each Party acknowledges that the Laws of the United States restrict the export and re-export of commodities and technical data of United States origin. Each Party agrees that it will not export or re-export restricted commodities or the technical data of the other Party in any form without the appropriate United States and foreign government licenses.

15.10 Waiver. Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term except to the extent set forth in writing.

15.11 Severability. If any provision hereof should be invalid, illegal or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.

15.12 Entire Agreement. This Agreement, together with the Schedules hereto, sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties and supersede and terminate all prior agreements and understanding between the Parties. In particular, and without limitation, this Agreement supersedes and replaces the Existing Confidentiality Agreement and any and all term sheets relating to the transactions contemplated by this Agreement and exchanged between the Parties prior to the Effective Date. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

15.13 Independent Contractors. Nothing herein shall be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have the authority to bind or obligate the other Party and neither Party shall represent that it has such authority.

15.14 CREATE Act. It is the intention of the Parties that this Agreement is a "joint research agreement" as that phrase is defined in Section 35 U.S.C. 100(h). Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the America Invents Act Joint Research Agreement exception codified at 35 U.S.C. § 102(c) (the "JRA Exception") when exercising its rights under this Agreement, but only with prior written consent of the other Party in its sole discretion. In the event that a Party intends to invoke the JRA Exception, once agreed to by the other Party if required by the preceding sentence, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof.

15.15 Headings; Construction; Interpretation. Headings and any table of contents used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. The terms of this Agreement represent the results of negotiations between the Parties and their representatives, each of which has been represented by counsel of its own choosing, and neither of which has acted under duress or compulsion, whether legal, economic or otherwise. Accordingly, the terms of this Agreement shall be interpreted and construed in accordance with their usual and customary meanings, and each of the Parties hereby waives the application in connection with the interpretation and construction of this Agreement of any rule of Law to the effect that ambiguous or conflicting terms or provisions contained in this Agreement shall be interpreted or construed against the Party whose attorney prepared the executed draft or any earlier draft of this Agreement. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause or Schedule shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause or Schedule, of or to, as the case may be, this Agreement. Except where the context otherwise requires, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument 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 or therein), (b) any reference to any Law refers to such Law including all rules and regulations thereunder and any successor Law, in each case as from time to time enacted, repealed or amended, (c) the words "herein," "hereof" and "hereunder," and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, (d) the words "include," "includes," and "including" shall be deemed to be followed by the phrase "but not limited to," "without limitation" or words of similar import, (e) the word "or" is used in the inclusive sense (and/or), (f) words in the singular or plural form include the plural and singular form, respectively, (g) references to any gender refer to each other gender, (h) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement, and (i) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein shall be interpreted in a correlative manner.

15.16 Further Actions. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

15.17 Parties in Interest. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the parties hereto and their respective successors, heirs, administrators and permitted assigns.

15.18 Counterparts. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

[*Signature page to follow****]***

IN WITNESS WHEREOF, and intending to be legally bound hereby, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Execution Date.

Voyager Therapeutics, Inc.

By: /s G. Andre Turenne
Name: G. Andre Turenne
Title: President and Chief Executive Officer

Neurocrine Biosciences, Inc.

By: /s/ Kevin Gorman
Name: Kevin Gorman
Title: CEO

Schedule 1.37

EXISTING IN-LICENSE AGREEMENTS

- [...***...] Agreement
- Genzyme Agreement
- [...***...] Agreement

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Schedule 1.68

KNOWLEDGE INDIVIDUALS

- Voyager: [...***...].
- Neurocrine: [...***...].

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Schedule 5.2.1

SPECIFIC OBLIGATIONS UNDER THE [...*...] AGREEMENT**

(Sections references are with respect to the [...***...] Agreement)

STATUTORY AND [...***...] REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the [**...*****...**], upon the [**...*****...**]**'s** written request, with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** solely for the [**...*****...**]**'s** research use to the extent that providing **Licensed Products** or materials to the [**...*****...**] will not adversely effect the development of **Licensed Products** or the practice of the **Licensed Process**.

5.2 The **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the [**...*****...**].

RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the [**...*****...**]. These records shall be retained for at least [...***...] following a given reporting period and shall be available during normal business hours for inspection, at the expense of the [**...*****...**], by an accountant or other designated auditor selected by the [**...*****...**] for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to the [**...*****...**] information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of [...***...] percent ([...***...]%) for any [...***...] period, then the **Licensee** shall reimburse the [**...*****...**] for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within [...***...] of the date the [**...*****...**] provides the **Licensee** notice of the payment due.

PERFORMANCE

10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include best efforts to adhere to the **Commercial Development Plan** in Appendix F and performance of the **Benchmarks** in Appendix E. The efforts of a **Sublicensee** shall be considered the efforts of the **Licensee**.

10.2 The **Licensee** agrees, after its **First Commercial Sale**, to make reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available to patient assistance programs.

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12.5 The **Licensee** shall indemnify and hold the [**...***...**], its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or properly damage in connection with or arising out of:

(a) the use by or on behalf of the **Licensee**, its **Sublicensees**, its directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or **Supplied Materials** by the **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

13.7 The [**...***...**] reserves the right according to 35 U.S.C, §209(d)(3) to terminate or modify this **Agreement** if it is determined that the action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

13.8 Within [...***...] of receipt of' written notice of the [**...***...**]**'s** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 CFR §404.11, appeal the decision by written submission to the designated the [**...***...**] official. The decision of the designated [**...***...**] official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.9 Within [...***...] of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to the [**...***...**] shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, **Sublicensees** may elect to convert their sublicenses to direct licenses with the [**...***...**] pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the Licensed Patent Rights to the [**...***...**] or provide the [**...***...**] with written certification of the destruction thereof. The **Licensee** may not be granted additional the [**...***...**] licenses if the final reporting requirement is not fulfilled.

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Schedule 5.2.4(a)

CERTAIN INTELLECTUAL PROPERTY

Intellectual property described in a communication from counsel to Voyager to counsel to Neurocrine dated the Execution Date.

Schedule 8.1

ALLOCATION SCHEDULE

$115,000,000 allocated as follows:

- $[...***...] to the AADC Program
- $[...***...] to the FA Program
- $[...***...] to each Discovery Program

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Exhibit A

STOCK PURCHASE AGREEMENT

EXECUTION VERSION

STOCK PURCHASE AGREEMENT

By and Between

NEUROCRINE BIOSCIENCES, INC.

AND

VOYAGER THERAPEUTICS, INC.

Dated as of January 28, 2019

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STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "**Agreement**"), dated as of January 28, 2019 (the "**Signing Date**"), by and between Neurocrine Biosciences, Inc. (the "**Investor**"), a Delaware corporation with its principal place of business at 12780 El Camino Real, San Diego, CA 92130, and Voyager Therapeutics, Inc. (the "**Company**"), a Delaware corporation, with its principal place of business at 75 Sidney Street, Cambridge, MA 02139.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value $0.001 per share, of the Company (the "**Common Stock**"); and

WHEREAS, simultaneously with the execution of this Agreement, the Company and the Investor are entering into the Collaboration Agreement and the Investor Agreement.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor and the Company agree as follows:

1. Definitions.

1.1 Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"**2014 Stock Option and Grant Plan**" shall mean the Company's 2014 Stock Option and Grant Plan, as amended to date and as the same may be amended and/or restated from time to time.

"**2015 Employee Stock Purchase Plan**" shall mean the Company's 2015 Employee Stock Purchase Plan, as amended to date and as the same may be amended and/or restated from time to time.

"**2015 Stock Option and Incentive Plan**" shall mean the Company's 2015 Stock Option and Incentive Plan, as amended to date and as the same may be amended and/or restated from time to time.

"**Affiliate**" shall mean, with respect to any Person, another Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if such Person (ii) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person. For the purposes of this Agreement, in no

event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

"**Aggregate Purchase Price**" shall mean $50,000,000.00.

"**Agreement**" shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.

"**Board**" shall mean the Board of Directors of the Company.

"**Business Day**" shall mean a day on which banking institutions in Boston, Massachusetts, United States and San Diego, California, United States are open for business, excluding any Saturday or Sunday.

"**Closing Conditions**" shall mean the conditions to Closing set forth in Sections 6, 7, and 8 hereof.

"**Collaboration Agreement**" shall mean the Collaboration and License Agreement, of even date herewith, between the Investor and the Company.

"**Company Financial Advisors**" shall mean Guggenheim Securities, LLC and Chestnut Securities, Inc.

"**DOJ**" shall mean the U.S. Department of Justice.

"**Effect**" shall have the meaning set forth in the definition of "Material Adverse Effect."

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

"**FTC**" shall mean the U.S. Federal Trade Commission.

"**GAAP**" shall mean generally accepted accounting principles in the United States.

"**Governmental Authority**" shall mean any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.

"**HSR Act**" shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time.

"**HSR Clearance**" shall mean the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.

"**HSR Filing**" shall mean the filings by the Company and Investor with the FTC and the Antitrust Division of the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in the Transaction Agreements and the Collaboration Agreement, together with all required documentary attachments thereto.

"**Investor Agreement**" shall mean that certain Investor Agreement, of even date herewith, between the Investor and the Company.

"LAS" shall mean the Nasdaq Notification Form: Listing of Additional Shares.

"**Law"** shall mean any law, statute, rule, regulation, order, judgment or ordinance having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

"**Material Adverse Effect**" shall mean any change, event or occurrence (each, an "**Effect**") that, individually or when taken together with all other Effects that have occurred prior to the date of determination of the occurrence of the Material Adverse Event, has had a material adverse effect on the business, properties, management, financial position, stockholders' equity or results of operations of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under the Transaction Agreements, except to the extent that any such Effect results from or arises out of: (A) changes in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (B) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles in the United States or interpretations thereof, (C) acts of war, sabotage or terrorism, or any escalation or worsening of any such acts of war, sabotage or terrorism, (D) earthquakes, hurricanes, floods or other natural disasters, (E) the announcement of the Transaction Agreements, the Collaboration Agreement or the Transaction, (F) any change in the Company's stock price or trading volume or any failure to meet internal projections or forecasts or published revenue or earnings projections of industry analysts (provided that the underlying events giving rise to any such change shall not be excluded) or (G) any breach, violation or non-performance by the Investor or any of its Affiliates under the Collaboration Agreement, provided, however, that the Effects excluded in clauses (A), (B), (C) and (D) shall only be excluded to the extent such Effects are not disproportionately adverse on the Company and its subsidiaries as compared to other companies operating in the Company's industry.

"**Per-Share Purchase Price**" shall mean $11.9625.

"**Person"** shall mean any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

"**Rule 144**" shall mean Rule 144 promulgated under the Securities Act.

"**Sales Agreement**" shall mean that certain Sales Agreement, by and between the Company and Cowen and Company, LLC, dated as of December 1, 2016.

"**SEC**" shall mean the U.S. Securities and Exchange Commission.

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

"**Termination Date**" shall mean the date that is one hundred and eighty (180) days after the effective date of the HSR Filing.

"**Third Party"** shall mean any Person other than the Investor, the Company or any Affiliate of the Investor or the Company.

"**Transaction"** shall mean the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor, in accordance with the terms hereof.

"**Transaction Agreements"** shall mean this Agreement and the Investor Agreement.

"**Transfer Agent**" shall mean the Company's transfer agent.

1.2 Additional Defined Terms. In addition to the terms defined in Section 1.1 hereof, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

Defined Term	Section
Closing	Section 3.1
Closing Date	Section 3.1
Common Stock	Preamble
Company	Preamble
Company SEC Documents	Section 4.11(a)
Investor	Preamble
Modified Clause	Section 11.6
Shares	Section 2.1
Signing Date	Preamble

2. Purchase and Sale of Common Stock.

2.1 General. Subject to the terms and conditions of this Agreement, at the Closing, the Company shall issue and sell to the Investor and the Investor shall purchase from the Company, a number of shares of Common Stock (the "**Shares**") calculated pursuant to Section 2.2 hereof.

2.2 Calculation. The number of Shares shall be 4,179,728, which is calculated by dividing the Aggregate Purchase Price by the Per-Share Purchase Price, rounded down to the nearest whole share.

3. Closing Date; Deliveries.

3.1 Closing Date. The closing of the purchase and sale of the Shares hereunder (the "**Closing**") shall take place remotely via the exchange of documents and signatures at 9:00 a.m. New York City time on the second (2nd) Business Day following the satisfaction or waiver of all of the Closing Conditions (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction at such time of such conditions), or at such other time, date, and location as the parties may agree. The date the Closing occurs is hereinafter referred to as the "**Closing Date**."

3.2 Deliveries.

(a) Deliveries by the Company. At the Closing, the Company shall deliver, or cause to be delivered, to the Investor the Shares, registered in the name of the Investor, and the Company shall instruct its transfer agent to register such issuance at the time of such issuance. The Company shall also deliver at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 6 and 8.2 hereof have been fulfilled and (ii) a certificate of the secretary or assistant secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the Amended and Restated By-laws of the Company as in effect at the time of the actions by the Board referred to in clause (B) below and on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board authorizing the execution, delivery and performance of the Transaction Agreements and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby and thereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the Company's Fifth Amended and Restated Certificate of Incorporation as in effect at the time of the actions by the Board referred to in clause (B) above and on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing a Transaction Agreement on behalf of the Company.

(b) Deliveries by the Investor. At the Closing, the Investor shall deliver, or cause to be delivered, to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by

the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than two (2) Business Days before the Closing Date. The Investor shall also deliver, or cause to be delivered, at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Company duly executed by an authorized executive officer of the Investor certifying that the conditions to Closing set forth in Section 7 hereof have been fulfilled and (ii) a certificate of the secretary or assistant secretary of the Investor dated as of the Closing Date certifying as to the incumbency and specimen signature of any officer executing a Transaction Agreement on behalf of the Investor.

4. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that:

4.1 Organization, Good Standing and Qualification.

(a) The Company has been duly organized and is validly existing and in good standing under the laws of its jurisdiction of organization, is duly qualified to do business and is in good standing in each jurisdiction in which its ownership or lease of property or the conduct of its businesses requires such qualification, and has all power and authority necessary to own or hold its properties and to conduct the businesses in which it is engaged, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a Material Adverse Effect.

(b) The Company has all requisite corporate power and corporate authority to enter into the Transaction Agreements and the Collaboration Agreement, to issue and sell the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements and the Collaboration Agreement.

4.2 Capitalization and Voting Rights.

(a) As of the Signing Date, the authorized capital of the Company consists of: (i) 120,000,000 shares of Common Stock of which, (A) 32,601,748 shares are issued and outstanding, (B) 4,886,021 shares are issuable upon the exercise of outstanding stock options or upon the settlement of outstanding equity awards issued pursuant to the 2014 Stock Option and Grant Plan or the 2015 Stock Option and Incentive Plan, (C) 2,259,224 shares are reserved for future issuance pursuant to the 2015 Stock Option and Incentive Plan, and (D) 1,289,093 shares are reserved for future issuance pursuant to the 2015 Employee Stock Purchase Plan, as amended to date and as the same may be amended and/or restated from time to time, and (ii) 5,000,000 shares of preferred stock, par value $0.001 per share, of which no shares are issued and outstanding. The Company is also party to the Sales Agreement pursuant to which the Company may issue and sell shares of its Common Stock having an aggregate offering price of up to $75,000,000 through Cowen and Company, LLC, from time to time, in “at-the-market” offerings or certain negotiated transactions. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued and

are fully paid and non-assessable, were issued in compliance with federal and state securities Laws, and are not subject to any pre-emptive rights.

(b) Except as described or referred to in Section 4.2(a) above and as provided in the Investor Agreement, as of the Signing Date, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company, or any contract, commitment, agreement, understanding or arrangement of any kind relating to the issuance of any capital stock of the Company, any such convertible or exchangeable securities or any such rights, warrants or options.

(c) Except as disclosed in the Company SEC Documents, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company.

(d) The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration.

4.3 Subsidiaries. As of the Signing Date, the Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Schedule 1 hereto. All the outstanding shares of capital stock or other equity interests of each subsidiary owned, directly or indirectly, by the Company have been duly authorized and validly issued, are fully paid and non-assessable (except, in the case of any foreign subsidiary, for directors' qualifying shares) and are owned directly or indirectly by the Company, free and clear of any lien, charge, encumbrance, security interest, restriction on voting or transfer or any other claim of any third party.

4.4 Authorization.

(a) The Company has full right, power and authority to execute and deliver the Transaction Agreements and the Collaboration Agreement and to perform its obligations hereunder and thereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of each of the Transaction Agreements and the Collaboration Agreement and the consummation by it of the transactions contemplated thereby has been duly and validly taken.

(b) The Transaction Agreements and the Collaboration Agreement have been duly executed and delivered by the Company and, upon the due execution and delivery of the Transaction Agreements and the Collaboration Agreement by the Investor, will constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms, except, with respect to the Investor Agreement and the Collaboration Agreement, as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or

similar laws affecting creditors' rights generally or by equitable principles relating to enforceability (collectively, the "**Enforceability Exceptions**").

(c) No stop order or suspension of trading of the Common Stock has been imposed by the Nasdaq Stock Market, the SEC or any other Governmental Authority and remains in effect.

4.5 No Defaults. The Company is not (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party, by which the Company is bound or to which any of the property or assets of the Company is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect.

4.6 No Conflicts. The execution, delivery and performance of the Transaction Agreements and the Collaboration Agreement, the issuance and sale of the Shares and the consummation of the transactions contemplated by the Transaction Agreements and the Collaboration Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party, by which the Company is bound or to which any of the property or assets of the Company is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a Material Adverse Effect.

4.7 No Governmental Authority or Third Party Consents. No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of each of the Transaction Agreements or the Collaboration Agreement or the issuance and sale of the Shares, except (i) such filings as may be required to be made with the SEC and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws, (ii) as required pursuant to the HSR Act and (iii) with respect to the Shares, the filing with the Nasdaq Stock Market of, and the absence of unresolved issues with respect to, an LAS and, if required, a Nasdaq Shares Outstanding Change Form.

4.8 Valid Issuance of Shares. When issued, sold and delivered at the Closing in accordance with the terms hereof for the Aggregate Purchase Price, the Shares shall be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including pre-emptive rights, rights of first refusal or other similar rights, other than as arising pursuant to the Transaction Agreements, as a result of any action by the Investor or under federal or state securities Laws.

4.9 Litigation. There are no legal, governmental or regulatory investigations, actions, suits or proceedings pending to which the Company is a party or to which any property of the Company is subject that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect; and no such investigations, actions, suits or proceedings are, to the knowledge of the Company, threatened or contemplated by any governmental or regulatory authority or others.

4.10 Licenses and Other Rights; Compliance with Laws. The Company and its subsidiaries possess or are in the process of obtaining all licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Company SEC Documents, except where the failure to possess or make the same would not, individually or in the aggregate, have a Material Adverse Effect; and except as described in the Company SEC Documents, neither the Company nor any of its subsidiaries has received notice of any revocation or modification of any such license, certificate, permit or authorization or has any reason to believe that any such license, certificate, permit or authorization will not be renewed. The Company and its subsidiaries are, and at all times since January 1, 2017, have been, in compliance with all statutes, rules and regulations applicable to the ownership, packaging, processing, use, distribution, import, or export of any product manufactured or distributed by the Company or its subsidiaries, except where such noncompliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

4.11 Company SEC Documents; Financial Statements; Nasdaq Stock Market.

(a) Since January 1, 2017, the Company has timely filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein) required to be filed by it under the Securities Act and the Exchange Act, and any required amendments to any of the foregoing, with the SEC (the "**Company SEC Documents**"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act, the Exchange Act, and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact

required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) As of the Signing Date, there are no outstanding or unresolved comments in comment letters received from the SEC or its staff.

(c) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in its quarterly reports on Form 10-Q for the quarterly periods ended March 31, 2018; June 30, 2018; and September 30, 2018 present fairly the financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified; such financial statements have been prepared in conformity with GAAP applied on a consistent basis throughout the periods covered thereby, except as otherwise disclosed therein and, in the case of unaudited, interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes, and any supporting schedules included in the Company SEC Documents present fairly the information required to be stated therein.

(d) The Common Stock is listed on the Nasdaq Stock Market, and the Company has taken no action designed to, or which is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Nasdaq Stock Market. The Company has not received any notification that, and has no knowledge that, the SEC or the Nasdaq Stock Market is contemplating terminating such listing or registration.

(e) The Company and its subsidiaries have established systems of “internal control over financial reporting” (as defined in Rule 13a-15(f) of the Exchange Act) that have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting control sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management’s general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (v) interactive data in eXtensible Business Reporting Language included in the Company SEC Documents fairly presents the information called for in all material respects and is prepared in accordance with the SEC’s rules and guidelines applicable thereto. Except as disclosed in the Company SEC Documents, there are no material weaknesses in the Company’s internal controls. The Company’s auditors and the Audit Committee of the Board have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which have adversely affected or are reasonably likely to adversely affect the Company’s ability to record, process, summarize and report financial

information; and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

(f) The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) that comply with the requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management to allow timely decisions regarding disclosures. The Company has conducted evaluations of the effectiveness of its disclosure controls as required by Rule 13a-15 of the Exchange Act.

(g) There is and has been no material failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including Section 402 related to loans and Sections 302 and 906 related to certifications.

4.12 Absence of Certain Changes.

(a) Except as disclosed in the Company SEC Documents, since September 30, 2018, (i) there has not been any material change in the capital stock (other than (x) the issuance of shares of Common Stock upon exercise of stock options, the settlement of equity awards and the exercise of warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Company SEC Documents and (y) the issuance of shares of Common Stock, options and equity awards granted to new employees of the Company as inducement awards pursuant to Nasdaq Listing Rule 5635(c)(4)), short-term debt or long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development that would reasonably be expected to result in a material adverse change, in or affecting the business, properties, management, financial position, stockholders' equity, results of operations of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority.

4.13 Offering. Subject to the accuracy of the Investor's representations set forth in Sections 5.5, 5.6, 5.7, 5.9, and 5.10 hereof, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption.

4.14 No Integration. The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act), that is or will be integrated with the sale of the Shares in a manner that would require registration of the Shares under the Securities Act.

4.15 Brokers' or Finders' Fees. Except with respect to the Company Financial Advisors, neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any of its subsidiaries for a brokerage commission, finder's fee or like payment in connection with the transactions contemplated by the Transaction Agreements and the Collaboration Agreement.

4.16 Investment Company. The Company is not and, immediately after giving effect to the offering and sale of the Shares and the application of the proceeds thereof, will not be required to register as an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the SEC thereunder.

4.17 No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Shares by any form of general solicitation or general advertising. The Company has offered the Shares for sale only to the Investor.

4.18 Foreign Corrupt Practices. Neither the Company nor, to the knowledge of the Company, any agent or other person acting on behalf of the Company, has: (i) directly or indirectly used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable non-U.S. anti-bribery Law.

4.19 Regulation M Compliance. The Company has not taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Stock to facilitate the sale or resale of the Shares.

4.20 Office of Foreign Assets Control. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or Affiliate of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

4.21 Development Matters.

(a) All preclinical and clinical studies conducted by or on behalf of the Company to support approval for commercialization of the Company's products have been conducted by the Company, or to the Company's knowledge by third parties, in compliance with all applicable federal, state or foreign laws, rules, orders and regulations, except for such failure or failures to be in compliance which would not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect.

(b) The studies, tests and preclinical or clinical trials conducted by or on behalf of the Company that are described in the Company SEC Documents (the "**Company Studies and Trials**") were and, if still pending, are being, conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional scientific standards; the descriptions of the results of the Company Studies and Trials contained in the Company SEC Documents are accurate in all material respects; the Company has no knowledge of any other studies or trials not described in the Company SEC Documents, the results of which are inconsistent with or call in question the results described or referred to in the Company SEC Documents; and the Company has not received any notices or correspondence from the United States Food and Drug Administration (the "**FDA**") or any foreign, state or local governmental authority exercising comparable authority requiring the termination, suspension or material modification of any Company Studies and Trials that termination, suspension or material modification would reasonably be expected to have a Material Adverse Effect and, to the Company's knowledge, there are no reasonable grounds for the same. The Company has obtained (or caused to be obtained) informed consent by or on behalf of each human subject who participated in the Company Studies and Trials. To the Company's knowledge, none of the Company Studies and Trials involved any investigator who has been disqualified as a clinical investigator or has been found by the FDA to have engaged in scientific misconduct. To the Company's knowledge, the manufacturing facilities and operations of its suppliers are operated in compliance in all material respects with all applicable statutes, rules, regulations and policies of the FDA and comparable governmental authorities outside of the United States to which the Company is subject.

4.22 Intellectual Property. The Company owns, possesses, or can acquire on reasonable terms the right to use all (i) patents, patent applications, trademarks, trademark registrations, service marks, service mark registrations, Internet domain name registrations, copyrights, copyright registrations, licenses and trade secret rights (collectively, "**Intellectual Property Rights**") and (ii) inventions, software, works of authorships, trademarks, service marks, trade names, databases, formulae, know how, Internet domain names and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or

procedures) (collectively, "**Intellectual Property Assets**") necessary to conduct its business as currently conducted, and as proposed to be conducted and described in the SEC Documents. The Company has not received any opinion from its legal counsel concluding that any activities of its business infringes, misappropriates, or otherwise violates, valid and enforceable Intellectual Property Rights of any other person, and has not received written notice of any challenge, which is to its knowledge still pending, by any other person to the rights of the Company with respect to any Intellectual Property Rights or Intellectual Property Assets owned or used by the Company. To the Company's knowledge, the Company's business as now conducted does not give rise to any infringement of, any misappropriation of, or other violation of, any valid and enforceable Intellectual Property Rights of any other person. All licenses for the use of the Intellectual Property Rights described in the SEC Documents are valid, binding upon, and enforceable by or against the Company, and to the Company's knowledge, by or against the parties thereto in accordance with their terms. The Company has complied in all material respects with, and is not in breach of, nor has it received any asserted or threatened claim of breach of any intellectual property licenses for the use of the Intellectual Property Rights, and the Company has no knowledge of any breach or anticipated breach by any other person of any such intellectual property licenses. No claim has been made or is pending against the Company alleging the infringement by the Company of any patent, trademark, service mark, trade name, copyright, trade secret, license in or other intellectual property right or franchise right of any person. The Company has taken reasonable steps to protect, maintain and safeguard its Intellectual Property Rights, including the execution of appropriate nondisclosure and confidentiality agreements. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other person in respect of, the Company's right to own, use, or hold for use any of the Intellectual Property Rights as owned, used or held for use in the conduct of the business as currently conducted. The Company has at all times complied in all material respects with all applicable laws relating to privacy, data protection, and the collection and use of personal information collected, used, or held for use by the Company in the conduct of the Company's business. No claims have been asserted or threatened against the Company alleging a violation of any person's privacy or personal information or data rights and the consummation of the transactions contemplated hereby will not breach or otherwise cause any violation of any law related to privacy, data protection, or the collection and use of personal information collected, used, or held for use by the Company in the conduct of the Company's business. The Company takes reasonable measures to ensure that such information is protected against unauthorized access, use, modification or other misuse. The Company has taken all necessary actions to secure and record its ownership of all works of authorship and inventions made by its employees, consultants and contractors with an obligation of assignment during the time they were employed by or under contract with the Company and which relate to the Company's business. All founders and key employees have signed confidentiality and invention assignment agreements with the Company.

4.23 Real and Personal Property. The Company has good and marketable title in fee simple (in the case of real property) to, or has valid and marketable

rights to lease or otherwise use, all items of real or personal property, which are material to the business of the Company taken as a whole, in each case free and clear of all liens, encumbrances, security interests, claims and defects that do not, singularly or in the aggregate, materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company; and all of the leases and subleases material to the business of the Company, and under which the Company holds properties described in the SEC Documents, are in full force and effect and the Company has not received any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company to the continued possession of the leased or subleased premises under any such lease or sublease.

4.24 Labor and Employment. There is (a) no unfair labor practice complaint pending against the Company, nor to the Company's knowledge, threatened against it, before the National Labor Relations Board, any state or local labor relations board or any foreign labor relations board, and no significant grievance or significant arbitration proceeding arising out of or under any collective bargaining agreement is so pending against the Company, or, to the Company's knowledge, threatened against it and (b) no labor disturbance by or dispute with, employees of the Company exists or, to the Company's knowledge, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers, customers or contractors, that would reasonably be expected, singularly or in the aggregate, to have a Material Adverse Effect. The Company is not aware that any key employee or significant group of employees of the Company plans to terminate employment with the Company.

4.25 ERISA Matters. No "prohibited transaction" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("**ERISA**"), or Section 4975 of the Internal Revenue Code of 1986, as amended from time to time (the "**Code**")) or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred or could reasonably be expected to occur with respect to any employee benefit plan of the Company which would, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. Each employee benefit plan of the Company is in compliance in all material respects with applicable law, including ERISA and the Code. The Company has not incurred and would not reasonably be expected to incur liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified, and nothing has occurred, whether by action or by failure to act, which would, singularly or in the aggregate, reasonably be expected to cause the loss of such qualification.

4.26 Environmental Matters. The Company is in compliance in all material respects with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to its businesses (the "**Environmental Laws**"). There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company (or, to the Company's knowledge, any other entity for whose acts or omissions the Company is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability; and there has been no disposal, discharge, emission or other release of any kind on to such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances.

4.27 Taxes. The Company (i) has timely filed all necessary federal, state, local and foreign tax returns (or timely filed extensions with respect to such returns), and all such returns were true, complete and correct, (ii) has paid all federal, state, local and foreign taxes, assessments, governmental or other charges due and payable for which it is liable, including, without limitation, all sales and use taxes and all taxes which the Company is obligated to withhold from amounts owing to employees, creditors and third parties, and (iii) does not have any tax deficiency or claims outstanding or assessed or, to its knowledge, proposed against it, except those, in each of the cases described in clauses (i), (ii) and (iii) above, that would not, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company has not engaged in any transaction which is a corporate tax shelter or which could be characterized as such by the Internal Revenue Service or any other taxing authority. The accruals and reserves on the books and records of the Company in respect of tax liabilities for any taxable period not yet finally determined are adequate to meet any assessments and related liabilities for any such period, and since January 1, 2017, the Company has not incurred any liability for taxes other than in the ordinary course.

4.28 Insurance. The Company carries or is covered by, insurance in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses, at a similar stage of development, in similar industries. The Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect. All policies of insurance owned by the Company are, to the Company's knowledge, in full force and effect and the Company is in compliance in all material respects with the terms of such policies. The Company has not received written notice from any insurer, agent of such insurer or the broker of the Company that any material capital improvements or any other material expenditures (other than premium

payments) are required or necessary to be made in order to continue such insurance. Except for customary deductibles, the Company does not insure risk of loss through any captive insurance, risk retention group, reciprocal group or by means of any fund or pool of assets specifically set aside for contingent liabilities other than as described in the SEC Documents.

5. Representations and Warranties of the Investor. The Investor hereby represents and warrants to the Company that:

5.1 Organization; Good Standing. The Investor is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Investor has all requisite corporate power and corporate authority to enter into the Transaction Agreements, to purchase the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements.

5.2 Authorization.

(a) The Investor has full right, power and authority to execute and deliver the Transaction Agreements and the Collaboration Agreement and to perform its obligations hereunder and thereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of each of the Transaction Agreements and the Collaboration Agreement and the consummation by it of the transactions contemplated thereby has been duly and validly taken.

(b) The Transaction Agreements and the Collaboration Agreement have been duly executed and delivered by the Investor and, upon the due execution and delivery of the Transaction Agreements and the Collaboration Agreement by the Company, will constitute valid and legally binding obligations of the Investor, enforceable against the Investor in accordance with their respective terms, except with respect to the Enforceability Exceptions.

5.3 No Conflicts. The execution, delivery and performance of the Transaction Agreements and the Collaboration Agreement, the subscription for and purchase of the Shares and the consummation of the transactions contemplated by the Transaction Agreements and the Collaboration Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Investor pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Investor is a party, by which the Investor is bound or to which any of the property or assets of the Investor is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Investor or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Investor or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a material adverse effect on

the Investor's ability to perform its obligations or consummate the Transaction in accordance with the terms of this Agreement.

5.4 No Governmental Authority or Third Party Consents. No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Investor of each of the Transaction Agreements or the Collaboration Agreement or with the subscription for and purchase of the Shares, except as required pursuant to the HSR Act.

5.5 Purchase Entirely for Own Account. The Investor acknowledges that the Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation or otherwise distributing the Shares. The Investor can bear the economic risk of an investment in the Shares indefinitely and a total loss with respect to such investment. The Investor does not have and will not have as of the Closing any contract, undertaking, agreement, arrangement or understanding with any Person to sell, transfer or grant participation to a Person any of the Shares.

5.6 Disclosure of Information. The Investor has received or has had full access to all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.

5.7 Investment Experience and Accredited Investor Status. The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.

5.8 Acquiring Person. As of the Signing Date, neither the Investor nor any of its Affiliates beneficially owns, and immediately prior to the Closing, neither the Investor nor any of its Affiliates will beneficially own (in each case, as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership, and without regard to Investor's rights under this Agreement), any securities of the Company, except for securities that may be beneficially owned by employee benefit plans of either the Investor or any of its Affiliates.

5.9 Restricted Securities. The Investor understands that the Shares, when issued, shall be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under

the Securities Act only in certain limited circumstances. The Investor represents that it is familiar with Rule 144, as presently in effect.

5.10 Legends. The Investor understands that any certificates representing the Shares shall bear the following legends:

(a) "THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER THE SECURITIES ACT OR AN OPINION OF COUNSEL (WHICH COUNSEL SHALL BE REASONABLY SATISFACTORY TO THE COMPANY) THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF THE SECURITIES ACT.";

(b) "THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO AND SHALL BE TRANSFERABLE ONLY UPON THE TERMS AND CONDITIONS OF AN INVESTOR AGREEMENT DATED AS OF JANUARY 28, 2019, BY AND BETWEEN VOYAGER THERAPEUTICS, INC. AND NEUROCRINE BIOSCIENCES, INC., A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF VOYAGER THERAPEUTICS, INC."; and

(c) any legend required by applicable state securities Laws or the other Transaction Agreements.

5.11 Financial Assurances. As of the Signing Date, the Investor has, and as of the Closing Date, the Investor will have, access to cash in an amount sufficient to pay to the Company the Aggregate Purchase Price.

5.12 SEC Reports. The Investor has reviewed the Company SEC Documents.

6. Investor's Conditions to Closing. The Investor's obligation to purchase the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Investor):

6.1 Representations and Warranties. The representations and warranties made by the Company in Section 4 hereof shall be true and correct as of the Signing Date and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 6.1, all such representations and warranties of the Company (other than Sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, and 4.11 hereof) shall be deemed to be true and correct for purposes of this Section 6.1 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material," "materiality" or "Material Adverse Effect" qualifiers set forth therein, constitute a Material Adverse Effect.

6.2 Representations and Warranties in the Collaboration Agreement. The representations and warranties made by the Company in Section 12.2 of the Collaboration Agreement shall be true and correct as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 6.2, all such representations and warranties of the Company shall be deemed to be true and correct for purposes of this Section 6.2 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material" or "materiality" qualifiers set forth therein, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

6.3 Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.

6.4 Investor Agreement. The Investor Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.

6.5 Collaboration Agreement. The Collaboration Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect as of the Closing Date.

6.6 No Material Adverse Effect. From and after the Signing Date until the Closing Date, there shall have occurred no event that has caused a Material Adverse Effect.

6.7 Listing. The Shares shall be eligible and approved for listing on the Nasdaq Stock Market.

7. Company's Conditions to Closing. The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Company):

7.1 Representations and Warranties. The representations and warranties made by the Investor in Section 5 hereof shall be true and correct as of the Signing Date and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date.

7.2 Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Investor on or prior to the Closing Date shall have been performed or complied with in all material respects.

7.3 Investor Agreement. The Investor Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.

7.4 Collaboration Agreement. The Collaboration Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.

8. Mutual Conditions to Closing. The obligations of the Investor and the Company to consummate the Closing are subject to the fulfillment as of the Closing Date of the following conditions:

8.1 HSR Act Qualification. Any required HSR Clearances shall have been obtained.

8.2 Absence of Litigation. There shall be no action, suit, proceeding or investigation by a Governmental Authority pending or currently threatened in writing against the Company or the Investor (i) that questions (A) the validity of any Transaction Agreement or (B) the right of the Company or the Investor to enter into any Transaction Agreement or to consummate the transactions contemplated hereby or thereby or (ii) which, if determined adversely, would impose substantial monetary damages on the Company or the Investor as a result of the consummation of the transactions contemplated by any Transaction Agreement.

8.3 No Prohibition. No provision of any applicable Law and no judgment, injunction (preliminary or permanent), order or decree that prohibits, makes illegal or enjoins the consummation of the Transaction shall be in effect.

9. Termination.

9.1 Ability to Terminate. This Agreement may be terminated at any time prior to the Closing by:

(a) mutual written consent of the Company and the Investor;

(b) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 8 hereof shall have become incapable of fulfillment by the Termination Date and shall not have been waived in writing by the other party within ten business days after receiving receipt of written notice of an intention to terminate pursuant to this clause (b); provided, however, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date;

(c) the Company, upon written notice to the Investor, so long as the Company is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 6.1, 6.2, 6.3, 6.4 or 6.5 hereof, as applicable, could not be satisfied by the Termination Date, (i) upon a material breach of any covenant or agreement on the part of the Investor set forth in this Agreement, or (ii) if any representation or warranty of the Investor shall have

been or become untrue, in each case such that any of the conditions set forth in Section 7.1, 7.2, 7.3 or 7.4 hereof, as applicable, could not be satisfied by the Termination Date;

(d) the Investor, upon written notice to the Company, so long as the Investor is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 7.1, 7.2, 7.3, or 7.4 hereof, as applicable, could not be satisfied by the Termination Date, (i) upon a material breach of any covenant or agreement on the part of the Company set forth in this Agreement, or (ii) if any representation or warranty of the Company shall have been or become untrue, in each case such that any of the conditions set forth in Section 6.1, 6.2, 6.3, 6.4 or 6.5 hereof, as applicable, could not be satisfied by the Termination Date.

9.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 9.1 hereof, (i) this Agreement (except for this Section 9.2 and Section 11 hereof (other than Section 11.12), and any definitions set forth in this Agreement and used in such sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and (ii) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 9.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

10. Additional Covenants and Agreements.

10.1 Market Listing. From the Signing Date through the Closing Date, Company shall use all commercially reasonable efforts to (i) maintain the listing and trading of the Common Stock on the Nasdaq Stock Market and (ii) effect the listing of the Shares on the Nasdaq Stock Market, including submitting the LAS to the Nasdaq Stock Market no later than fifteen (15) calendar days prior to the Closing Date.

10.2 Notification under the HSR Act. Each party will use reasonable efforts to do, or cause to be done, all things necessary, proper and advisable to, as promptly as practicable, take all actions necessary to make the filings required of such party or its Affiliates under the HSR Act, including filing with the FTC and Antitrust Division of the DOJ within ten (10) Business Days of the Signing Date (or such later time as may be agreed to in writing by the parties). The parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing and during the review by the FTC and/or the Antitrust Division of the DOJ. Each party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; provided, however, that the Investor shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of the Company) required to be paid to any Governmental Agency in connection with making any such HSR Filing. This Agreement shall terminate at the election of either party, immediately upon notice to the other party, if the FTC or the DOJ seeks a preliminary injunction (or its equivalent) in connection therewith against the Investor and the

Company to enjoin the transactions contemplated hereby and thereby. In the event of such termination, this Agreement shall be of no further force and effect.

10.3 Assistance and Cooperation. Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including using all reasonable efforts to accomplish the following: (i) taking all reasonable acts necessary to cause the conditions precedent set forth in Sections 6, 7 and 8 hereof to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from the Nasdaq Stock Market with respect to the LAS); (ii) taking all reasonable actions necessary to obtain all necessary actions or non-actions, waivers, consents, approvals, orders and authorizations from Governmental Authorities and the making of all necessary registrations, declarations and filings (including registrations, declarations and filings with Governmental Authorities, if any); (iii) taking all reasonable actions necessary to obtain all necessary consents, approvals or waivers from Third Parties; and (iv) except as otherwise provided for in Section 10.2 hereof, defending any suits, claims, actions, investigations or proceedings, whether judicial or administrative, challenging this Agreement or the consummation of the transactions contemplated hereby, including seeking to have any stay or temporary restraining order entered by any court or other Governmental Authority vacated or reversed.

10.4 Legend Removal.

(a) Certificates evidencing the Shares shall not contain the legend set forth in Section 5.10(a) hereof: (i) following a sale of such Shares pursuant to a registration statement covering the resale of such Shares, while such registration statement is effective under the Securities Act, (ii) following any sale of such Shares pursuant to Rule 144, (iii) if such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions under Rule 144 or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the SEC).

(b) Certificates evidencing the Shares shall not contain the legend set forth in Section 5.10(b) hereof following: (i) a sale of such Shares pursuant to a registration statement covering the resale of such Shares, while such registration statement is effective under the Securities Act, (ii) any sale of such Shares pursuant to Rule 144 or (iii) the expiration of the Standstill Term (as defined in the Investor Agreement), the Lock-Up Term (as defined in the Investor Agreement) and the Voting Agreement Term (as defined in the Investor Agreement); provided that any transfer described in clause (i) or (ii) above shall have been in compliance with all applicable provisions of the Investor Agreement.

(c) The Company agrees that at such time as any legend set forth in Section 5.10 hereof is no longer required under this Section 10.4, the Company will, no later than three (3) Business Days following the delivery by the Investor to the Company or notice by the Investor to the Company of delivery by the Investor to the Transfer Agent of a certificate representing Shares issued with such legend (together with any legal opinion required by the Transfer Agent), deliver or cause to be delivered to the Investor a certificate representing such Shares that is free from such legend, or, in the event that such shares are uncertificated, remove any such legend in the Company's stock records. The Company may not make any notation on its records or give instructions to the Transfer Agent that enlarge the restrictions on transfer set forth in Section 5.10 hereof.

10.5 Conduct of Business. During the period from the Signing Date until the Closing, except as consented to in writing by the Investor, the Company shall not (i) declare, set aside or pay any dividend or make any other distribution or payment (whether in cash, stock or property or any combination thereof) in respect of its capital stock, or establish a record date for any of the foregoing, or (ii) make any other actual, constructive or deemed distribution in respect of any shares of its capital stock or otherwise make any payments to stockholders in their capacity as such, except pursuant to repurchases of equity pursuant to the terms of its equity compensation plans.

11. Miscellaneous.

11.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 11.3 hereof or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

11.2 Waiver. Neither party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term except to the extent set forth in writing.

11.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit A attached hereto and shall be (i) delivered personally; (ii) sent by certified mail (return receipt requested), postage prepaid; or (iii) sent via a reputable nationwide overnight express courier service (signature required). Any such notice, instruction or communication shall be deemed to have been delivered (A) upon receipt if delivered by hand; (B) three (3) Business Days after it is sent by certified mail, return receipt requested, postage prepaid; or (C) one (1) Business Day after it is sent via a reputable nationwide overnight courier service. Either party may change its address by giving notice to the other party in the manner provided above; provided that notices of a change of address shall be effective only upon receipt thereof.

11.4 Entire Agreement. This Agreement, the Investor Agreement and the Collaboration Agreement, in each case together with the schedules and exhibits thereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the parties and supersede and terminate all prior agreements and understanding between the parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties unless reduced to writing and signed by the respective authorized officers of the parties.

11.5 Headings; Nouns and Pronouns; Section References. Headings and any table of contents used in this Agreement are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

11.6 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

11.7 Assignment. Except for an assignment of this Agreement or any rights hereunder by the Investor to an Affiliate, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (i) the prior written consent of Company in the case of any assignment by the

Investor or (ii) the prior written consent of the Investor in the case of an assignment by the Company.

11.8 Parties in Interest. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the parties hereto and their respective successors, heirs, administrators and permitted assigns.

11.9 Counterparts. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

11.10 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

11.11 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either party.

11.12 Survival of Warranties. The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing and the delivery of the Shares.

11.13 Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

11.14 Expenses. Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of the Transaction Agreements.

11.15 No Publicity. The parties hereto agree that the provisions of Section 11.3 of the Collaboration Agreement shall be applicable to the parties to this Agreement with respect to any public disclosures regarding the proposed transactions contemplated by the Transaction Agreements and the Collaboration Agreement or regarding the parties hereto or their Affiliates (it being understood that the provisions of Section 11.3 of the Collaboration Agreement shall be read to apply to disclosures of information relating to this Agreement and the transactions contemplated hereby).

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

NEUROCRINE BIOSCIENCES, INC.

By: /s/ Kevin Gorman
Name: Kevin Gorman
Title: CEO

VOYAGER THERAPEUTICS, INC.

By: /s/ G. Andre Turenne
Name: G. Andre Turenne
Title: President and Chief Executive Officer

(Signature Page to Stock Purchase Agreement)

SCHEDULE 1

LIST OF SUBSIDIARIES

1. Voyager Securities Corporation, a Massachusetts corporation

EXHIBIT A

NOTICES

If to the Investor:

Neurocrine Biosciences, Inc.
12780 El Camino Real
San Diego, CA 92130
Attention: General Counsel

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Attention: Jason L. Kent, Esq.

If to the Company:

Voyager Therapeutics, Inc.
75 Sidney Street
Cambridge, MA 02139
Attention: Chief Executive Officer

with a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Attention: Brian A. Johnson, Esq.

Exhibit B

VOYAGER LICENSED PATENT RIGHTS

Exhibit B

Voyager Ref	Status	Application No. Publication No. Patent No.	Filing Date/ Pub Date/ Issue Date	Assignment Recordation Date; Reel/Frame	Named Inventors	Application Title
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Exhibit C

SCHEDULE OF EXCEPTIONS

None.

Exhibit 10.6

EXECUTION VERSION

STOCK PURCHASE AGREEMENT

By and Between

NEUROCRINE BIOSCIENCES, INC.

AND

VOYAGER THERAPEUTICS, INC.

Dated as of January 28, 2019

TABLE OF CONTENTS

STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "**Agreement**"), dated as of January 28, 2019 (the "**Signing Date**"), by and between Neurocrine Biosciences, Inc. (the "**Investor**"), a Delaware corporation with its principal place of business at 12780 El Camino Real, San Diego, CA 92130, and Voyager Therapeutics, Inc. (the "**Company**"), a Delaware corporation, with its principal place of business at 75 Sidney Street, Cambridge, MA 02139.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value $0.001 per share, of the Company (the "**Common Stock**"); and

WHEREAS, simultaneously with the execution of this Agreement, the Company and the Investor are entering into the Collaboration Agreement and the Investor Agreement.

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor and the Company agree as follows:

1. Definitions.

1.1 Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"**2014 Stock Option and Grant Plan**" shall mean the Company's 2014 Stock Option and Grant Plan, as amended to date and as the same may be amended and/or restated from time to time.

"**2015 Employee Stock Purchase Plan**" shall mean the Company's 2015 Employee Stock Purchase Plan, as amended to date and as the same may be amended and/or restated from time to time.

"**2015 Stock Option and Incentive Plan**" shall mean the Company's 2015 Stock Option and Incentive Plan, as amended to date and as the same may be amended and/or restated from time to time.

"**Affiliate**" shall mean, with respect to any Person, another Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if such Person (ii) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

"**Aggregate Purchase Price**" shall mean $50,000,000.00.

"**Agreement**" shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.

"**Board**" shall mean the Board of Directors of the Company.

"**Business Day**" shall mean a day on which banking institutions in Boston, Massachusetts, United States and San Diego, California, United States are open for business, excluding any Saturday or Sunday.

"**Closing Conditions**" shall mean the conditions to Closing set forth in Sections 6, 7, and 8 hereof.

"**Collaboration Agreement**" shall mean the Collaboration and License Agreement, of even date herewith, between the Investor and the Company.

"**Company Financial Advisors**" shall mean Guggenheim Securities, LLC and Chestnut Securities, Inc.

"**DOJ**" shall mean the U.S. Department of Justice.

"**Effect**" shall have the meaning set forth in the definition of "Material Adverse Effect."

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

"**FTC**" shall mean the U.S. Federal Trade Commission.

"**GAAP**" shall mean generally accepted accounting principles in the United States.

"**Governmental Authority**" shall mean any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.

"**HSR Act**" shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended from time to time.

"**HSR Clearance**" shall mean the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the HSR Act.

"**HSR Filing**" shall mean the filings by the Company and Investor with the FTC and the Antitrust Division of the DOJ of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in the Transaction Agreements and the Collaboration Agreement, together with all required documentary attachments thereto.

"**Investor Agreement**" shall mean that certain Investor Agreement, of even date herewith, between the Investor and the Company.

"LAS" shall mean the Nasdaq Notification Form: Listing of Additional Shares.

"**Law"** shall mean any law, statute, rule, regulation, order, judgment or ordinance having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

"**Material Adverse Effect**" shall mean any change, event or occurrence (each, an "**Effect**") that, individually or when taken together with all other Effects that have occurred prior to the date of determination of the occurrence of the Material Adverse Event, has had a material adverse effect on the business, properties, management, financial position, stockholders' equity or results of operations of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under the Transaction Agreements, except to the extent that any such Effect results from or arises out of: (A) changes in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (B) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles in the United States or interpretations thereof, (C) acts of war, sabotage or terrorism, or any escalation or worsening of any such acts of war, sabotage or terrorism, (D) earthquakes, hurricanes, floods or other natural disasters, (E) the announcement of the Transaction Agreements, the Collaboration Agreement or the Transaction, (F) any change in the Company's stock price or trading volume or any failure to meet internal projections or forecasts or published revenue or earnings projections of industry analysts (provided that the underlying events giving rise to any such change shall not be excluded) or (G) any breach, violation or non-performance by the Investor or any of its Affiliates under the Collaboration Agreement, provided, however, that the Effects excluded in clauses (A), (B), (C) and (D) shall only be excluded to the extent such Effects are not disproportionately adverse on the Company and its subsidiaries as compared to other companies operating in the Company's industry.

"**Per-Share Purchase Price**" shall mean $11.9625.

"**Person"** shall mean any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

"**Rule 144**" shall mean Rule 144 promulgated under the Securities Act.

"**Sales Agreement**" shall mean that certain Sales Agreement, by and between the Company and Cowen and Company, LLC, dated as of December 1, 2016.

"**SEC**" shall mean the U.S. Securities and Exchange Commission.

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

"**Termination Date**" shall mean the date that is one hundred and eighty (180) days after the effective date of the HSR Filing.

"**Third Party"** shall mean any Person other than the Investor, the Company or any Affiliate of the Investor or the Company.

"**Transaction"** shall mean the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor, in accordance with the terms hereof.

"**Transaction Agreements"** shall mean this Agreement and the Investor Agreement.

"**Transfer Agent**" shall mean the Company's transfer agent.

1.2 Additional Defined Terms. In addition to the terms defined in Section 1.1 hereof, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

Defined Term	Section
Closing	Section 3.1
Closing Date	Section 3.1
Common Stock	Preamble
Company	Preamble
Company SEC Documents	Section 4.11(a)
Investor	Preamble
Modified Clause	Section 11.6
Shares	Section 2.1
Signing Date	Preamble

2. Purchase and Sale of Common Stock.

2.1 General. Subject to the terms and conditions of this Agreement, at the Closing, the Company shall issue and sell to the Investor and the Investor shall purchase from the Company, a number of shares of Common Stock (the "**Shares**") calculated pursuant to Section 2.2 hereof.

2.2 Calculation. The number of Shares shall be 4,179,728, which is calculated by dividing the Aggregate Purchase Price by the Per-Share Purchase Price, rounded down to the nearest whole share.

3. Closing Date; Deliveries.

3.1 Closing Date. The closing of the purchase and sale of the Shares hereunder (the "**Closing**") shall take place remotely via the exchange of documents and signatures at 9:00 a.m. New York City time on the second (2nd) Business Day following the satisfaction or waiver of all of the Closing Conditions (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction at such time of such conditions), or at such other time, date, and location as the parties may agree. The date the Closing occurs is hereinafter referred to as the "**Closing Date**."

3.2 Deliveries.

(a) Deliveries by the Company. At the Closing, the Company shall deliver, or cause to be delivered, to the Investor the Shares, registered in the name of the Investor, and the Company shall instruct its transfer agent to register such issuance at the time of such issuance. The Company shall also deliver at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 6 and 8.2 hereof have been fulfilled and (ii) a certificate of the secretary or assistant secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the Amended and Restated By-laws of the Company as in effect at the time of the actions by the Board referred to in clause (B) below and on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board authorizing the execution, delivery and performance of the Transaction Agreements and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby and thereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the Company's Fifth Amended and Restated Certificate of Incorporation as in effect at the time of the actions by the Board referred to in clause (B) above and on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing a Transaction Agreement on behalf of the Company.

(b) Deliveries by the Investor. At the Closing, the Investor shall deliver, or cause to be delivered, to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than two (2) Business Days before the Closing Date. The Investor shall also deliver, or cause to be delivered, at the Closing: (i) a certificate in form and substance reasonably satisfactory to the Company duly executed by an authorized executive officer of the Investor certifying that the conditions to Closing set forth in Section 7 hereof have been fulfilled and (ii) a certificate of the secretary or assistant secretary of the Investor dated as of the Closing Date certifying as to the incumbency and specimen signature of any officer executing a Transaction Agreement on behalf of the Investor.

4. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that:

4.1 Organization, Good Standing and Qualification.

(a) The Company has been duly organized and is validly existing and in good standing under the laws of its jurisdiction of organization, is duly qualified to do business and is in good standing in each jurisdiction in which its ownership or lease of property or the conduct of its businesses requires such qualification, and has all power and authority necessary to own or hold its properties and to conduct the businesses in which it is engaged, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a Material Adverse Effect.

(b) The Company has all requisite corporate power and corporate authority to enter into the Transaction Agreements and the Collaboration Agreement, to issue and sell the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements and the Collaboration Agreement.

4.2 Capitalization and Voting Rights.

(a) As of the Signing Date, the authorized capital of the Company consists of: (i) 120,000,000 shares of Common Stock of which, (A) 32,601,748 shares are issued and outstanding, (B) 4,886,021 shares are issuable upon the exercise of outstanding stock options or upon the settlement of outstanding equity awards issued pursuant to the 2014 Stock Option and Grant Plan or the 2015 Stock Option and Incentive Plan, (C) 2,259,224 shares are reserved for future issuance pursuant to the 2015 Stock Option and Incentive Plan, and (D) 1,289,093 shares are reserved for future issuance pursuant to the 2015 Employee Stock Purchase Plan, as amended to date and as the same may be amended and/or restated from time to time, and (ii) 5,000,000 shares of preferred stock, par value $0.001 per share, of which no shares are issued and outstanding. The Company is also party to the Sales Agreement pursuant to which the Company may issue and sell shares of its Common Stock having an aggregate offering price of up to $75,000,000 through Cowen and Company, LLC, from time to time, in "at-the-market" offerings or certain negotiated transactions. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued and are fully paid and non-assessable, were issued in compliance with federal and state securities Laws, and are not subject to any pre-emptive rights.

(b) Except as described or referred to in Section 4.2(a) above and as provided in the Investor Agreement, as of the Signing Date, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company, or any contract, commitment, agreement, understanding or arrangement of any kind relating to the issuance of any capital stock of the Company, any such convertible or exchangeable securities or any such rights, warrants or options.

(c) Except as disclosed in the Company SEC Documents, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company.

(d) The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration.

4.3 Subsidiaries. As of the Signing Date, the Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Schedule 1 hereto. All the outstanding shares of capital stock or other equity interests of each subsidiary owned, directly or indirectly, by the Company have been duly authorized and validly issued, are fully paid and non-assessable (except, in the case of any foreign subsidiary, for directors' qualifying shares) and are owned directly or indirectly by the Company, free and clear of any lien, charge, encumbrance, security interest, restriction on voting or transfer or any other claim of any third party.

4.4 Authorization.

(a) The Company has full right, power and authority to execute and deliver the Transaction Agreements and the Collaboration Agreement and to perform its obligations hereunder and thereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of each of the Transaction Agreements and the Collaboration Agreement and the consummation by it of the transactions contemplated thereby has been duly and validly taken.

(b) The Transaction Agreements and the Collaboration Agreement have been duly executed and delivered by the Company and, upon the due execution and delivery of the Transaction Agreements and the Collaboration Agreement by the Investor, will constitute valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms, except, with respect to the Investor Agreement and the Collaboration Agreement, as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles relating to enforceability (collectively, the "**Enforceability Exceptions**").

(c) No stop order or suspension of trading of the Common Stock has been imposed by the Nasdaq Stock Market, the SEC or any other Governmental Authority and remains in effect.

4.5 No Defaults. The Company is not (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to

which the Company is a party, by which the Company is bound or to which any of the property or assets of the Company is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect.

4.6 No Conflicts. The execution, delivery and performance of the Transaction Agreements and the Collaboration Agreement, the issuance and sale of the Shares and the consummation of the transactions contemplated by the Transaction Agreements and the Collaboration Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party, by which the Company is bound or to which any of the property or assets of the Company is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a Material Adverse Effect.

4.7 No Governmental Authority or Third Party Consents. No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of each of the Transaction Agreements or the Collaboration Agreement or the issuance and sale of the Shares, except (i) such filings as may be required to be made with the SEC and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws, (ii) as required pursuant to the HSR Act and (iii) with respect to the Shares, the filing with the Nasdaq Stock Market of, and the absence of unresolved issues with respect to, an LAS and, if required, a Nasdaq Shares Outstanding Change Form.

4.8 Valid Issuance of Shares. When issued, sold and delivered at the Closing in accordance with the terms hereof for the Aggregate Purchase Price, the Shares shall be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including pre-emptive rights, rights of first refusal or other similar rights, other than as arising pursuant to the Transaction Agreements, as a result of any action by the Investor or under federal or state securities Laws.

4.9 Litigation. There are no legal, governmental or regulatory investigations, actions, suits or proceedings pending to which the Company is a party or to which any property of the Company is subject that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect; and no such investigations, actions, suits or proceedings are, to the knowledge of the Company, threatened or contemplated by any governmental or regulatory authority or others.

4.10 Licenses and Other Rights; Compliance with Laws. The Company and its subsidiaries possess or are in the process of obtaining all licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Company SEC Documents, except where the failure to possess or make the same would not, individually or in the aggregate, have a Material Adverse Effect; and except as described in the Company SEC Documents, neither the Company nor any of its subsidiaries has received notice of any revocation or modification of any such license, certificate, permit or authorization or has any reason to believe that any such license, certificate, permit or authorization will not be renewed. The Company and its subsidiaries are, and at all times since January 1, 2017, have been, in compliance with all statutes, rules and regulations applicable to the ownership, packaging, processing, use, distribution, import, or export of any product manufactured or distributed by the Company or its subsidiaries, except where such noncompliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

4.11 Company SEC Documents; Financial Statements; Nasdaq Stock Market.

(a) Since January 1, 2017, the Company has timely filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein) required to be filed by it under the Securities Act and the Exchange Act, and any required amendments to any of the foregoing, with the SEC (the "**Company SEC Documents**"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act, the Exchange Act, and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) As of the Signing Date, there are no outstanding or unresolved comments in comment letters received from the SEC or its staff.

(c) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in its quarterly reports on Form 10-Q for the quarterly periods ended March 31, 2018; June 30, 2018; and September 30, 2018 present fairly the financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified; such financial statements have been prepared in conformity with GAAP applied on a consistent basis throughout the periods covered thereby, except as otherwise disclosed therein and, in the case of unaudited, interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes, and any supporting schedules included in the Company SEC Documents present fairly the information required to be stated therein.

(d) The Common Stock is listed on the Nasdaq Stock Market, and the Company has taken no action designed to, or which is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Nasdaq Stock Market. The Company has not received any notification that, and has no knowledge that, the SEC or the Nasdaq Stock Market is contemplating terminating such listing or registration.

(e) The Company and its subsidiaries have established systems of "internal control over financial reporting" (as defined in Rule 13a-15(f) of the Exchange Act) that have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting control sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences and (v) interactive data in eXtensible Business Reporting Language included in the Company SEC Documents fairly presents the information called for in all material respects and is prepared in accordance with the SEC's rules and guidelines applicable thereto. Except as disclosed in the Company SEC Documents, there are no material weaknesses in the Company's internal controls. The Company's auditors and the Audit Committee of the Board have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which have adversely affected or are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

(f) The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) that comply with the requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management to allow timely decisions regarding disclosures. The Company has conducted evaluations of the effectiveness of its disclosure controls as required by Rule 13a-15 of the Exchange Act.

(g) There is and has been no material failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith, including Section 402 related to loans and Sections 302 and 906 related to certifications.

4.12 Absence of Certain Changes.

(a) Except as disclosed in the Company SEC Documents, since September 30, 2018, (i) there has not been any material change in the capital stock (other than (x) the issuance of shares of Common Stock upon exercise of stock options, the settlement of equity awards and the exercise of warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Company SEC Documents and (y) the issuance of shares of Common Stock, options and equity awards granted to new employees of the Company as inducement awards pursuant to Nasdaq Listing Rule 5635(c)(4)), short-term debt or long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development that would reasonably be expected to result in a material adverse change, in or affecting the business, properties, management, financial position, stockholders' equity, results of operations of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority.

4.13 Offering. Subject to the accuracy of the Investor's representations set forth in Sections 5.5, 5.6, 5.7, 5.9, and 5.10 hereof, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption.

4.14 No Integration. The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act), that is or will be integrated with the sale of the Shares in a manner that would require registration of the Shares under the Securities Act.

4.15 Brokers' or Finders' Fees. Except with respect to the Company Financial Advisors, neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any of its subsidiaries for a brokerage commission, finder's fee or like payment in connection with the transactions contemplated by the Transaction Agreements and the Collaboration Agreement.

4.16 Investment Company. The Company is not and, immediately after giving effect to the offering and sale of the Shares and the application of the proceeds thereof, will not be required to register as an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the SEC thereunder.

4.17 No General Solicitation. Neither the Company nor any person acting on behalf of the Company has offered or sold any of the Shares by any form of general solicitation or general advertising. The Company has offered the Shares for sale only to the Investor.

4.18 Foreign Corrupt Practices. Neither the Company nor, to the knowledge of the Company, any agent or other person acting on behalf of the Company, has: (i) directly or indirectly used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable non-U.S. anti-bribery Law.

4.19 Regulation M Compliance. The Company has not taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Common Stock to facilitate the sale or resale of the Shares.

4.20 Office of Foreign Assets Control. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee or Affiliate of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

4.21 Development Matters.

(a) All preclinical and clinical studies conducted by or on behalf of the Company to support approval for commercialization of the Company's products have been conducted by the Company, or to the Company's knowledge by third parties, in compliance with all applicable federal, state or foreign laws, rules, orders and regulations, except for such failure or failures to be in compliance which would not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect.

(b) The studies, tests and preclinical or clinical trials conducted by or on behalf of the Company that are described in the Company SEC Documents (the "**Company Studies and Trials**") were and, if still pending, are being, conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional scientific standards; the descriptions of the results of the Company Studies and Trials contained in the Company SEC

Documents are accurate in all material respects; the Company has no knowledge of any other studies or trials not described in the Company SEC Documents, the results of which are inconsistent with or call in question the results described or referred to in the Company SEC Documents; and the Company has not received any notices or correspondence from the United States Food and Drug Administration (the "**FDA**") or any foreign, state or local governmental authority exercising comparable authority requiring the termination, suspension or material modification of any Company Studies and Trials that termination, suspension or material modification would reasonably be expected to have a Material Adverse Effect and, to the Company's knowledge, there are no reasonable grounds for the same. The Company has obtained (or caused to be obtained) informed consent by or on behalf of each human subject who participated in the Company Studies and Trials. To the Company's knowledge, none of the Company Studies and Trials involved any investigator who has been disqualified as a clinical investigator or has been found by the FDA to have engaged in scientific misconduct. To the Company's knowledge, the manufacturing facilities and operations of its suppliers are operated in compliance in all material respects with all applicable statutes, rules, regulations and policies of the FDA and comparable governmental authorities outside of the United States to which the Company is subject.

4.22 Intellectual Property. The Company owns, possesses, or can acquire on reasonable terms the right to use all (i) patents, patent applications, trademarks, trademark registrations, service marks, service mark registrations, Internet domain name registrations, copyrights, copyright registrations, licenses and trade secret rights (collectively, "**Intellectual Property Rights**") and (ii) inventions, software, works of authorships, trademarks, service marks, trade names, databases, formulae, know how, Internet domain names and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or procedures) (collectively, "**Intellectual Property Assets**") necessary to conduct its business as currently conducted, and as proposed to be conducted and described in the SEC Documents. The Company has not received any opinion from its legal counsel concluding that any activities of its business infringes, misappropriates, or otherwise violates, valid and enforceable Intellectual Property Rights of any other person, and has not received written notice of any challenge, which is to its knowledge still pending, by any other person to the rights of the Company with respect to any Intellectual Property Rights or Intellectual Property Assets owned or used by the Company. To the Company's knowledge, the Company's business as now conducted does not give rise to any infringement of, any misappropriation of, or other violation of, any valid and enforceable Intellectual Property Rights of any other person. All licenses for the use of the Intellectual Property Rights described in the SEC Documents are valid, binding upon, and enforceable by or against the Company, and to the Company's knowledge, by or against the parties thereto in accordance with their terms. The Company has complied in all material respects with, and is not in breach of, nor has it received any asserted or threatened claim of breach of any intellectual property licenses for the use of the Intellectual Property Rights, and the Company has no knowledge of any breach or anticipated breach by any other person of any such intellectual property licenses. No claim has been made or is pending against the Company alleging the infringement by the

Company of any patent, trademark, service mark, trade name, copyright, trade secret, license in or other intellectual property right or franchise right of any person. The Company has taken reasonable steps to protect, maintain and safeguard its Intellectual Property Rights, including the execution of appropriate nondisclosure and confidentiality agreements. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other person in respect of, the Company's right to own, use, or hold for use any of the Intellectual Property Rights as owned, used or held for use in the conduct of the business as currently conducted. The Company has at all times complied in all material respects with all applicable laws relating to privacy, data protection, and the collection and use of personal information collected, used, or held for use by the Company in the conduct of the Company's business. No claims have been asserted or threatened against the Company alleging a violation of any person's privacy or personal information or data rights and the consummation of the transactions contemplated hereby will not breach or otherwise cause any violation of any law related to privacy, data protection, or the collection and use of personal information collected, used, or held for use by the Company in the conduct of the Company's business. The Company takes reasonable measures to ensure that such information is protected against unauthorized access, use, modification or other misuse. The Company has taken all necessary actions to secure and record its ownership of all works of authorship and inventions made by its employees, consultants and contractors with an obligation of assignment during the time they were employed by or under contract with the Company and which relate to the Company's business. All founders and key employees have signed confidentiality and invention assignment agreements with the Company.

4.23 Real and Personal Property. The Company has good and marketable title in fee simple (in the case of real property) to, or has valid and marketable rights to lease or otherwise use, all items of real or personal property, which are material to the business of the Company taken as a whole, in each case free and clear of all liens, encumbrances, security interests, claims and defects that do not, singularly or in the aggregate, materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company; and all of the leases and subleases material to the business of the Company, and under which the Company holds properties described in the SEC Documents, are in full force and effect and the Company has not received any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company to the continued possession of the leased or subleased premises under any such lease or sublease.

4.24 Labor and Employment. There is (a) no unfair labor practice complaint pending against the Company, nor to the Company's knowledge, threatened against it, before the National Labor Relations Board, any state or local labor relations board or any foreign labor relations board, and no significant grievance or significant arbitration proceeding arising out of or under any collective bargaining agreement is so pending against the Company, or, to the Company's knowledge, threatened against it and

(b) no labor disturbance by or dispute with, employees of the Company exists or, to the Company's knowledge, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers, customers or contractors, that would reasonably be expected, singularly or in the aggregate, to have a Material Adverse Effect. The Company is not aware that any key employee or significant group of employees of the Company plans to terminate employment with the Company.

4.25 ERISA Matters. No "prohibited transaction" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("**ERISA**"), or Section 4975 of the Internal Revenue Code of 1986, as amended from time to time (the "**Code**")) or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred or could reasonably be expected to occur with respect to any employee benefit plan of the Company which would, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. Each employee benefit plan of the Company is in compliance in all material respects with applicable law, including ERISA and the Code. The Company has not incurred and would not reasonably be expected to incur liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company would have any liability that is intended to be qualified under Section 401(a) of the Code is so qualified, and nothing has occurred, whether by action or by failure to act, which would, singularly or in the aggregate, reasonably be expected to cause the loss of such qualification.

4.26 Environmental Matters. The Company is in compliance in all material respects with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to its businesses (the "**Environmental Laws**"). There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company (or, to the Company's knowledge, any other entity for whose acts or omissions the Company is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability; and there has been no disposal, discharge, emission or other release of any kind on to such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances.

4.27 Taxes. The Company (i) has timely filed all necessary federal, state, local and foreign tax returns (or timely filed extensions with respect to such returns), and all such returns were true, complete and correct, (ii) has paid all federal, state, local and foreign taxes, assessments, governmental or other charges due and payable for which it is liable, including, without limitation, all sales and use taxes and all taxes which the Company is obligated to withhold from amounts owing to employees, creditors and third parties, and (iii) does not have any tax deficiency or claims outstanding or assessed or, to its knowledge, proposed against it, except those, in each of the cases described in clauses (i), (ii) and (iii) above, that would not, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company has not engaged in any transaction which is a corporate tax shelter or which could be characterized as such by the Internal Revenue Service or any other taxing authority. The accruals and reserves on the books and records of the Company in respect of tax liabilities for any taxable period not yet finally determined are adequate to meet any assessments and related liabilities for any such period, and since January 1, 2017, the Company has not incurred any liability for taxes other than in the ordinary course.

4.28 Insurance. The Company carries or is covered by, insurance in such amounts and covering such risks as is adequate for the conduct of its business and the value of its properties and as is customary for companies engaged in similar businesses, at a similar stage of development, in similar industries. The Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect. All policies of insurance owned by the Company are, to the Company's knowledge, in full force and effect and the Company is in compliance in all material respects with the terms of such policies. The Company has not received written notice from any insurer, agent of such insurer or the broker of the Company that any material capital improvements or any other material expenditures (other than premium payments) are required or necessary to be made in order to continue such insurance. Except for customary deductibles, the Company does not insure risk of loss through any captive insurance, risk retention group, reciprocal group or by means of any fund or pool of assets specifically set aside for contingent liabilities other than as described in the SEC Documents.

5. Representations and Warranties of the Investor. The Investor hereby represents and warrants to the Company that:

5.1 Organization; Good Standing. The Investor is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Investor has all requisite corporate power and corporate authority to enter into the Transaction Agreements, to purchase the Shares and to perform its obligations under and to carry out the other transactions contemplated by the Transaction Agreements.

5.2 Authorization.

(a) The Investor has full right, power and authority to execute and deliver the Transaction Agreements and the Collaboration Agreement and to perform its obligations hereunder and thereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of each of the Transaction Agreements and the Collaboration Agreement and the consummation by it of the transactions contemplated thereby has been duly and validly taken.

(b) The Transaction Agreements and the Collaboration Agreement have been duly executed and delivered by the Investor and, upon the due execution and delivery of the Transaction Agreements and the Collaboration Agreement by the Company, will constitute valid and legally binding obligations of the Investor, enforceable against the Investor in accordance with their respective terms, except with respect to the Enforceability Exceptions.

5.3 No Conflicts. The execution, delivery and performance of the Transaction Agreements and the Collaboration Agreement, the subscription for and purchase of the Shares and the consummation of the transactions contemplated by the Transaction Agreements and the Collaboration Agreement will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Investor pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Investor is a party, by which the Investor is bound or to which any of the property or assets of the Investor is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Investor or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Investor or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, have a material adverse effect on the Investor's ability to perform its obligations or consummate the Transaction in accordance with the terms of this Agreement.

5.4 No Governmental Authority or Third Party Consents. No consent, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Investor of each of the Transaction Agreements or the Collaboration Agreement or with the subscription for and purchase of the Shares, except as required pursuant to the HSR Act.

5.5 Purchase Entirely for Own Account. The Investor acknowledges that the Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation or otherwise distributing the Shares. The Investor can bear the economic risk of an investment in the Shares indefinitely and a total loss with respect to such investment. The Investor does not have and will not have as of the Closing any contract, undertaking, agreement, arrangement or understanding with any Person to sell, transfer or grant participation to a Person any of the Shares.

5.6 Disclosure of Information. The Investor has received or has had full access to all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.

5.7 Investment Experience and Accredited Investor Status. The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.

5.8 Acquiring Person. As of the Signing Date, neither the Investor nor any of its Affiliates beneficially owns, and immediately prior to the Closing, neither the Investor nor any of its Affiliates will beneficially own (in each case, as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership, and without regard to Investor's rights under this Agreement), any securities of the Company, except for securities that may be beneficially owned by employee benefit plans of either the Investor or any of its Affiliates.

5.9 Restricted Securities. The Investor understands that the Shares, when issued, shall be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under the Securities Act only in certain limited circumstances. The Investor represents that it is familiar with Rule 144, as presently in effect.

5.10 Legends. The Investor understands that any certificates representing the Shares shall bear the following legends:

(a) "THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF A REGISTRATION STATEMENT IN EFFECT WITH RESPECT TO THE SECURITIES UNDER THE SECURITIES ACT OR AN OPINION OF COUNSEL (WHICH COUNSEL SHALL BE REASONABLY SATISFACTORY TO THE COMPANY) THAT SUCH REGISTRATION IS NOT REQUIRED OR UNLESS SOLD PURSUANT TO RULE 144 OF THE SECURITIES ACT.";

(b) "THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO AND SHALL BE TRANSFERABLE ONLY UPON THE TERMS AND CONDITIONS OF AN INVESTOR AGREEMENT DATED AS OF JANUARY 28, 2019, BY AND BETWEEN VOYAGER THERAPEUTICS, INC. AND NEUROCRINE BIOSCIENCES, INC., A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF VOYAGER THERAPEUTICS, INC."; and

(c) any legend required by applicable state securities Laws or the other Transaction Agreements.

5.11 Financial Assurances. As of the Signing Date, the Investor has, and as of the Closing Date, the Investor will have, access to cash in an amount sufficient to pay to the Company the Aggregate Purchase Price.

5.12 SEC Reports. The Investor has reviewed the Company SEC Documents.

6. Investor's Conditions to Closing. The Investor's obligation to purchase the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Investor):

6.1 Representations and Warranties. The representations and warranties made by the Company in Section 4 hereof shall be true and correct as of the Signing Date and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 6.1, all such representations and warranties of the Company (other than Sections 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, and 4.11 hereof) shall be deemed to be true and correct for purposes of this Section 6.1 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material," "materiality" or "Material Adverse Effect" qualifiers set forth therein, constitute a Material Adverse Effect.

6.2 Representations and Warranties in the Collaboration Agreement. The representations and warranties made by the Company in Section 12.2 of the Collaboration Agreement shall be true and correct as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 6.2, all such representations and warranties of the Company shall be deemed to be true and correct for purposes of this Section 6.2 unless the failure or failures of such representations and warranties to be so true and correct, without regard to any "material" or "materiality" qualifiers set forth therein, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

6.3 Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.

6.4 Investor Agreement. The Investor Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.

6.5 Collaboration Agreement. The Collaboration Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect as of the Closing Date.

6.6 No Material Adverse Effect. From and after the Signing Date until the Closing Date, there shall have occurred no event that has caused a Material Adverse Effect.

6.7 Listing. The Shares shall be eligible and approved for listing on the Nasdaq Stock Market.

7. Company's Conditions to Closing. The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of the Closing of the following conditions (unless waived in writing by the Company):

7.1 Representations and Warranties. The representations and warranties made by the Investor in Section 5 hereof shall be true and correct as of the Signing Date and as of the Closing Date as though made on and as of such Closing Date, except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date.

7.2 Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Investor on or prior to the Closing Date shall have been performed or complied with in all material respects.

7.3 Investor Agreement. The Investor Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.

7.4 Collaboration Agreement. The Collaboration Agreement shall not have been terminated in accordance with its terms and shall be in full force and effect.

8. Mutual Conditions to Closing. The obligations of the Investor and the Company to consummate the Closing are subject to the fulfillment as of the Closing Date of the following conditions:

8.1 HSR Act Qualification. Any required HSR Clearances shall have been obtained.

8.2 Absence of Litigation. There shall be no action, suit, proceeding or investigation by a Governmental Authority pending or currently threatened in writing against the Company or the Investor (i) that questions (A) the validity of any Transaction Agreement or (B) the right of the Company or the Investor to enter into any Transaction Agreement or to consummate the transactions contemplated hereby or thereby or (ii) which, if determined adversely, would impose substantial monetary damages on the Company or the Investor as a result of the consummation of the transactions contemplated by any Transaction Agreement.

8.3 No Prohibition. No provision of any applicable Law and no judgment, injunction (preliminary or permanent), order or decree that prohibits, makes illegal or enjoins the consummation of the Transaction shall be in effect.

9. Termination.

9.1 Ability to Terminate. This Agreement may be terminated at any time prior to the Closing by:

(a) mutual written consent of the Company and the Investor;

(b) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 8 hereof shall have become incapable of fulfillment by the Termination Date and shall not have been waived in writing by the other party within ten business days after receiving receipt of written notice of an intention to terminate pursuant to this clause (b); provided, however, that the right to terminate this Agreement under this Section 9.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Termination Date;

(c) the Company, upon written notice to the Investor, so long as the Company is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 6.1, 6.2, 6.3, 6.4 or 6.5 hereof, as applicable, could not be satisfied by the Termination Date, (i) upon a material breach of any covenant or agreement on the part of the Investor set forth in this Agreement, or (ii) if any representation or warranty of the Investor shall have been or become untrue, in each case such that any of the conditions set forth in Section 7.1, 7.2, 7.3 or 7.4 hereof, as applicable, could not be satisfied by the Termination Date;

(d) the Investor, upon written notice to the Company, so long as the Investor is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 7.1, 7.2, 7.3, or 7.4 hereof, as applicable, could not be satisfied by the Termination Date, (i) upon a material breach of any covenant or agreement on the part of the Company set forth in this Agreement, or (ii) if any representation or warranty of the Company shall have been or become untrue, in each case such that any of the conditions set forth in Section 6.1, 6.2, 6.3, 6.4 or 6.5 hereof, as applicable, could not be satisfied by the Termination Date.

9.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 9.1 hereof, (i) this Agreement (except for this Section 9.2 and Section 11 hereof (other than Section 11.12), and any definitions set forth in this Agreement and used in such sections) shall forthwith become void and have no effect, without any liability on the part of any party hereto or its Affiliates, and (ii) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; provided, however, that nothing contained in this Section 9.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

10. Additional Covenants and Agreements.

10.1 Market Listing. From the Signing Date through the Closing Date, Company shall use all commercially reasonable efforts to (i) maintain the listing and trading of the Common Stock on the Nasdaq Stock Market and (ii) effect the listing of the Shares on the Nasdaq Stock Market, including submitting the LAS to the Nasdaq Stock Market no later than fifteen (15) calendar days prior to the Closing Date.

10.2 Notification under the HSR Act. Each party will use reasonable efforts to do, or cause to be done, all things necessary, proper and advisable to, as promptly as practicable, take all actions necessary to make the filings required of such party or its Affiliates under the HSR Act, including filing with the FTC and Antitrust Division of the DOJ within ten (10) Business Days of the Signing Date (or such later time as may be agreed to in writing by the parties). The parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing and during the review by the FTC and/or the Antitrust Division of the DOJ. Each party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; provided, however, that the Investor shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of the Company) required to be paid to any Governmental Agency in connection with making any such HSR Filing. This Agreement shall terminate at the election of either party, immediately upon notice to the other party, if the FTC or the DOJ seeks a preliminary injunction (or its equivalent) in connection therewith against the Investor and the Company to enjoin the transactions contemplated hereby and thereby. In the event of such termination, this Agreement shall be of no further force and effect.

10.3 Assistance and Cooperation. Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including using all reasonable efforts to accomplish the following: (i) taking all reasonable acts necessary to cause the conditions precedent set forth in Sections 6, 7 and 8 hereof to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from the Nasdaq Stock Market with respect to the LAS); (ii) taking all reasonable actions necessary to obtain all necessary actions or non-actions, waivers, consents, approvals, orders and authorizations from Governmental Authorities and the making of all necessary registrations, declarations and filings (including registrations, declarations and filings with Governmental Authorities, if any); (iii) taking all reasonable actions necessary to obtain all necessary consents, approvals or waivers from Third Parties; and (iv) except as otherwise provided for in Section 10.2 hereof, defending any suits, claims, actions, investigations or proceedings, whether judicial or administrative, challenging this Agreement or the consummation of the transactions contemplated hereby, including seeking to have any stay or temporary restraining order entered by any court or other Governmental Authority vacated or reversed.

10.4 Legend Removal.

(a) Certificates evidencing the Shares shall not contain the legend set forth in Section 5.10(a) hereof: (i) following a sale of such Shares pursuant to a registration statement covering the resale of such Shares, while such registration statement is effective under the Securities Act, (ii) following any sale of such Shares pursuant to Rule 144, (iii) if such Shares are eligible for sale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions under Rule 144 or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the SEC).

(b) Certificates evidencing the Shares shall not contain the legend set forth in Section 5.10(b) hereof following: (i) a sale of such Shares pursuant to a registration statement covering the resale of such Shares, while such registration statement is effective under the Securities Act, (ii) any sale of such Shares pursuant to Rule 144 or (iii) the expiration of the Standstill Term (as defined in the Investor Agreement), the Lock-Up Term (as defined in the Investor Agreement) and the Voting Agreement Term (as defined in the Investor Agreement); provided that any transfer described in clause (i) or (ii) above shall have been in compliance with all applicable provisions of the Investor Agreement.

(c) The Company agrees that at such time as any legend set forth in Section 5.10 hereof is no longer required under this Section 10.4, the Company will, no later than three (3) Business Days following the delivery by the Investor to the

Company or notice by the Investor to the Company of delivery by the Investor to the Transfer Agent of a certificate representing Shares issued with such legend (together with any legal opinion required by the Transfer Agent), deliver or cause to be delivered to the Investor a certificate representing such Shares that is free from such legend, or, in the event that such shares are uncertificated, remove any such legend in the Company's stock records. The Company may not make any notation on its records or give instructions to the Transfer Agent that enlarge the restrictions on transfer set forth in Section 5.10 hereof.

10.5 Conduct of Business. During the period from the Signing Date until the Closing, except as consented to in writing by the Investor, the Company shall not (i) declare, set aside or pay any dividend or make any other distribution or payment (whether in cash, stock or property or any combination thereof) in respect of its capital stock, or establish a record date for any of the foregoing, or (ii) make any other actual, constructive or deemed distribution in respect of any shares of its capital stock or otherwise make any payments to stockholders in their capacity as such, except pursuant to repurchases of equity pursuant to the terms of its equity compensation plans.

11. Miscellaneous.

11.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 11.3 hereof or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

11.2 Waiver. Neither party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term except to the extent set forth in writing.

11.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit A attached hereto and shall be (i) delivered personally;

(ii) sent by certified mail (return receipt requested), postage prepaid; or (iii) sent via a reputable nationwide overnight express courier service (signature required). Any such notice, instruction or communication shall be deemed to have been delivered (A) upon receipt if delivered by hand; (B) three (3) Business Days after it is sent by certified mail, return receipt requested, postage prepaid; or (C) one (1) Business Day after it is sent via a reputable nationwide overnight courier service. Either party may change its address by giving notice to the other party in the manner provided above; provided that notices of a change of address shall be effective only upon receipt thereof.

11.4 Entire Agreement. This Agreement, the Investor Agreement and the Collaboration Agreement, in each case together with the schedules and exhibits thereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the parties and supersede and terminate all prior agreements and understanding between the parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties unless reduced to writing and signed by the respective authorized officers of the parties.

11.5 Headings; Nouns and Pronouns; Section References. Headings and any table of contents used in this Agreement are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

11.6 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

11.7 Assignment. Except for an assignment of this Agreement or any rights hereunder by the Investor to an Affiliate, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (i) the prior written consent of Company in the case of any assignment by the Investor or (ii) the prior written consent of the Investor in the case of an assignment by the Company.

11.8 Parties in Interest. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the parties hereto and their respective successors, heirs, administrators and permitted assigns.

11.9 Counterparts. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

11.10 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

11.11 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either party.

11.12 Survival of Warranties. The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing and the delivery of the Shares.

11.13 Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

11.14 Expenses. Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of the Transaction Agreements.

11.15 No Publicity. The parties hereto agree that the provisions of Section 11.3 of the Collaboration Agreement shall be applicable to the parties to this Agreement with respect to any public disclosures regarding the proposed transactions contemplated by the Transaction Agreements and the Collaboration Agreement or regarding the parties hereto or their Affiliates (it being understood that the provisions of Section 11.3 of the Collaboration Agreement shall be read to apply to disclosures of information relating to this Agreement and the transactions contemplated hereby).

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

NEUROCRINE BIOSCIENCES, INC.

By: /s/ Kevin Gorman
Name: Kevin Gorman
Title: CEO

VOYAGER THERAPEUTICS, INC.

By: /s/ G. Andre Turenne
Name: G. Andre Turenne
Title: President and Chief Executive Officer

(Signature Page to Stock Purchase Agreement)

SCHEDULE 1

LIST OF SUBSIDIARIES

1. Voyager Securities Corporation, a Massachusetts corporation

EXHIBIT A

NOTICES

If to the Investor:

Neurocrine Biosciences, Inc.
12780 El Camino Real
San Diego, CA 92130
Attention: General Counsel

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Attention: Jason L. Kent, Esq.

If to the Company:

Voyager Therapeutics, Inc.
75 Sidney Street
Cambridge, MA 02139
Attention: Chief Executive Officer

with a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Attention: Brian A. Johnson, Esq.

Exhibit 10.7

EXECUTION VERSION

INVESTOR AGREEMENT

By and Between

NEUROCRINE BIOSCIENCES, INC.

AND

VOYAGER THERAPEUTICS, INC.

Dated as of January 28, 2019

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INVESTOR AGREEMENT

THIS INVESTOR AGREEMENT (this "**Agreement**") is made as of January 28, 2019, by and between Neurocrine Biosciences, Inc. (the "**Investor**"), a Delaware corporation with its principal place of business at 12780 El Camino Real, San Diego, CA 92130, and Voyager Therapeutics, Inc. (the "**Company**"), a Delaware corporation, with its principal place of business at 75 Sidney Street, Cambridge, MA 02139.

WHEREAS, the Stock Purchase Agreement, of even date herewith, by and between the Investor and the Company (the "**Purchase Agreement**") provides for the issuance and sale by the Company to the Investor, and the purchase by the Investor, of a number of shares (such shares, the "**Purchased Shares**") of the Company's common stock, par value $0.001 per share (the "**Common Stock**");

WHEREAS, as a condition to consummating the transactions contemplated by the Purchase Agreement, the Investor and the Company have agreed upon certain rights and restrictions as set forth herein with respect to the Purchased Shares and other securities of the Company beneficially owned by the Investor and its Affiliates, and it is a condition to the closing under the Purchase Agreement (the "**Closing**") that this Agreement be in full force and effect; and

WHEREAS, simultaneously with the execution of the Purchase Agreement and this Agreement, the Company and the Investor entered into the Collaboration Agreement.

NOW, THEREFORE, in consideration of the premises and mutual agreements hereinafter set forth, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Definitions. As used in this Agreement, the following terms shall have the following meanings:

(a) "**Affiliate**" shall mean, with respect to any Person, another Person that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if such Person (ii) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of such other Person. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

(b) "**Agreement**" shall have the meaning set forth in the Preamble to this Agreement, including all Exhibits attached hereto.

(c) "**Beneficial owner**," "**beneficially owns**," "**beneficial ownership**" and terms of similar import used in this Agreement shall, with respect to a Person, have the meaning set forth in Rule 13d-3 under the Exchange Act (i) assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by such Person and (ii) determined without regard for the number of days in which such Person has the right to acquire such beneficial ownership.

(d) "**Business Day**" shall mean a day on which banking institutions in Boston, Massachusetts, United States and San Diego, California, United States are open for business, excluding any Saturday or Sunday.

(e) "**Change of Control**" shall mean (i) the acquisition of beneficial ownership, directly or indirectly, by any Third Party of securities or other voting interests of the Company representing a majority or more of the combined voting power of the Company's then outstanding securities or other voting interests; (ii) any merger, consolidation or business combination involving the Company with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies) of voting securities or other voting interests of the Company immediately prior to such merger, consolidation or other business combination ceasing to hold beneficial ownership of more than fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, consolidation or business combination; (iii) any sale, lease, exchange, contribution or other transfer to a Third Party (in one transaction or a series of related transactions) of all or substantially all of the Company's assets; or (iv) individuals who, as of the date hereof, constitute the Board of Directors of the Company (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the Board of Directors of the Company (provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by the Company's shareholders, was recommended or approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of the Company).

(f) "**Closing Date**" shall have the meaning set forth in the Purchase Agreement.

(g) "**Collaboration Agreement**" shall mean the Collaboration and License Agreement, of even date herewith, between the Investor and the Company.

(h) "**Common Stock**" shall have the meaning set forth in the Preamble to this Agreement.

(i) "**Common Stock Equivalents**" shall mean any options, restricted stock units, warrants or other securities or rights convertible into or exercisable,

exchangeable or settleable for, whether directly or following conversion into or exercise, exchange or settlement for other options, restricted stock units, warrants or other securities or rights, shares of Common Stock or any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of, or voting or other rights of, the Common Stock.

(j) "**Company**" shall have the meaning set forth in the Preamble to this Agreement.

(k) "**Competitor**" shall mean any operating company with a biopharmaceutical business involving the Development and/or Commercialization of any Competitive Product (as such terms are defined in the Collaboration Agreement), or any other Person that directly or indirectly beneficially owns a majority of the voting securities of or voting interests in such a company, or any direct or indirect majority-owned subsidiary of such a company or of such a Person.

(l) "**Disposition**" or "**Dispose of**" shall mean any (i) pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (ii) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.

(m) "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(n) "**Existing Pivotal Trial Readout**" shall mean the initial public announcement or release by the Company (or an Affiliate authorized by the Company) of topline results from the Existing Pivotal Trial (as such term is defined in the Collaboration Agreement).

(o) "**Extraordinary Matter**" shall have the meaning set forth in Section 4.2 hereof.

(p) "**Governmental Authority**" shall mean any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.

(q) "**Investor**" shall have the meaning set forth in the Preamble to this Agreement.

(r) "**Irrevocable Proxy**" shall have the meaning set forth in Section 4.1 hereof.

(s) "**Law**" shall mean any law, statute, rule, regulation, order, judgment or ordinance having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

(t) "**Lock-Up Agreement**" shall have the meaning set forth in Section 3.4 hereof.

(u) "**Lock-Up Term**" shall mean the period from and after the date of this Agreement until the occurrence of any event set forth in Section 5.2 hereof.

(v) "**Modified Clause**" shall have the meaning set forth in Section 6.6 hereof.

(w) "**Permitted Transferee**" shall mean (i) a controlled Affiliate of the Investor that is wholly owned, directly or indirectly, by the Investor, or (ii) a controlling Affiliate of the Investor (or any controlled Affiliate of such controlling Affiliate) that wholly owns, directly or indirectly, the Investor, or the acquiring Person in the case of a Change of Control of the Investor (replacing references to "Company" with "Investor" in the definition of "Change of Control"); it being understood that for purposes of this definition "wholly owned" shall mean an Affiliate in which the Investor owns, or an Affiliate that owns, as applicable, directly or indirectly, at least ninety-nine percent (99%) of the outstanding capital stock of such Affiliate or the Investor, as applicable.

(x) "**Permitted Transferee Irrevocable Proxy**" shall have the meaning set forth in Section 4.1 hereof.

(y) "**Person**" shall mean any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Governmental Authority or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

(z) "**Second Pivotal Clinical Trial Readout**" shall mean the initial public announcement or release by the Company (or an Affiliate authorized by the Company) of topline results from a Pivotal Clinical Trial of VY-AADC other than the Existing Pivotal Trial (as such terms are defined in the Collaboration Agreement).

(aa) "**Purchase Agreement**" shall have the meaning set forth in the Preamble to this Agreement, and shall include all Exhibits attached thereto.

(bb) "**Purchased Shares**" shall have the meaning set forth in the Preamble to this Agreement, and shall be adjusted for (i) any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Purchased Shares.

(cc) "**SEC**" shall mean the U.S. Securities and Exchange Commission.

(dd) "**Securities Act**" shall mean the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

(ee) "**Shares of Then-Outstanding Common Stock**" shall mean, at any time, the issued and outstanding shares of Common Stock at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend, or reclassification of Common Stock distributable, on a pro rata basis, to all holders of Common Stock.

(ff) "**Standstill and Lock-Up Relaxation Date**" shall mean the later of (i) the second anniversary of the Closing Date and (ii) the date of the Existing Pivotal Trial Readout.

(gg) "**Standstill Parties**" shall have the meaning set forth in Section 2.1 hereof.

(hh) "**Standstill Period**" shall mean the period from and after the date of this Agreement until the occurrence of any event set forth in Section 5.1 hereof.

(ii) "**Third Party**" shall mean any Person other than the Investor, the Company or any Affiliate of the Investor or the Company.

(jj) "**Voting Agreement Term**" shall mean the period from and after the date of this Agreement until the occurrence of any event set forth in Section 5.3 hereof.

2. Restrictions on Beneficial Ownership.

2.1 For the duration of the Standstill Period, unless the Company or its Affiliates or representatives have specifically invited or approved the Investor to do so in writing, neither the Investor nor any of its Affiliates or representatives acting on behalf of the Investor (collectively, the "**Standstill Parties**") will in any manner, directly or indirectly: (i) effect or seek, offer or propose (whether publicly or otherwise) to effect, or cause or knowingly participate in or in any way advise, assist or knowingly encourage any other Person to effect or seek, offer or propose (whether publicly or otherwise) to effect or participate in, (A) any acquisition of any securities (or beneficial ownership thereof) or assets of the Company, or any rights to acquire any such securities (including derivative securities representing the right to vote or economic benefit of any such securities) or assets; (B) any tender or exchange offer, merger or other business combination involving the Company; (C) any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company; or (D) any "solicitation" of "proxies" (as such terms are used in the proxy rules of the SEC) or consents to vote any voting securities of the Company; (ii) form, join or in any way participate in a "group" (as defined under the Exchange Act) with respect to any securities of the Company; (iii) otherwise act, alone or in concert with others, to seek to control or influence the management, Board of Directors or policies of the Company; (iv) take any action that would reasonably be expected to require the Company to make a public announcement regarding any of the types of matters set forth in clause (i) above; or (v) enter into any discussions or arrangements with any Third Party other than Investor's advisors with respect to any of the foregoing. Notwithstanding anything to the contrary contained in this Agreement, Investor and its Affiliates shall not be precluded from owning or acquiring interests in mutual funds or similar entities that own capital stock of the Company, and nothing herein shall prohibit passive investments by pension or employee benefit plans of Investor.

2.2 The Investor also agrees during the Standstill Period not to request the Company (or its directors, officers, employees or agents), directly or indirectly, to amend or waive any provision of this Section 2 (including this sentence).

2.3 Notwithstanding anything to the contrary contained in this Agreement, if, at any time (i) a Third Party enters into an agreement with the Company contemplating the acquisition (by way of merger, tender offer or otherwise) of more than fifty percent (50%) of the then-outstanding Common Stock of the Company, of securities representing more than fifty percent (50%) of the voting power of all then-outstanding securities of the Company or all or substantially all of the consolidated assets of the Company or publicly announces its intention to do so, then the restrictions set forth in Section 2.1 shall terminate and cease to be of any further force or effect or (ii) a Third Party commences, or publicly announces an intention to commence, a tender or exchange offer that, if consummated, would make such third party the beneficial owner (within the meaning of Section 13(d)(1) of the Exchange Act) of at least 50% of the voting power of all then-outstanding securities of the Company, then until the expiration or termination of a tender or exchange offer that has been commenced or until the public announcement of a withdrawal or abandonment of an intention to commence a tender or exchange offer, the restrictions set forth in Section 2.1 shall be suspended and of no force or effect.

2.4 Notwithstanding anything to the contrary contained in this Agreement, on and after the Standstill and Lock-Up Relaxation Date, Investor shall not be precluded from making any confidential offers or proposals to the Board of Directors of the Company in a manner reasonably believed not to require the Company to make a public announcement of such offer or proposal.

3. Restrictions on Dispositions.

3.1 Lock-Up. During the Lock-Up Term, without the prior approval of the Company, the Investor shall not, and shall cause its Affiliates not to, Dispose of any of the Purchased Shares; provided, however, that the foregoing shall not prohibit the Investor from (i) transferring the Purchased Shares to a Permitted Transferee or (ii) Disposing of any Purchased Shares to reduce the beneficial ownership of the Standstill Parties to nineteen and ninety-nine hundredths percent (19.99%), or such lesser percentage as advised in good faith and in writing by the Investor's certified public accountants that would be necessary pursuant to applicable accounting rules and guidelines so as to not require the Investor to include in its financial statements its portion of the Company's financial results, of the Shares of Then-Outstanding Common Stock; and provided further that, notwithstanding anything in this Section 3.1, the Investor shall not be precluded from the Disposition of Purchased Shares through open market sales effected through one or more "brokers' transactions" (as such term is used in Rule 144 promulgated under the Securities Act) on or after the Standstill and Lock-Up Relaxation Date in an amount not to exceed one percent (1%) of the Shares of Then-Outstanding Common Stock in any three (3) month period.

3.2 Certain Tender Offers. Subject to the restrictions set forth in Section 3.3 hereof, this Section 3 shall not prohibit or restrict any Disposition of Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents by the Standstill Parties into (i) a tender offer by a Third Party or (ii) an issuer tender offer by the Company.

3.3 Sale Limitations. Subject to the restrictions set forth in Section 3.1 hereof, the Investor agrees that, except for any transfer of Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents by the Investor to a Permitted Transferee or the Company, it (i) shall not, and shall cause its Affiliates not to, Dispose of any Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents, in a "block trade" private placement transaction, at any time to any Person that such Investor or Affiliate knows (after a reasonable inquiry) is a Competitor of the Company and (ii) shall, and shall cause its Affiliates to, instruct the broker(s) in any such "block trade" not to Dispose Shares to a Competitor (unless the identity of the Person purchasing the Shares is not known to the broker(s) or such Person Disposing of Shares).

3.4 Offering Lock-Up. The Investor shall, if requested by the Company and an underwriter of Common Stock of the Company in connection with any public offering involving an underwriting of Common Stock of the Company, agree not to Dispose of any Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents for a specified period of time immediately following the launch of such offering, such period of time not to exceed ninety (90) days following the pricing of such offering (a "**Lock-Up Agreement**"), provided that all officers and directors of the Company are subject to the same restrictions, and provided, further, that such agreement shall not restrict the Investor's ability to Dispose of any Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents in accordance with Section 3.2 hereof. Any Lock-Up Agreement shall be in writing in a form reasonably satisfactory to the Company and the underwriter(s) in such offering. The Company may impose stop transfer instructions with respect to the Shares of Then-Outstanding Common Stock and/or Common Stock Equivalents subject to the foregoing restrictions until the end of the specified period of time. Any discretionary waiver or termination of the restrictions of any or all of such Lock-Up Agreements by the Company or the underwriters shall apply pro rata to the Investor based on the number of shares subject to such Lock-Up Agreements, excluding any waivers granted that fall within a customary de minimis exemption set forth in the associated Lock-Up Agreement.

3.5 Transactions for Personal Account; Change of Control of the Investor. For the avoidance of doubt, nothing in this Article 3 will restrict any Disposition of shares of Common Stock (i) held by an executive officer or director of the Investor for his or her personal account or (ii) that may occur (or be deemed to occur) in connection with a Change of Control of the Investor (replacing references to "Company" with "Investor" in the definition of "Change of Control").

4. Voting Agreement.

4.1 Voting of Securities. During the Voting Agreement Term, other than as permitted by Section 4.2 hereof with respect to Extraordinary Matters, in any vote or action by written consent of the stockholders of the Company (including, without limitation, with respect to the election of directors), the Investor shall, and shall cause any Permitted Transferees to, vote or execute a written consent with respect to the Purchased Shares, in the sole discretion of the

Investor, in accordance with the recommendation of the Company's Board of Directors. In furtherance of this Section 4.1, the Investor hereby irrevocably appoints the Company and any individuals designated by the Company (such designated individuals to be limited to the President and Chief Executive Officer, the Chief Financial Officer the Chief Operating Officer and the Secretary of the Company), and each of them individually, as the attorneys, agents and proxies, with full power of substitution and resubstitution in each of them, for the Investor, and in the name, place and stead of the Investor, to vote (or cause to be voted) in such manner as set forth in this Section 4.1 (but in any case, excluding any matter that is an Extraordinary Matter described in Section 4.2 hereof) with respect to the Purchased Shares to which the Investor is or may be entitled to vote at any meeting of the Company held after the date hereof, whether annual or special and whether or not an adjourned meeting (the "**Irrevocable Proxy**"). This Irrevocable Proxy is coupled with an interest, shall be irrevocable and binding on any successor-in-interest of the Investor and shall not be terminated by operation of Law upon the occurrence of any event. This Irrevocable Proxy shall operate to revoke and render void any prior proxy as to voting securities heretofore granted by the Investor which is inconsistent herewith. Notwithstanding the foregoing, the Irrevocable Proxy shall be effective only if, at any annual or special meeting of the stockholders of the Company and at any adjournments or postponements of any such meetings, the Investor (i) fails to appear or otherwise fails to cause its voting securities of the Company to be counted as present for purposes of calculating a quorum, or (ii) fails to vote such voting securities in accordance with this Section 4.1, in each case at least five (5) Business Days prior to the date of such stockholders' meeting. The Irrevocable Proxy shall terminate upon the earlier of the expiration or termination of the Voting Agreement Term. The Investor shall cause any Permitted Transferee to promptly execute and deliver to the Company an irrevocable proxy, substantially in the form of Exhibit A attached hereto, and irrevocably appoint the Company and any individuals designated by the Company, and each of them individually, with full power of substitution and resubstitution, as the attorneys, agents and proxies to vote (or cause to be voted) such Purchased Shares of the Company as to which such Permitted Transferee is entitled to vote, in such manner as each such attorney, agent and proxy or his substitute shall in its, his or her sole discretion deem appropriate or desirable with respect to the matters set forth in this Section 4.1 (the "**Permitted Transferee Irrevocable Proxy**"). The Investor acknowledges, and shall cause any Permitted Transferees to acknowledge, that any such proxy executed and delivered shall be coupled with an interest, shall constitute, among other things, an inducement for the Company to enter into this Agreement, shall be irrevocable and binding on any successor-in-interest of such Permitted Transferee and shall not be terminated by operation of Law upon the occurrence of any event. Such proxy shall operate to revoke and render void any prior proxy as to any voting securities of the Company heretofore granted by such Permitted Transferee, to the extent it is inconsistent herewith. The Investor acknowledges and agrees that it shall be a condition to any proposed transfer of voting securities of the Company by the Investor to such Permitted Transferee that such Permitted Transferee execute and deliver to the Company a Permitted Transferee Irrevocable Proxy, and that any purported transfer shall be void and of no force or effect if such Permitted Transferee Irrevocable Proxy is not so executed and delivered at the closing of such transfer. Such proxy shall terminate upon the earlier of the expiration or termination of the Voting Agreement Term. The Investor acknowledges and agrees that it shall be a condition to any proposed transfer of voting securities of the Company by the Investor to any Permitted Transferee during the Voting Agreement Term that such Permitted Transferee shall agree in writing to be subject to and bound by all restrictions and obligations set forth in this Section 4.1.

In the event the Company's stockholders are permitted to act by written consent, the Company and the Investor shall each negotiate in good faith with the other provisions as consistent as possible with the foregoing to govern the voting of the Investor's and its Permitted Transferees' Shares of Then-Outstanding Common Stock as closely as practicable to the foregoing.

4.2 Certain Extraordinary Matters. The Investor and its Permitted Transferees may vote, or execute a written consent with respect to, any or all of the voting securities of the Company as to which they are entitled to vote or execute a written consent, as they may determine in their sole discretion, with respect to the following matters (each such matter being an "**Extraordinary Matter**"):

(a) any transaction which would result in a Change of Control of the Company; and

(b) any liquidation or dissolution of the Company.

4.3 Quorum. In furtherance of Section 4.1 hereof, the Investor shall be, and shall cause each of its Permitted Transferees to be, present in person or represented by proxy at all meetings of stockholders to the extent necessary so that all voting securities of the Company as to which they are entitled to vote shall be counted as present for the purpose of determining the presence of a quorum at such meeting.

5. Termination of Certain Rights and Obligations.

5.1 Termination of Standstill Term. Section 2 hereof shall terminate and have no further force or effect upon the earliest to occur of:

(a) the expiration or earlier valid termination of the Collaboration Agreement;

(b) the date that is the later of (i) the third anniversary of the Closing Date and (ii) the date of the Second Pivotal Clinical Trial Readout;

(c) a liquidation or dissolution of the Company; and

(d) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.

5.2 Termination of Lock-Up Term. Section 3.1 hereof shall terminate and have no further force or effect upon the earliest to occur of:

(a) the date that is the later of (i) the third anniversary of the Closing Date and (ii) the date of the Second Pivotal Clinical Trial Readout;

(b) the beneficial ownership of the Standstill Parties falls below three percent (3%) of the Shares of Then-Outstanding Common Stock;

(c) a Change of Control of the Company;

(d) a liquidation or dissolution of the Company; and

(e) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.

5.3 Termination of Voting Agreement Term. Section 5 hereof shall terminate and have no further force or effect upon the earliest to occur of:

(a) the date that is the later of (i) the third anniversary of the Closing Date and (ii) the date of the Second Pivotal Clinical Trial Readout;

(b) the beneficial ownership of the Standstill Parties falls below three percent (3%) of the Shares of Then-Outstanding Common Stock;

(c) a Change of Control of the Company;

(d) the expiration or earlier valid termination of the Collaboration Agreement; and

(e) a liquidation or dissolution of the Company.

5.4 Termination of Agreement. This Agreement shall terminate and have no further force or effect upon any termination of the Purchase Agreement prior to the Closing pursuant to Section 9.1 thereof.

5.5 Effect of Termination. No termination pursuant to any of Sections 5.1, 5.2, 5.3, or 5.4 hereof shall relieve any of the parties (or the Permitted Transferee, if any) for liability for breach of or default under any of their respective obligations or restrictions under any terminated provision of this Agreement, which breach or default arose out of events or circumstances occurring or existing prior to the date of such termination.

6. Miscellaneous.

6.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of Delaware, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 6.3 hereof or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

6.2 Waiver. Neither party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either party to assert a right hereunder or to insist upon compliance with any term of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term except to the extent set forth in writing.

6.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit B attached hereto and shall be (i) delivered personally; (ii) sent by certified mail (return receipt requested), postage prepaid; or (iii) sent via a reputable nationwide overnight express courier service (signature required). Any such notice, instruction or communication shall be deemed to have been delivered (A) upon receipt if delivered by hand; (B) three (3) Business Days after it is sent by certified mail, return receipt requested, postage prepaid; or (C) one (1) Business Day after it is sent via a reputable nationwide overnight courier service. Either party may change its address by giving notice to the other party in the manner provided above; provided that notices of a change of address shall be effective only upon receipt thereof.

6.4 Entire Agreement. This Agreement, the Purchase Agreement and the Collaboration Agreement, in each case together with the schedules and exhibits thereto, set forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the parties and supersede and terminate all prior agreements and understanding between the parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the parties other than as set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the parties unless reduced to writing and signed by the respective authorized officers of the parties.

6.5 Headings; Nouns and Pronouns; Section References. Headings and any table of contents used in this Agreement are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.

6.6 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("**Modified Clause**"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

6.7 Assignment. Except for an assignment of this Agreement by the Investor to a Permitted Transferee, neither this Agreement nor any rights or duties of a party hereto may be assigned by such party, in whole or in part, without (i) the prior written consent of the Company in the case of any assignment by the Investor; or (ii) the prior written consent of the Investor in the case of an assignment by the Company.

6.8 Parties in Interest. All of the terms and provisions of this Agreement shall be binding upon, and shall inure to the benefit of and be enforceable by the parties hereto and their respective successors, heirs, administrators and permitted assigns.

6.9 Counterparts. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

6.10 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party with the exception of any Affiliate of the Investor shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.

6.11 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either party.

6.12 Remedies. The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.

6.13 Specific Performance. The Company and the Investor hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Investor, as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.

6.14 No Conflicting Agreements. The Investor hereby represents and warrants to the Company that neither it nor any of its Affiliates is, as of the date of this Agreement, a party to, and agrees that neither it nor any of its Affiliates shall, on or after the date of this Agreement,

enter into any agreement that conflicts with the rights granted to the Company in this Agreement. The Company hereby represents and warrants to the Investor that it is not, as of the date of this Agreement, a party to, and agrees that it shall not, on or after the date of this Agreement, enter into any agreement or approve any amendment to its charter or by-laws or similar organizational documents of the Company with respect to its securities that conflicts with the rights granted to the Investor in this Agreement which have not expired or been terminated in accordance with the terms hereof. The Company further represents and warrants that the rights granted to the Investor hereunder do not in any way conflict with the rights granted to any other holder of the Company's securities under any other agreements.

6.15 Use of Proceeds. The Company shall use the proceeds from the sale of the Purchased Shares for research and development and other working capital purposes and shall not use such proceeds for the redemption of any shares of Common Stock or for the payment of any dividends on shares of Common Stock.

6.16 No Publicity. The parties hereto agree that the provisions of Section 11.3 of the Collaboration Agreement shall be applicable to the parties to this Agreement with respect to any public disclosures regarding the proposed transactions contemplated by the Purchase Agreement and the Collaboration Agreement or regarding the parties hereto or their Affiliates (it being understood that the provisions of Section 11.3 of the Collaboration Agreement shall be read to apply to disclosures of information relating to this Agreement and the transactions contemplated hereby).

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

NEUROCRINE BIOSCIENCES, INC.

By: /s/ Kevin Gorman
Name: Kevin Gorman
Title: CEO

VOYAGER THERAPEUTICS, INC.

By: /s/ G. Andre Turenne
Name: G. Andre Turenne
Title: President and Chief Executive Officer

EXHIBIT A

FORM OF IRREVOCABLE PROXY

To secure the performance of the duties of the undersigned pursuant to Section 4.1 of the Investor Agreement, dated as of January 28, 2019 (the "**Agreement**"), by and between Neurocrine Biosciences, Inc. and Voyager Therapeutics, Inc. (the "**Company**"), the undersigned hereby irrevocably appoints the Company and any individual designated by the Company, and each of them individually, as the attorneys, agents and proxies, with full power of substitution and resubstitution in each of them, for the undersigned, and in the name, place and stead of the undersigned, to vote (or cause to be voted) in such manner as set forth in Section 4.1 of the Agreement (but in any case excluding any matter that is an Extraordinary Matter described in Section 4.2) with respect to all Purchased Shares, which the undersigned is or may be entitled to vote at any meeting of the Company held after the date hereof, whether annual or special and whether or not an adjourned meeting. This proxy is coupled with an interest, shall be irrevocable and binding on any successor-in-interest of the undersigned and shall not be terminated by operation of Law upon the occurrence of any event. This proxy shall operate to revoke and render void any prior proxy as to voting securities heretofore granted by the undersigned which is inconsistent herewith. Notwithstanding the foregoing, this irrevocable proxy shall be effective only if, at any annual or special meeting of the stockholders of the Company (or any consent in lieu thereof) and at any adjournments or postponements of any such meetings, the undersigned (A) fails to appear or otherwise fails to cause its voting securities of the Company to be counted as present for purposes of calculating a quorum, or (B) fails to vote such voting securities in accordance with Section 4.1 of the Agreement, in each case at least five (5) Business Days prior to the date of such stockholders' meeting. This proxy shall terminate upon the earlier of the expiration or termination of the Voting Agreement Term. Capitalized terms used but not defined herein shall have the meanings given them in the Agreement.

NEUROCRINE BIOSCIENCES, INC.

By: _____

Name:
Title:

EXHIBIT B

NOTICES

If to the Investor:

Neurocrine Biosciences, Inc.
12780 El Camino Real
San Diego, CA 92130
Attention: General Counsel

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Attention: Jason L. Kent, Esq.

If to the Company:

Voyager Therapeutics, Inc.
75 Sidney Street
Cambridge, MA 02139
Attention: Chief Executive Officer

with a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
Attention: Brian A. Johnson, Esq.

Exhibit 10.10

*****Text Omitted and Filed Separately**
with the Securities and Exchange Commission.
Confidential Treatment Requested
Under 17 C.F.R. Sections 200.80(c) and Rule 24b-2

COMMERCIAL API SUPPLY AGREEMENT

BETWEEN

F.I.S. - FABBRICA ITALIANA SINTETICI S.p.A.

AND

NEUROCRINE BIOSCIENCES INC.,

DATED AS OF

March 9, 2017

EXHIBITS AND SCHEDULES TO AGREEMENT

1.1	Initial Validation Stability Studies
1.2	Commercial Stability Studies
2.1	Initial Non-Binding Forecast
2.2	Batch Sizes
3.1	API Prices
4.1	Minimum Expiration Dating
5.1	Quality Agreement

COMMERCIAL SUPPLY AGREEMENT

THIS COMMERCIAL SUPPLY AGREEMENT (the "Agreement") is made and entered into as of the 9th day of March, 2017 (the "Effective Date") by and between F.I.S. - FABBRICA ITALIANA SINTETICI S.p.A., a corporation organized under the laws of the Republic of Italy, with offices at Viale Milano 26, 36075 Montecchio Maggiore (VI), Italy (hereinafter "FIS") and NEUROCRINE BIOSCIENCES Inc., a corporation organized under the laws of Delaware, with offices at 12780 El Camino Real, San Diego, California, 92130, USA ("Neurocrine"), on behalf of itself and its wholly-owned subsidiary, Neurocrine Therapeutics, Ltd., a corporation organized under the laws of the Republic of Ireland, ("Subsidiary", and together with Neurocrine, "Purchaser").

FIS and Purchaser are sometimes referred to herein individually as a "Party" and collectively as "Parties."

RECITALS

WHEREAS, FIS is a pharmaceutical company engaged in the development, manufacture and sale of pharmaceutical active ingredients;

WHEREAS, Purchaser is a company that is engaged in the development, distribution and sale of certain pharmaceutical products;

WHEREAS, FIS and Purchaser entered into a Master Services Agreement dated July 18, 2014 for Services including process scale up and manufacture of fine chemicals.

WHEREAS, FIS and Purchaser also entered into a Validation Agreement dated September 22, 2015 (the "Validation Agreement") for validation and stability services for the API, which will automatically terminate as of the Effective Date with remaining services, specification, and payment schedules incorporated by reference into Exhibit 1.1.

WHEREAS, FIS is now willing to supply the API and, in general, the Services to Purchaser upon the terms and conditions set forth herein. This agreement now supersedes all previous Agreements entered into by the Parties for supply of API and the Services.

NOW, THEREFORE, in consideration of the foregoing recitals, mutual covenants, agreements, representations and warranties contained herein, the Parties hereby agree as follows:

Article I
Definitions

"API" shall mean the active pharmaceutical ingredient, valbenazine tosylate (NBI-98854).

"API Price" shall have the meaning provided in Section 3.1 of this Agreement.

"Adverse Event" shall mean any adverse event associated with the use of the Finished Product in humans, whether or not considered drug-related, including (i) an adverse event

occurring in the course of the use of the Products in professional practice; (ii) an adverse event occurring from an overdose, whether accidental or intentional, related to the Products; (iii) an adverse event occurring from drug abuse related to the Products; (iv) an adverse event occurring from withdrawal of the Products; and (v) any failure of expected pharmacological action, or such other definition as may from time to time be set forth in 21 CFR Part 314.80.

"Alternative Dispute Resolution" shall have the meaning provided in Section 15.7(b) to this Agreement.

"Breach Notice" has the meaning specified in Section 14.2(a).

"Business Day" shall mean a day when both (i) banks operating in Vicenza, Italy are generally open for business and (ii) banks operating in San Diego, California are generally open for business.

"Certificate of Analysis" shall mean a document identified as such and provided by FIS to Purchaser that (i) sets forth the analytical test results for a specified lot of API shipped to Purchaser hereunder, (ii) is in conformance with each applicable Drug Application and (iii) states whether such API is manufactured in accordance with the Specifications and cGMPs.

"Certificate of Conformance" shall mean a document identified as such and provided by FIS to Purchaser that states that the specified lot of API shipped to Purchaser hereunder is manufactured in accordance with the Specifications and cGMPs.

"Confidential Information" shall have the meaning provided in Section 12.3 of this Agreement.

"Consent" shall mean any consent, authorization, permit, certificate, license or approval of, exemption by, or filing or registration with, any Governmental Authority or other Person.

"Current Good Manufacturing Practices" or "cGMPs" shall mean the regulatory requirements for the current good manufacturing practices in the United States Code of Federal Regulations 21 CFR Part 210 & Part 211, as amended, European Union ("EU") "Eudralex Volume 4 Good Manufacturing Guidelines - Part 2 - Basic Requirements for Active Substances used as Starting Materials", also known as the ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (Q7) the MHLW GMP/GQP ordinances and accompanying regulations in Japan, as applicable to the API manufacturing, and all applicable rules, regulations, promulgations, policies and guidelines in effect at any given time during the applicable Term.

"Data" shall mean information relating to: (i) the business of Purchaser or any Purchaser Affiliate; (ii) customers or suppliers of Purchaser or any Purchaser Affiliate, as it relates to any API or Finished Product; (iii) any of the API or Finished Product information including all Specifications therefore and any other information relating thereto delivered by Purchaser to FIS under this Agreement."Delivery Date" shall mean the date specified by Purchaser that FIS shall make particular API(s) available for shipment out of the applicable Facility(ies) in accordance with this Agreement.

"Disclosing Party" shall have the meaning provided in Section 12.3(a) of this Agreement.

"Drug Application" shall mean any New Drug Application filed with the FDA, any Supplemental New Drug Application filed with the FDA, any product license or any equivalent drug application or similar pharmaceutical product approval administered by any foreign Governmental Authority, or extension or renewal of any of the foregoing.

"Facility" shall mean, with respect to the APIs, FIS's manufacturing facility located at Viale Milano 26, 36075 Montecchio Maggiore (Vicenza), Italy, or other facilities of FIS as are mutually agreed upon in writing by the parties.

"FCA" shall mean the Incoterm Free Carrier.

"FDA" shall mean the US Food and Drug Administration .

"FD&C Act" shall mean the Food, Drug, and Cosmetic Act., a set of laws amended from time to time giving authority to the U.S. Food and Drug Administration (FDA) to oversee the safety of food, drugs, and cosmetics.

"Finished Product" means commercially packaged and labeled valbenazine tosylate.

"Firm Zone" shall have the meaning provided in Section 2.2(b) of this Agreement.

"FIS Affiliate" shall mean any Person who, directly or indirectly, through one or more intermediaries, Owns, is Owned by or is under common Ownership with FIS, a Party, where "Own," "Owned" or "Ownership" refers to (i) direct or indirect possession of at least fifty percent (50%) of the outstanding voting securities of a corporation or a comparable ownership in any other type of entity; or (ii) the actual ability of a Person or group to control and direct the management of the Person, whether by contract or otherwise.

"Force Majeure Event" shall have the meaning provided in Article XIII of this Agreement.

"FIS Confidential Information" shall have the meaning provided in Section 12.1 of this Agreement.

"FIS Indemnitee" shall have the meaning provided in Section 10.2 of this Agreement.

"FIS Intellectual Property" shall mean (i) all Intellectual Property owned by or licensed to FIS prior to the Effective Date and (ii) all Intellectual Property developed by FIS independent of FIS's performance of its obligations under this Agreement; provided, however, that such Intellectual Property does not relate to the API, or utilizes or is based on any Purchaser Intellectual Property

"FIS Nonconformity" shall have the meaning set forth in Section 5.7 of this Agreement.

"Governmental Authority" shall mean any nation or government, any state, province, or other political subdivision thereof or any entity with legal authority to exercise executive, legislative, judicial, regulatory or administrative functions or pertaining to government in any of the Markets.

"Key Raw Materials" shall have the meaning as set forth on Schedule 4.4(c) of this Agreement.

"Incoterm" shall mean the mean the international commercial terms published by the International Chamber of Commerce, 2010 edition.

"Indemnified Party" shall have the meaning provided in Section 10.3 of this Agreement.

"Indemnifying Party" shall have the meaning provided in Section 10.3 of this Agreement.

"Intellectual Property" shall mean (i) trademarks, trademark registrations, trademark applications, service marks, service mark registrations, service mark applications, business marks, brand names, trade names, trade dress, names, logos and slogans and all goodwill associated therewith; (ii) patents, patent rights, provisional patent applications, patent applications, designs, registered designs, registered design applications, industrial designs, industrial design applications and industrial design registrations, including any and all divisions, continuations, continuations-in-part, extensions, substitutions, renewals, registrations, revalidations, reexaminations, reissues or additions, including supplementary certificates of protection, of or to any of the foregoing items; (iii) copyrights, copyright registrations, copyright applications, original works of authorship fixed in any tangible medium of expression, including literary works (including all forms and types of computer software, including all source code, object code, firmware, development tools, files, records and data, and all documentation related to any of the foregoing), musical, dramatic, pictorial, graphic and sculptured works; (iv) trade secrets, technology, discoveries and improvements, know-how, proprietary rights, formulae, confidential and proprietary information, technical information, techniques, inventions, designs, drawings, procedures, processes, models, formulations, manuals and systems (whether or not patented, patentable, copyrighted, or copyrightable) including all biological, chemical, biochemical, toxicological, pharmacological and metabolic material and information and data relating thereto and formulation, clinical, analytical and stability information and data which have actual or potential commercial value and are not available in the public domain; and (v) all other intellectual property or proprietary rights, in each case whether or not subject to statutory registration or protection.

"Laws" shall mean any and all applicable local, municipal, provincial, federal and international laws, statutes, ordinances, rules, regulations or operating procedures now or hereafter enacted or promulgated by any Governmental Authority, including the FD&C Act.

"Losses" shall mean, collectively, any and all costs, expenses, including reasonable fees and disbursements of counsel and any consultants or experts and expenses of investigation, obligations, liens, assessments, judgments, damages, liabilities, fines and penalties imposed upon or incurred by an Indemnified Party.

"Materials" shall mean (i) all raw materials (including Key Raw Materials), components, work-in-process and other ingredients required to manufacture the APIs and (ii) all packaging materials used in the manufacture, storage and shipment of APIs.

"Materials Certification" shall have the meaning provided in Section 4.4(b) of this Agreement.

"Nonconformity" shall have the meaning provided in Section 5.3(a) of this Agreement.

"Non-binding Forecast" shall have the meaning provided in Section 2.2(a) of this Agreement.

"Party" and "Parties" shall have the meanings given such terms, respectively, in the first paragraph of this Agreement.

"Purchaser Affiliate" shall mean any Person who, directly or indirectly, through one or more intermediaries, Owns, is Owned by or is under common Ownership with Purchaser, where "Own," "Owned" or "Ownership" refers to (i) direct or indirect possession of at least fifty percent (50%) of the outstanding voting securities of a corporation or a comparable ownership in any other type of entity; or (ii) the actual ability of a Person or group to control and direct the management of the Person, whether by contract or otherwise.

"Purchase Order" shall have the meaning provided in Section 2.3 of this Agreement.

"Purchaser Confidential Information" shall have the meaning provided in Section 12.2 of this Agreement.

"Purchaser Indemnitee" shall have the meaning provided in Section 10.1 of this Agreement.

"Purchaser Intellectual Property" shall mean any and all Intellectual Property relating to the APIs that is (i) owned or controlled by Purchaser as of the Effective Date, or (ii) developed, acquired, or controlled by Purchaser after the Effective Date.

"Quality Agreement" shall have the meaning provided in Section 4.5 of this Agreement.

"Receiving Party" shall have the meaning provided in Section 12.3(a) of this Agreement.

"Regulatory Approval" means all approvals, product and/or establishment licenses, registrations or authorizations of federal, state or local regulatory agency, department, bureau or other governmental entity, necessary for the sale, offering for sale, and distribution of a human pharmaceutical product in the Territory.

"Remediation Period" has the meaning specified in Section 14.2(a).

"Representative" shall have the meaning provided in Section 12.3(b) of this Agreement.

"Services" shall mean activities contemplated to be completed pursuant to the Validation Agreement dated September 22, 2015.

"Specifications" shall mean, with respect to any API, all specifications for Materials, approved suppliers, formula, manufacturing, analytical and testing procedures, release, packaging, storage, and other processes relating to the manufacture of such API as agreed by the Parties and specified in the Quality Agreement (Exhibit 5.1), including all master formulas, process flow

diagrams, bills of materials, master batch records and all manufacturing and packaging work orders, all as amended from time to time by the Parties.

"Tax" shall mean any liability imposed by a Governmental Authority (as defined above and applied without geographical or other restriction) on gross receipts, sales, use, permits, value added, personal property, intangibles, and any stamp duty, customs duty, transfer, license, registration, premium or withholding tax, or any other kind of tax of any kind whatsoever; except that the term, "Tax" shall include any interest, fines, penalties, additions to tax, or additional amounts in respect of the foregoing Taxes or returns required to be filed under applicable Laws.

"Term" shall mean, with respect to a particular API, the period during which this Agreement is in effect with respect to such API pursuant to Article XIV.

"Third-Party" shall mean a person or entity other than FIS or Purchaser, or either of their respective Affiliates or successors.

"Third-Party Claim" shall have the meaning provided in Section 10.1 of this Agreement.

Article II
Sale and Purchase of API

2.1 General.

(a) Subject to the terms and conditions of this Agreement, FIS agrees to manufacture, to the extent ordered by Purchaser in accordance with this Agreement, the API at the applicable Facility(ies) for sale to Purchaser.

(b) Subject to the terms and conditions of this Agreement, FIS agrees to perform the Services at a price and timing as agreed between the Parties and set forth on Schedule listed in Exhibit 3.1.

2.2 Quarterly Forecasts.

(a)General. During the Term of this Agreement, Purchaser shall provide to FIS a non-binding projection for the next succeeding […***…] (or such shorter period remaining under the term of this Agreement) of the anticipated volumes of each API to be ordered by Purchaser pursuant to Section 2.3 below (each, a "Non-binding Forecast"). The initial such Non-binding Forecast is set forth on Schedule 2.1. Beginning on the […***…] after the Effective Date, Purchaser shall provide such rolling projections to FIS on the 10th day of the first month of each calendar quarter (January 10, April 10, July 10, October 10) during the Term of this Agreement. FIS shall notify the Purchaser in writing within ten (10) Business Days of receipt of any Non-binding Forecast if the quantities of API indicated therein by the Purchaser exceed FIS's production capacity.

(b) Firm Zone. The volume requirements for each API as set forth for each of the first […***…] of each such Non-binding Forecast will be a binding commitment by FIS to manufacture and supply to Purchaser, and by Purchaser to purchase,

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the specified volumes of those APIs (each such […***…] period shall be referred to herein as the "Firm Zone"). FIS acknowledges and agrees that the first […***…] of the Term the Non-Binding Forecast submitted by Purchaser may, at the discretion of the Purchaser, be zero. Should Purchaser wish to increase order quantities at any time in excess of the volumes permitted under this Section 2.2(b), then the Purchaser may contact FIS to request and FIS shall determine subject to Section 2.4, if and how it will supply any such increase in volumes.

(c) Non-Binding Forecasts. The API volumes specified for the […***…] through the […***…] month (or, if earlier, the final month) of each volume forecast shall be non-binding estimates of future API requirements.

2.3 Purchase Orders. Purchaser shall deliver to FIS an initial purchase order for the aggregate volume of API in Firm Zone. Thereafter with the release of each Quarterly Forecast, Purchaser shall deliver […***…] for each subsequent […***…] period which becomes the new Firm Zone (each a "Purchase Order"). Each such aggregate API volume shall constitute an amount equal to a multiple of FIS's standard batch size for the applicable API (as specified in Schedule 2.3), which such amount shall be at least […***…] batches for the year 2019, and at least […***…] batches for the years 2020 and 2021. Each Purchase Order shall specify the volume of each API ordered, which shall be comprised of volumes equivalent to FIS's standard batch size for applicable API (as specified in Schedule 2.3) or multiples thereof, and the Delivery Date the API is to be made available to Purchaser for pick-up by the carrier or freight forwarder. Acceptance of any Purchase Order which does not represent a full batch size for the relevant API (or multiple thereof) will be subject to FIS's sole discretion. Purchase Orders may be delivered electronically or by other means to such location as FIS shall designate. Each Purchase Order that is submitted, or deemed submitted, in accordance with this Section 2.3 shall be accepted or rejected by FIS within […***…] Business Days. If FIS does not accept or reject any Purchase Order within […***…] Business Days, such Purchase Order shall be deemed accepted. If FIS rejects any Purchase Order, Purchaser shall have the right to modify such Purchase Order within […***…] Business Days, and FIS shall have […***…] Business Days to accept or reject such modified Purchase Order. If FIS deosn't accept or reject such modified Purchase Order within […***…] Business Days, then such modified Purchase Order shall be deemed accepted.

2.4 Accommodations. From time to time, due to significant unforeseen circumstances, Purchaser may deliver to FIS a Purchase Order for volumes of a particular API in excess of those specified in any Firm Zone. FIS shall use its commercially reasonable efforts to provide Purchaser with such excess API volumes.

2.5 Meetings and Reports. Unless otherwise mutually agreed in writing, the Parties shall use commercially reasonable efforts to meet four (4) times per year in person to discuss and review the business relationship, including development/review of key performance indicators, the forecasts delivered by Purchaser pursuant to this Agreement, quality and any nonconformance, and other matters relevant to the supply of APIs hereunder (each such meeting hereinafter referred to as the "Business Review Meeting"). Purchaser shall provide to FIS at each Business Review Meeting all other readily available, appropriate data relating to the APIs and Purchaser's prospective demands and trends for the Finished Product and API.

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2.6 […***…]. If at any time […***…] determines […***…], or […***…] which is of a type that would […***…] shall first […***…] and agrees to […***…].

Article III
Prices for APIs; Shipment; Payments

3.1 Price.

(a) During the Term of this Agreement, Purchaser shall pay the applicable price for the API set forth on Schedule 3.1, attached hereto and incorporated herein ("API Price"). Unless otherwise agreed upon by both Parties and specified in the Purchase Order, such price shall include the costs of labor, facilities, Key Raw Materials as set forth on Schedule 4.4(c), raw Materials, starting Materials, reagents, solvents, analysis, standard packaging, waste disposal and reports.

(b) During the Term of this Agreement, the Parties agree to share cost improvement measures related to the manufacturing of the API. All cost improvement investments specific to each API shall require the written consent of both Parties. FIS shall be entitled to receive reimbursement for reasonable costs which it incurred in developing such cost improvements. Cost improvement benefits concerning such manufacturing shall be allocated 50:50 between the Parties and reflected in the price set forth on an amended Schedule 3.1.

(c) During the Term of this Agreement, Purchaser shall pay the applicable price for the Services as forth on Schedule 3.1, and as specified in a Purchase Order.

3.2 Invoices. All invoices for expenses and fees due under this Agreement, other than invoices for API, shall be submitted by FIS to Purchaser on a […***…] basis during the Term of this Agreement. Invoices for API shall be submitted after any API purchased that […***…] is released by FIS upon completion of its QA procedures, in accordance with the terms of Quality Agreement, for shipment from the Facility(ies) or within […***…] after any API purchased that […***…] is released by FIS upon completion of its QA procedures, in accordance with the terms of Quality Agreement, for shipment from the Facility(ies), whichever is earlier.

3.3 Payment. Payments for APIs invoiced under Section 3.2 above shall be due net […***…] from the date of invoice provided, however, if Purchaser places any portion of a shipment on hold pursuant to Section 5.2, or rejects any portion of a shipment pursuant to section 5.3, no payment shall be required on the rejected portion of the shipment until resolution on the rejected portion of the rejected shipment has been reached.

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3.4 Payment Denominations. All payments to be made under this Agreement shall be made in United States dollars unless otherwise specified herein or agreed by the Parties.

3.5 Shipment; Title; Transport.

(a) General. Title to API supplied by FIS to Purchaser hereunder, as well as all the relevant risks and costs, shall pass to Purchaser upon delivery of said API to the Purchaser or to a forwarder delegated by Purchaser in accordance with the FCA Incoterm. The API shall be shipped FCA/FIS's facilities in Montecchio Maggiore (Vicenza), Italy, packaged ready for export, including such items required to confirm shipment of goods under controlled condition such as temp tales, documentation suitable for export of the supplied API under controlled conditions and other measures required to satisfy EC Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01) and other Regulatory Agency's guidance. In amplification of the provisions regarding FCA, and not in limitation thereof, FIS shall directly or indirectly through Purchaser, upon request of Purchaser and at Purchaser's cost and risk, assist in (i) addressing special shipping requirements, (ii) obtaining licenses, official authorizations, clearances, customs, or any other documents and/or Information, including security related Information that Purchaser may require for the export, import or transport of the API to the final destination; (iii) making a contract for carriage; and (iv) loading the packed API in any container, collecting vehicle or other means of transport. Purchaser shall, upon request of FIS, provide Information required for taxation or reporting purposes in respect of the export of the API.

3.6 Taxes.

(a) Purchaser shall timely pay any and all Taxes arising out of any payment, transaction, or activity under this Agreement to the extent that Purchaser is liable for such Taxes under the Laws of the Governmental Authority that imposes said Taxes.

(b) Purchaser shall indemnify FIS, FIS's Affiliates, successors or assigns, and shall save and hold FIS harmless from and against Losses attributable to all Taxes (or the nonpayment thereof) that are the responsibility of Purchaser pursuant to this Section 3.6. The procedures set forth in Section 10.3 will apply, and the Parties expressly acknowledge that any payment of Tax by FIS will not constitute the settlement of a Third-Party Claim.

Article IV
Manufacture of Product

4.1 General. FIS shall manufacture, test, package, store, label, release and deliver all APIs in accordance with the Specifications, cGMPs, Laws, FD&C Act, and the Quality Agreement. Each API must have the minimum number of months of expiration dating remaining at the time of delivery from FIS to the Purchaser ("Minimum Retest Dating") as specified on Schedule 4.1.

4.2 Specification Changes.

(a) General.

(i) Either Party may request a Specifications change. The Parties shall discuss in good faith the implementation of any such requested changes; provided however, that such changes shall be made only with the Parties' mutual written consent which consent shall not be unreasonably withheld. Either Party may request a Specifications change required for compliance with Laws, and the Parties agree to implement such change as soon as is reasonably possible. All requests by FIS for such Specification changes shall be submitted in writing to Purchaser in accordance with the Quality Agreement.

(ii) Prior to implementation of any change to the Specifications, the Parties shall agree upon a procedure to ensure that applicable Governmental Authorities have approved the Specifications, to the extent necessary, and that FIS is given a reasonable period of time to implement any changes required by any such applicable Governmental Authority with regard to the Specifications.

(b) Payment.

(i) From time to time Purchaser may require Specification changes that will affect the API. These changes may be initiated by Purchaser, pursuant to Section 4.2(a) above. In the event of any change to Specifications other than any change contemplated by Section 4.2(b)(ii) or 4.2(b)(iii) below, Purchaser shall bear all costs associated with such a change. Should such Purchaser change to Specifications have an impact on API Price, either to increase or decrease such API Price, the Parties will agree to modifications, if any, to Schedule 3.1.

(ii) Should either Party initiate a Specification change designed to improve the API manufacturing process, the cost of such change will be agreed between the Parties and subsequent cost improvement shall be shared between the Parties subject to Section 3.1(b). The Parties will agree to modifications, if any, to the Product Price and to Schedule 3.1.

(iii) The costs of revisions (including any capital expenditure incurred to implement any revision, costs of additional materials and one-time expenditures) requested by either Party to maintain the Specificationsin conformity with cGMPs, laws, Regulatory Acts or Applicable Laws that are applicable (A) solely to the API shall be borne by Purchaser or (B) to the general manufacture of active pharmaceutical ingredients shall be borne pro-rata by FIS customers relative to their pro-rata use of the Facility and, to the extent reasonably economically feasible, without any increase in the price of that API, if subsequently sold to Purchaser.

4.3 Validations and Stability Studies.

(a) General. The Parties shall perform on an on-going basis all validations and stability studies required by the Specifications, cGMPs or Laws in connection with the

regular course of manufacturing the APIs for commercial supply, provided that Purchaser shall reimburse FIS for the cost of any validation or stability studies necessitated by a change to the Specifications.

(b) Reference Standards. The Purchaser shall provide all analytical reference standards for each of the APIs manufactured under this Agreement, at its own cost and Purchaser shall have the right to refer to and otherwise use such standards as may be reasonably necessary in connection with the manufacture and sale in the Territory of Finished Product.

4.4 Materials.

(a) General. FIS shall perform all testing of Materials required by the applicable Specifications.

(b) Materials Certifications. FIS shall prepare or cause to be prepared by FISs, as the case may be, certifications as to any Materials required by cGMPs or Laws (each, a "Materials Certification"), as detailed in the Quality Agreement.

(c) Procurement. FIS will be responsible for procuring all Materials required for the manufacture of APIs under this Agreement, in particular the Key Raw Materials as set forth in the Quality Agreement. FIS will procure the Key Raw Materials from the approved suppliers set forth on in the Quality Agreement) and at the Purchaser negotiated cost, such cost to be a pass through in the final API price as set forth on Schedule 3.1. FIS shall not procure the Key Raw Materials from any supplier not listed in the Quality Agreement without the prior written consent of Purchaser.

4.5 Quality Agreement. Within sixty (60) days of the Effective Date, Purchaser and FIS shall enter into a quality agreement for the APIs substantially in the form set forth in Schedule 4.5 to this Agreement (the "Quality Agreement"). Each Party shall comply with its obligations set forth in the Quality Agreement. In the event of a conflict between the terms of the Quality Agreement and the terms of this Agreement, the terms of this Agreement shall control with respect to all commercial or business matters, and the terms of the Quality Agreement shall control with respect to all quality matters. The Quality Agreement shall establish the procedure to be followed if either FIS or Purchaser desires to change any aspect of the manufacturing process for any API, including but not limited to any change in the Specifications as described in Section 4.2 above.

Article V
Testing and Quality Assurance

5.1 Testing of Product. Prior to release of API, FIS shall test the API in accordance with the testing procedures described in the Specifications, and shall provide Purchaser with a completed Batch Record, a Certificate of Analysis ("CofA"), a Certificate of Conformance ("CofC") and any other raw data or documents requested by Purchaser as agreed upon in the Quality Agreement for each batch of API.

5.2 FIS Holds and Rejections.

(a) General. Purchaser shall notify FIS of Purchaser's placing any API on hold for further investigation of a Nonconformity, or of Purchaser's rejection of any batch (or part thereof) of any API within […***…] after receipt of such API by Purchaser. Purchaser's notice shall state in as much detail as possible the basis for the hold or rejection. Failure to give notice within this […***…] period shall constitute acceptance of any API delivered, except in the case of a latent FIS Nonconformity that (i) would not have been revealed by a timely inspection in accordance with customary and reasonable procedures, and (ii) is discovered prior to the expiration date of the applicable API.

(b) Independent Testing. If the Parties disagree as to whether any API(s) subject to hold or rejected meets the Specifications, Purchaser's most senior quality assurance officer and FIS's most senior quality assurance officer, or such other persons as they may designate in writing, shall confer to review samples and/or batch records, as appropriate. If the disagreement is not resolved, then samples, batch records and other data relating to the batch in dispute shall promptly be submitted for testing and evaluation to an independent Third Party (including a testing laboratory) approved in writing by both Parties. The findings of the Third Party shall be final and binding on the Parties. The cost of the testing and evaluation by the Third Party shall be borne by the Party whose position was not supported by the determination of the Third Party.

(c) Notice. In the event that after the release of any APIs, Purchaser becomes aware that any batch of the APIs may have a Nonconformity, despite any testing and quality assurance activities, Purchaser shall immediately notify FIS in writing.

5.3 Nonconformity.

(a) Nonconformity. If FIS becomes aware that any batch or shipment of APIs has a Nonconformity, at any time regardless of the status of FIS's testing and quality assurance activities, FIS shall notify Purchaser within one (1) business day of becoming aware of a Nonconformity. "Nonconformity" means a product characteristic that (i) is attributable to FIS's failure to manufacture, test, package, store, label, release or deliver any API in accordance with the Specifications or cGMPs or (ii) causes any API to fail to conform to the applicable Specifications or cGMPs or meet the expiration dating requirement in Section 4.1. In the event of a Nonconformity, the Parties shall follow the procedure for investigations as set forth in the Quality Agreement.

(b) APIs Subject to Nonconformity. Any batch or shipment of API, or Finished Product that was manufactured using API, that is the subject of a Nonconformity or notice of Nonconformity shall be handled as follows:

(i) any portion of such batch or shipment of API held in inventory by FIS shall not be delivered to Purchaser;

(ii) any portion of such batch or shipment of API shipped to Purchaser and held in stock by Purchaser or Purchaser's designee shall maintain a "hold" or "unpassed" status, and shall not be released into passed inventory of Purchaser or used in the manufacture of any Finished Product, until Purchaser has completed

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any investigations related to such APIs and approved in writing the disposition of the API subject to the Nonconformity; and

(iii) any portion of any batch of Finished Product manufactured using such API that is held in stock by Purchaser shall maintain a "hold" or "unpassed" status, and shall not be released by Purchaser, until Purchaser has completed any investigations related to the API that was the subject of the Nonconformity and approved in writing the disposition of such API.

5.4 Product Complaints. Any and all complaints of which FIS becomes aware relating to any API or corresponding Finished Product shall promptly be forwarded to Purchaser's senior quality officer or his designee. Purchaser shall promptly inform FIS of any and all complaints that Purchaser receives which implicate FIS's manufacturing or other processes at the applicable Facility. Notification shall follow the procedure as set forth in the Quality Agreement.

5.5 Adverse Events. With respect to any Finished Product, FIS shall notify Purchaser promptly following any receipt of information of a possible Adverse Event. To the extent an Adverse Event of which Purchaser becomes aware potentially implicates FIS's manufacturing of any API or other processes at any applicable Facility(ies), Purchaser shall promptly inform FIS of such Adverse Event and shall disclose to FIS any information it has regarding that Adverse Event.

5.6 Investigations. The Parties shall investigate all reports of Nonconformity, API-related complaints or Finished Product-related complaints and Adverse Events in order to assure the conformity of APIs to the applicable Specifications and cGMPs. The Parties shall act promptly and shall cooperate fully in such investigations.

5.7 Certain Product Events. In the event Purchaser shall be required by a Governmental Authority to initiate a recall (or Purchaser voluntarily initiates a recall), withdrawal or field correction of, field alert report or comparable report with respect to, any Finished Product manufactured using API supplied by FIS pursuant to this Agreement, Purchaser shall notify FIS within 48 hours.

Purchaser shall be responsible for the costs of all recalls of Finished Products and initiated by Purchaser or any Affiliate or licensee thereof; provided that, notwithstanding the foregoing, FIS shall reimburse Purchaser for all reasonable costs and expenses incurred by Purchaser in procuring or complying with the requirements of any recall of Finished Products that is attributable to FIS's failure to manufacture, test, package, store, label, release or deliver any API in accordance with the Specifications, Laws, or cGMPs. FIS shall, at Purchaser's sole option, either (a) replace the API which is the subject of such recall at no additional cost to the Purchaser as soon as reasonably practicable, or (b) reimburse Purchaser for the amount paid by Purchaser to purchase and ship the API which is the subject of such recall.

5.8 Retained Samples. FIS shall retain samples from each batch of API for a period of one (1) year after the shipment of such batch to Purchaser or such longer period required by Laws or cGMPS and FIS internal procedure for record keeping, testing and regulatory purposes. FIS shall provide thirty (30) days notice to Purchaser prior to desctruction of any samples. Purchaser shall also have the right to retain, at its own cost, samples from each batch of API.

Article VI
Regulatory Matters

6.1 Manufacturing Consents. FIS holds all Consents required by FIS for the performance of its obligations under this Agreement. FIS is responsible for submitting to Italian Health Authorities (AIFA) the documents, also related to the APIs, requested for obtaining and maintaining the manufacturing licence. In the event any Consent held by FIS relating to the performance of its obligations hereunder is suspended or revoked, FIS shall promptly notify Purchaser of the event and shall promptly inform Purchaser of the impact on Purchaser's past and planned purchases of API.

6.2 Product Consents. Purchaser shall, at its expense, obtain and maintain any Consents which may from time to time be required by any Governmental Authority with respect to ownership of the Drug Applications or with respect to the marketing, distribution, clinical investigation, import or export of APIs. Purchaser shall be responsible for responding to all requests for information related to such Consents made by, and making all legally required filings relating to such Consents with any Governmental Authority. In the event any Consent held by Purchaser relating directly to any of the APIs is hereafter suspended or revoked, Purchaser shall promptly notify FIS of the event and shall promptly inform FIS of the impact on Purchaser's purchases of the affected API and Purchaser's general intentions with respect to the affected API.

6.3 Drug Application Documentation. Purchaser shall maintain all Drug Applications with respect to the Finished Products. Upon request from FIS, Purchaser shall provide FIS with information regarding the CMC sections of such Drug Applications, or discrete sections thereof.

6.4 Regulatory Changes. The Parties will promptly notify each other of any material revisions or amendment of or additions to cGMPs and will confer with each other with respect to the best means to comply with such requirements.

6.5 Regulatory Inspections. If FIS is notified that any API or Facility will be subject to an inspection, which involves any APIs manufactured for Purchaser, by any Governmental Authority, FIS shall promptly advise Purchaser of such investigation and fully cooperate with and allow any such inspection to the extent required by Laws. Purchaser shall have the right to have representatives present during any such inspection by a Governmental Authority.

Article VII
Intellectual Property

7.1 Ownership.

(a)Purchaser Intellectual Property. FIS acknowledges and agrees that, as between Purchaser and FIS, Purchaser owns all rights in and to the Purchaser Intellectual Property, including all rights in and to the API, the Finished Product, the Drug Applications for the Products, the Data and documentation, specifications and processes associated with the API and/or Finished Product. In particular, FIS acknowledges and agrees that: (i) all of the Specifications contain confidential information of Purchaser and are and shall remain the property of Purchaser; and (ii) all of the patents, trademarks and API formulation owned by Purchaser which apply to the manufacture, or use of API

covered by this Agreement are and shall remain Purchaser Intellectual Property. Except as expressly provided in Section 7.3 below, nothing in the Agreement shall be deemed to transfer or convey, expressly or by implication, any Purchaser Intellectual Property to FIS.

(b)FIS Rights. Purchaser acknowledges and agrees that FIS owns all rights in and to the FIS Intellectual Property.

7.2 New Developments and Modifications.

(a)API Developments. All Intellectual Property relating to an API conceived, reduced to practice, authored, or otherwise generated or developed in whole or in part in the course of activities under this Agreement, whether patentable or not, shall be "API Developments." Such API Developments shall include without limitation, any know-how or improvements relating to the API or the manufacture of the API, conceived, reduced to practice or otherwise developed solely by or on behalf of FIS, in connection with the performance of its obligations hereunder.

(b)Ownership of API Developments. FIS will, in accordance with applicable Law, obtain the rights to assign to Purchaser all of the rights, title and interest in and to API Developments and rights to Intellectual Property arising therefrom to the extent any such API Developments and/or Intellectual Property are developed wholly or in part by FIS personnel. Without further payment to FIS, as between the Parties, Purchaser shall own all right, title and interest in and to all API Developments, whether made, conceived, reduced to practice, authored or otherwise generated or developed solely by FIS personnel, solely by Purchaser personnel, or jointly by FIS and Purchaser personnel, and all rights to Intellectual Property arising therefrom. FIS will, and hereby does, assign to Purchaser all of its rights, title and interest in and to API Developments and rights to Intellectual Property arising therefrom. FIS will provide reasonable assistance to Purchaser, at Purchaser's expense, in obtaining and enforcing and defending Purchaser's ownership of the API Developments and appurtenant rights to Intellectual Property, including without limitation and as applicable, the assignment to Purchaser of all their right, title and interest of its employees or independent contractors in and to such API Developments and appurtenant rights to Intellectual Property.

7.3 Grant of Licenses.

(a)By Purchaser. Under the terms and subject to the conditions of this Agreement, Purchaser hereby grants FIS the non-exclusive, royalty-free, fully-paid, under the Purchaser Intellectual Property solely to perform FIS's obligations under this Agreement.

Article VIII
Access; Audit Rights

8.1 Audit and Inspection Rights. During the Term of this Agreement, Purchaser shall have the right to audit and inspect those portions of the Facilities used in the manufacture, packaging, generation, storage, testing, treatment, holding, transportation, or other handling or receiving of the APIs and Materials. Purchaser shall have the right to audit and inspect all

inventory of APIs and Materials contained at the Facilities. Such audits or inspections shall occur during normal business hours and shall be scheduled by Purchaser at least […***…] in advance; provided, however, that in the event of an Adverse Event with respect to any Finished Product manufactured using any API supplied hereunder or any proposed or actual inspection by the FDA or other Governmental Authority, Purchaser shall have the right at any time upon oral or written notice to FIS of […***…] to conduct an audit or inspection hereunder. Except in the case of an Adverse Event with respect to any Finished Product manufactured using any API supplied hereunder, Purchaser shall limit such audits to no more than […***…] per calendar year for each Facility except for audit for cause, follow-up of corrective ation plans, or Pre-Approval Inspection (PAI) preparation. FIS and Purchaser may agree to reduce the audit frequency depending upon the results of the previous audit(s) and the quality performance of Purchaser.

Purchaser's audit and inspection rights under this Section 8.1 shall not extend to any portions of any Facility, documents, records or other information which do not relate to APIs or Materials or, to the extent they relate or pertain to Third Parties or their products or materials, FIS may redact information relating to Third Parties and their respective products or materials from any documents deliverable to Purchaser in connection with Purchaser's exercise of its audit and inspection rights hereunder. FIS shall participate in Purchaser's audit and shall respond to any issues raised by Purchaser based on such audit with a corrective action plan.

8.2 Documentation. Each Party shall maintain, in accordance with and for the period required under cGMPs and all other Laws, complete and adequate records pertaining to the methods and facilities used for the cGMPs manufacture, processing, testing, packing, labeling, holding and distribution of the APIs and, in the case of Purchaser, Finished Products.

Article IX
Representations, Warranties, and Covenants

9.1 Representations and Warranties of FIS. FIS represents and warrants that:

(a) Status; Enforceability. FIS is a validly existing corporation under the laws of Italy; the execution, delivery and performance of this Agreement by FIS (where applicable) has been duly authorized by all requisite corporate action; this Agreement constitutes the legal, valid and binding obligation of FIS, enforceable against FIS in accordance with the terms hereof; and the execution, delivery and performance of this Agreement by FIS will not violate or conflict with any other agreement or instrument to which FIS is a Party.

(b) Certain Persons. FIS has not used, in any capacity associated with or related to the manufacture of the APIs, the services of any persons who have been, or are in the process of being, debarred under 21 U.S.C. § 335a(a) or (b) or any comparable Regulatory Act. Furthermore, neither FIS nor any of its officers, employees, or consultants involved in the manufacture of APIs hereunder has been convicted of an offense under (i) either a federal or state law that is cited in 21 U.S.C. § 335(a) as a ground for debarment, denial of approval, or suspension, or (ii) any other law cited in any comparable Regulatory Act as a ground for debarment, denial of approval or suspension.

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(c) Consents. FIS has all governmental approvals, permits and licenses necessary for the performance of its obligations hereunder.

(d) Compliance. The manufacture, packaging, generation, processing, distribution, transport, treatment, storage, disposal and other handling of any Materials or APIs by FIS until delivery to a carrier or freight forwarder shall be in accordance with and conform to the Specifications, cGMPs, the FD&C Act and all other material Laws.

9.2 Representations and Warranties of Purchaser. Purchaser represents and warrants to FIS that:

(a) Status; Enforceability. Purchaser is a validly existing corporation and is in good standing under the laws of the jurisdiction of its incorporation; the execution, delivery and performance of this Agreement by Purchaser has been duly authorized by all requisite corporate action; this Agreement constitutes the legal, valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with the terms hereof; and the execution, delivery and performance of this Agreement will not violate or conflict with any other agreement or instrument to which it is a Party.

(b) Intellectual Property. The portion of Purchaser Intellectual Property licensed to FIS under this Agreement is free and clear of any lien, encumbrance, security interest or restriction on license inconsistent with the rights granted to FIS herein. The Purchaser has not previously granted and will not grant to any Third Party during the Term of this Agreement, any right, license or interest in or to the Purchaser Intellectual Property, or any portion thereof, inconsistent with the rights granted to FIS herein.

(c) No Other License Required. To Purchaser's knowledge, the manufacture and supply of APIs pursuant to this Agreement do not and shall not require a license under any Intellectual Property owned or controlled by Purchaser or any Third Party other than as provided to FIS hereunder.

(d) Noninfringement. To Purchaser's knowledge, the manufacture and supply of APIs pursuant to this Agreement in accordance with the Specifications will not infringe the Intellectual Property of any Third Party.

9.3 Storage and Distribution of the APIs. Purchaser shall comply with cGMPs, the Specifications, and all applicable Laws in the storage, handling, and distribution of the APIs supplied by FIS pursuant to this Agreement and in the manufacture, storage, handling, sale, and distribution of all Finished Products manufactured using such API.

Article X
Liability and Indemnification

10.1 Purchaser Indemnity: Purchaser shall indemnify, defend and hold harmless FIS, its directors, officers, employees and agents, from and against any and all Losses resulting from claims of any kind and character by any Third Party (a "Third Party Claim") arising out of, or in connection with, or with respect to the API supplied to and accepted by Purchaser pursuant to this

Agreement, as well as including without limitation (a) the negligence and/or wilful misconduct of the Purchaser (or any of its directors, officers, employees or agents) in the performance of its obligations hereunder, or (b) the breach by the Purchser of any of the terms of this Agreement. Notwithstanding the foregoing, FIS and its directors, officers, employees, and agents shall not be entitled to indemnification under this paragraph against any claim to the extent resulting from (a) the negligence or wilful misconduct of FIS or any of its directors, officers, employees or agents or (b) the breach by FIS of any of the terms of this Agreement.

10.2 FIS Indemnity: FIS shall indemnify, defend and hold harmless, Purchaser, its directors, officers, employees and agents, from and against any and all Losses resulting from claims of any kind and character by any Third Party arising out of or in connection with FIS's performance of its obligations hereunder including without limitation (a) the negligence and/or wilful misconduct of FIS (or any of its directors, officers, employees or agents) in the performance of its obligations hereunder, or (b) the breach by FIS of any of the terms of this Agreement. Notwithstanding the foregoing, Purchaser and its directors, officers, employees, and agents shall not be entitled to indemnification under this paragraph against any claim to the extent resulting from (a) the negligence or wilful misconduct of Purchaser or any of its directors, officers, employees or agents or (b) the breach by Purchaser of any of the terms of this Agreement.

10.3 Limitation of Liability: Notwithstanding anything to the contrary herein, neither Party shall be liable to the other for indirect, incidental or consequential damages arising out of any terms or conditions in this Agreement or with respect to the performance thereof.

10.4 Indemnification Procedures: Should a Party (the "Indemnified Party") be notified of any Third Party claim in respect of which the other Party (the "Indemnifying Party") may be reasonably liable under the indemnification obligation provided for in this Section 10, the Indemnified Party shall (i) give the Indemnifying Party prompt written notice thereof; and (ii) give the Indemnifying Party the opportunity to defend, negotiate, and settle any such action or claim. To such extent, the Indemnified Party shall provide the Indemnifying Party with all information in its possession, and all authority and assistance necessary to enable Indemnifying Party to defend, negotiate, compromise or settle any such claim, action or suit. The Indemnified Party shall further cooperate fully with the Indemnifying Party and its legal representatives (at the Indemnifying Party's sole cost and expense) in the investigation, negotiation, compromise, settlement and defence of such claim, action or suit. In any case, it is hereby understood that (i) the Indemnified Party reserves the right to retain its own counsel to defend itself (at its own cost and expense) in such claim, action or suit; and (ii) in no event shall either Party enter into any settlement without the prior written consent of the other Party, which shall not be unreasonably withheld.

10.5 Survival of Indemnification Obligations: The provisions of this Section 10 shall survive the expiration or termination of this Agreement.

10.6 Procedures. Any Person that may be entitled to indemnification under this Agreement (an “Indemnified Party”) shall give written notice to the Person obligated to indemnify it (an “Indemnifying Party”) with reasonable promptness upon becoming aware of any Third-Party Claim or other facts upon which a claim for indemnification will be based. Such notice shall set

forth such information with respect thereto as is then reasonably available to the Indemnified Party. The Indemnifying Party shall have the right to undertake the defense of any such Third-Party Claim with counsel reasonably satisfactory to the Indemnified Party and the Indemnified Party shall cooperate in such defense and make available all records, materials and witnesses reasonably requested by the Indemnifying Party in connection therewith at the Indemnifying Party's expense. If the Indemnifying Party shall have assumed the defense of the Third-Party Claim with counsel reasonably satisfactory to the Indemnified Party, the Indemnifying Party shall not be liable to the Indemnified Party for any legal or other expenses (other than for reasonable costs of investigation) subsequently incurred by the Indemnified Party in connection with the defense thereof. The Indemnifying Party shall not be liable for any Third-Party Claim settled without its consent, which consent shall not be unreasonably withheld or delayed. The Indemnifying Party shall obtain the written consent of the Indemnified Party prior to ceasing to defend, settling or otherwise disposing of any Third-Party Claim.

Article XI
Insurance

11.1 FIS Insurance Requirements. During the Term of this Agreement and for […***…] after its expiration or termination, FIS shall at all times maintain insurance policies or self-insurance in such amounts and with such scope of coverage as are adequate to cover FIS's obligations under this Agreement.

11.2 Purchaser Insurance Requirements. During the Term of this Agreement and for […***…] after its expiration or termination, Purchaser shall at all times maintain insurance policies or self-insurance in such amounts and with such scope of coverage as are adequate to cover Purchaser's obligations under this Agreement.

Article XII
Confidentiality

12.1 Definition of "Purchaser Confidential Information". As used herein, the term "Purchaser Confidential Information" shall mean all confidential business and technical communications, documents and other information, whether in written, oral or other form, which Purchaser or a Purchaser Affiliate furnishes or discloses to FIS or which FIS otherwise learns in connection with the negotiation or performance of this Agreement (whether relating to Purchaser, a Purchaser Affiliate or any Third Party for which Purchaser has an obligation of confidentiality). FIS agrees that the provisions of this Agreement shall apply to all Purchaser Confidential Information disclosed by Purchaser or a Purchaser Affiliate to FIS or learned by FIS prior to the Effective Date. FIS represents and warrants that prior to the Effective Date, it has not used or disclosed to any Third Party any Purchaser Confidential Information, except as would be permitted hereunder.

12.2 Definition of "FIS Confidential Information". As used herein, the term "FIS Confidential Information" shall mean (i) all confidential business information and (ii) technical communications, documents or other information in each case, not constituting Purchaser Rights whether in written, oral or other form, of FIS or a FIS Affiliate that are disclosed to Purchaser by

* ***** Confidential Treatment Requested**

FIS or an FIS Affiliate, or Purchaser otherwise learns in connection with the negotiation or performance of this Agreement; provided, however, that subject to the terms of this Agreement, all information relating to the API shall be Purchaser Confidential Information. Purchaser agrees that the provisions of this Agreement shall apply to all FIS Confidential Information disclosed by FIS or any FIS Affiliate or learned by Purchaser prior to the Effective Date.

12.3 Treatment of Confidential Information. Both during the Term of this Agreement and thereafter, FIS shall treat all Purchaser Confidential Information and Purchaser shall treat all FIS Confidential Information in accordance with the requirements of this Article XII. For convenience, Purchaser Confidential Information and FIS Confidential Information are both referred to herein as "Confidential Information" for purposes of establishing the obligations of each Party with regard to the other Party's Confidential Information.

(a) Nondisclosure. Confidential Information of the other Party shall be kept strictly confidential by the receiving Party and, except as expressly permitted herein, shall not be disclosed to any Third Party by the receiving Party in any manner whatsoever including without limitation, any affiliates, in whole or in part, without first obtaining the other Party's prior written consent to such disclosure. The standard of care required of each Party in protecting the confidentiality of the other Party's Confidential Information shall be at least the same standard of care that the receiving Party uses in protecting its own confidential and trade secret information, but in no event shall either Party use less than a reasonable standard of care. Confidential Information may be used by the receiving Party only for the purpose of performing under this Agreement.

(b) Permitted Exceptions. Each Party may disclose the other Party's Confidential Information (i) to its employees or outside advisors and financing sources in connection with this Agreement who reasonably need to know such information for the purpose of advising or assisting it in connection with this Agreement (each, a "Representative"), (ii) to a Third Party pursuant to a contractual obligation under a material contract, whereby failure to disclose such Confidential Information shall have material adverse effect on the disclosing Party, and (iii) to any Parties required under operation of law. FIS acknowledges that Purchaser will be required to file a copy of this Agreement with Purchaser's filings to the U.S. Securities Exchange Commission. Purchaser and FIS agree to cooperate in the preparation of a request for confidential treatment with respect to the Agreement, pursuant to which portions of this Agreement will be redacted from all public access. Prior to disclosing any Confidential Information to any Representative pursuant to this Section 13.3(b), the receiving Party will inform such Representative of the proprietary nature of the Confidential Information and will require such Representative to agree in writing (except in the case of outside legal advisors or auditors engaged to prepare either Party's financial statements or Purchaser's filings with the Securities Exchange Commission, who may orally agree) to be bound by the requirements of this Article XIII and not to use or disclose the Confidential Information except as permitted herein. Each Party agrees to be responsible for any breach of these confidentiality obligations by its Representatives. It is specifically agreed that (i) Purchaser may disclose FIS Confidential Information to any Purchaser Affiliate under the same conditions provided in this Article XII on a need-to-know basis and (ii) FIS may disclose Purchaser Confidential Information to any FIS Affiliate under the same conditions provided in this Article XII on a need-to-know basis.

(c) Consent. Confidential Information of the other Party shall not be utilized by a receiving Party except as expressly permitted herein, without first obtaining the other Party's prior written consent to such utilization and without first entering into a separate agreement duly executed by authorized representatives of the Parties hereto.

12.4 Excluded Information. Notwithstanding any provision herein to the contrary, the requirements of this Article XII shall not apply to any information of either Party which:

(a) at the time of disclosure hereunder is generally available to the public;

(b) after disclosure hereunder becomes generally available to the public, except through breach of this Article XII by the receiving Party or its Representatives;

(c) was not acquired directly or indirectly from the disclosing Party or its Affiliates and which the receiving Party lawfully had in its possession prior to disclosure by the disclosing Party;

(d) is independently developed by employees or agents of the receiving Party without the use of the Confidential Information of the disclosing Party; or

(e) becomes available to the receiving Party from a Third Party that is not legally prohibited from disclosing such Confidential Information, provided such information was not acquired directly or indirectly from the disclosing Party or its Affiliates.

12.6 Return of Confidential Information. At any time upon the request of the Disclosing Party, to the extent such Confidential Information is not reasonably necessary to enable a Receiving Party to perform its obligations under this Agreement, the Receiving Party shall promptly return to the Disclosing Party or destroy the Disclosing Party's Confidential Information, and shall destroy all copies thereof, together with all notes, drawings, abstracts and other information relating to the Disclosing Party's Confidential Information prepared by the Receiving Party or any of its Representatives, regardless of the medium in which such information is stored; provided, however, that the Receiving Party may maintain a single archival copy of the Disclosing Party's Confidential Information in its files solely for purposes of establishing the extent of disclosures by the Disclosing Party under this Agreement. At the Disclosing Party's written request, the Disclosing Party's Confidential Information that is otherwise required to be returned to it shall be destroyed by the Receiving Party and such destruction shall be certified in writing by an authorized officer of the Receiving Party. The return and/or destruction of such Confidential Information as provided above shall not relieve the Receiving Party of its other obligations under this Article XII.

Article XIII
Force Majeure Event

13.1 General. Neither Party shall be liable to the other on account of any failure to perform or on account of any delay in performance of any obligation under this Agreement, if and to the extent that such failure or delay shall be due to a cause beyond the reasonable control of the relevant Party and which, by the exercise of its commercially reasonable efforts of diligence and care, such Party could not reasonably have been expected to avoid (a "Force Majeure Event"). The Party experiencing the delay and seeking relief under this Article XIII shall promptly notify the

other Party of the delay and the probable duration of the delay and shall use commercially reasonable efforts to overcome such delay. The Party affected shall be excused from the performance of such obligation to the extent such performance is prevented, hindered or delayed thereby during the continuance of any such happening or event. This Agreement, in so far as it relates to such obligation, shall be deemed suspended so long as and to the extent that such cause delays the performance of any Force Majeure Event obligation.

Article XIV
Term; Termination; Remedies

14.1 Term. Unless earlier terminated in accordance with this Article XIV, this Agreement shall commence on the Effective Date and, with respect to each API, will continue until either Party provides the other Party with written notice of termination with respect to such API, in which case this Agreement shall expire, and such termination shall be effective, on the date twenty four (24) months following the date of such notice with respect to the API(s) which is(are) the subject of such notice, provided that such notice shall not be given by either Party prior to the fifth (5th) anniversary of the Effective Date.

14.2 Termination.

(a) Material Breach. Either party at its sole option may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under this Agreement within […***…] following receipt of a written notice (the "Remediation Period") of the breach from the aggrieved party that expressly states that it is a notice under this Section 14.2(a) (a "Breach Notice"). The aggrieved party's right to terminate this Agreement under this Section 14.2(a) may only be exercised for a period of […***…] following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice.

(b) Either party at its sole option may immediately terminate this Agreement or a Product Agreement upon written notice, but without prior advance notice, to the other party if: (i) to the extent and if permitted under applicable Law the other party is declared insolvent or bankrupt by a court of competent jurisdiction; or (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party;

(c) Purchaser may terminate this Agreement upon six months' prior written notice if it intends to no longer order API due to the Finished Product's discontinuance in the market.

14.3 Injunctive Relief. In the event that either Purchaser or FIS breaches or threatens to breach any provision of Article XII of this Agreement, the Parties agree that irreparable harm to the other Party is presumed and the damage to such Party likely would be very difficult to ascertain and would be inadequate. Accordingly, in the event of such circumstances, each of Purchaser and FIS agree that, in addition to any other right and remedies available at law or in equity, the non-breaching Party shall have the right to obtain injunctive relief from any court of competent jurisdiction, and the breaching party waives the requirement that a bond be posted.

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Article XV
Miscellaneous

15.1 Standard Forms. In all communications, FIS and Purchaser may employ their standard forms, but nothing in those forms, including Purchase Orders, shall be construed to modify or amend the terms and conditions of this Agreement, and, in the case of any conflict herewith, the terms and conditions of this Agreement shall control.

15.2 Notices. In addition to the other specific procedures for notification required herein, all notices, demands, requests and other communications made hereunder shall be in writing and shall be given either by personal delivery, by nationally recognized overnight courier (with charges prepaid), or by facsimile transmission (with telephone confirmation), and shall be deemed to have been given or made: (i) if personally delivered, on the day of such delivery; (ii) if sent by overnight courier, on the day following the date deposited with such overnight courier service; or (iii) if by facsimile transmission, on the date transmitted to receiving facsimile machine and confirmed by telephone, in each case pending the designation of another address, addressed as follows:

If to FIS:

F.I.S. FABBRICA ITALIANA SINTETICI S.p.A.
Viale Milano 26, 36075 Montecchio Maggiore (VI), Italy
Attn: Marketing & Sales Director

If to Purchaser:

NEUROCRINE BIOSCIENCES Inc.,
12780 El Camino Real, San Diego, California, 92130, USA
Attention: Vice President, Manufacturing

With a copy to
Attention: Chief Legal Officer
Email: dlippoldt@neurocrine.com

15.3 Independent Contractors. In the exercise of its obligations and in respect of its rights and entitlements hereunder or in respect hereof, Purchaser and FIS are and shall in all respects be treated as independent contractors with respect to each other. Neither Party shall be deemed to be a co-venturer or partner of the other. Neither Party is an employee or a legal representative of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party.

15.4 Entire Understanding. This Agreement and Quality Agreement, the Schedules attached hereto, and any other document identified herein, represents the entire understanding and agreement between the Parties hereto with respect to the subject matter hereof, and supersedes all prior and contemporaneous agreements and understandings between the Parties with respect to such subject matter, which are hereby expressly terminated.

15.5 Unintentional Omissions. The Parties acknowledge that they have expended substantial effort in preparing this Agreement and attempting to describe, in the Schedules hereto, as thoroughly and precisely as possible, Specifications, APIs, and other information. However, despite these efforts, the Parties acknowledge the possibility of involuntary or inadvertent omissions from the Schedules. The Parties will agree in writing to the changes to be made to the Schedules to add these inadvertent or involuntary omissions and any such written agreement executed by the Parties shall serve as an amendment to this Agreement.

15.6 Transferability; Binding Effect. Neither this Agreement, nor any of the rights or obligations of a Party may be directly or indirectly assigned, sold, delegated or otherwise disposed of without the prior written consent of the other Party, which consent may not be unreasonably withheld; provided, however, that either Party may assign this Agreement to an Affiliate, and either Party may assign this Agreement, in whole or part, to a successor by merger, acquisition, or sale of all or substantially all of such Party's business or assets to which this Agreement relates, without the consent of the other Party.

15.7 Dispute Resolution.

(a) If the Parties fail to resolve any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement (other than one relating to a breach of Article XII or to the validity, enforceability, infringement or misappropriation of Intellectual Property rights, which shall not be subject to this Section 15.7), or concerning the interpretation, effect, termination, validity, performance and/or breach of this Agreement (a "Claim"), either Party may refer the dispute, by notice to the other Party, to their respective chief executive officers, or their designees, for attempted resolution by good faith negotiations within thirty (30) days after that notice is received.

(b) Alternative Dispute Resolution. If the Parties cannot reach a resolution of the dispute according to Section 15.7(a), then such dispute shall be finally resolved by binding arbitration in accordance with the then existing commercial arbitration rules under the Rules of Arbitration of the International Chamber of Commerce ("ICC") by a single arbitrator appointed by ICC in accordance with the said rules. Arbitration shall be conducted in New York City, New York, United States if Purchaser is the defendant party, and in Vicenza, Italy, if FIS is the defendant party, and shall be conducted in the English language.

15.8 Subcontractors. FIS may not subcontract to Third Parties any manufacturing functions in connection with the API without prior written approval from Purchaser.

15.9 Amendment. Any amendment, modification or supplement of or to any provision of this Agreement, including the Schedules hereto, shall be effective only in writing and manually signed by a duly authorized officer of suitable title of all Parties hereto. The Parties hereto waive the right to amend the provisions of this Section 15.9 orally.

15.10 Severability. If and to the extent that any court of competent jurisdiction holds any provision (or any part thereof) of this Agreement to be invalid or unenforceable, such holding shall in no way affect the validity or enforceability of the remainder of this Agreement, and the invalid

or unenforceable provision shall be fully severed from this Agreement and there shall automatically be added in lieu thereof a provision as similar in terms and intent to such severed provision as may be legal, valid and enforceable.

15.11 Waiver. Any failure of Purchaser or FIS to comply with any obligation, covenant, agreement or condition herein contained may be expressly waived, in writing only, by the other Party hereto and such waiver shall be effective only in the specific instance and for the specific purpose for which made or given.

15.12 Survival. Article I, Article VII, Article X, Article XI, Article XII, Article XV, and Sections 2.8, 3.3, 3.6, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 9.1(e), 9.3 13.2, and 14.3, and any other provision which by its terms specifically shall so state, together with any obligation to make accrued but unpaid payments due hereunder, shall survive the termination or expiration of this Agreement.

15.13 Drafting Ambiguities. Each Party to this Agreement and its counsel have reviewed and revised this Agreement. The rule of construction to the effect that any ambiguities are to be resolved against the drafting Party shall not be employed in the interpretation of this Agreement or any amendment or Schedule to this Agreement.

15.14 Headings; Schedules; Counterparts.

(a) Headings. The headings of the Sections of this Agreement are for reference purposes only, are not part of this Agreement and shall not in any way affect the meaning or interpretation of this Agreement.

(b) Schedules. All Schedules delivered pursuant to this Agreement shall be deemed part of this Agreement and incorporated herein by reference, as if fully set forth herein. All provisions contained in any Schedule delivered by or on behalf of the Parties hereto, or in connection with the transactions contemplated hereby, are an integral part of this Agreement.

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

15.15 Governing Law. This Agreement shall be governed by, construed and enforced in accordance with the laws of the State of New York without regard to principles of conflicts of law,.

[Signature page to follow.**]**

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be duly executed as of the date first written above.

By: F.I.S. - FABBRICA ITALIANA SINTETICI S.p.A

Name: /s/ illegible

Title: illegible

By: NEUROCRINE BIOSCIENCES Inc.

Name: /s/ Darin Lippoldt

Title: Chief Legal Officer

Schedule 1.1
Initial Validation Stability Studies

Schedule 1.2
Commercial Stability Studies

Services

Stability Studies
•**Total cost = $[**…***…**]** •Long term stability study ([…***…]) @ $[…***…] •Accelerated stability study ([…***…]) @ $[…***…] •Intermediate stability study ([…***…]) @ $[…***…] •Long term stability study ([…***…]) @ $[…***…]

Terms of payment	[…***…] from invoice date for each delivery $[…***…] down payment upon signature $[…***…] after first stability pull $[…***…] year 2 stability start $[…***…] year 3 stability start $[…***…] year 4 stability start

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Exhibit 2.1

Initial Non-Binding Forecast
Valbenazine Tosylate

Schedule 2.3

Batch Sizes

API	Batch Sizes (in Kilograms)
valbenazine tosylate	[…***…]

Schedule 3.1

API Prices

API	Number of Batches[1] Purchased per Year	Price Per Kilogram ($)
valbenazine tosylate	[…***…]	[…***…]
valbenazine tosylate	[…***…]	
valbenazine tosylate	[…***…]	
valbenazine tosylate	[…***…]	
valbenazine tosylate	[…***…]	

Note 1 - Based Upon Batch Size Detailed in Schedule 2.2

Schedule 4.1

Minimum Retest Dating

API	Number of Months
valbenazine tosylate	[…***…]

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Exhibit 5.1

Quality Agreement

EXHIBIT 21.1

NEUROCRINE BIOSCIENCES INC. SUBSIDIARIES

NAME OF SUBSIDIARY	JURISDICTION
Neurocrine Continental, Inc.	Delaware, USA
Neurocrine Europe, Ltd.	Ireland
Neurocrine Therapeutics, Ltd.	Ireland

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 No. 333-216066) of Neurocrine Biosciences, Inc.,

(2) Registration Statements (Form S-8 Nos. 333-105907, 333-135909, 333-147120, 333-152689, and 333-160934) pertaining to the 2003 Incentive Stock Plan, as amended, of Neurocrine Biosciences, Inc.,

(3) Registration Statement (Form S-8 No. 333-127214) pertaining to the Employment Commencement Nonstatutory Stock Option with Richard Ranieri and 2003 Incentive Stock Plan, as amended, of Neurocrine Biosciences, Inc.,

(4) Registration Statement (Form S-8 No. 333-118773) pertaining to the Employment Commencement Nonstatutory Stock Option and 2003 Incentive Stock Plan, as amended May 25, 2004 and August 2, 2004, of Neurocrine Biosciences, Inc.,

(5) Registration Statements (Form S-8 Nos. 333-175889, 333-190178, 333-197916, and 333-212871) pertaining to the 2011 Equity Incentive Plan of Neurocrine Biosciences, Inc.,

(6) Registration Statement (Form S-8 Nos. 333-199837, and 333-216067) pertaining to the Inducement Plan of Neurocrine Biosciences, Inc., and

(7) Registration Statement (Form S-8 No. 333-205933) pertaining to the 2011 Equity Incentive Plan and Inducement Plan of Neurocrine Biosciences, Inc.

of our reports dated February 7, 2019 with respect to the consolidated financial statements of Neurocrine Biosciences, Inc., and the effectiveness of internal control over financial reporting of Neurocrine Biosciences, Inc., included in this Annual Report (Form 10-K) of Neurocrine Biosciences, Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

San Diego, California
February 7, 2019

EXHIBIT 31.1

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 annual report on Form 10-K of Neurocrine Biosciences, Inc.;

2. Based on my knowledge, this annual 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 annual 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 annual 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 annual report based on such evaluation; and

   d) Disclosed in this annual 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 the internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   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 controls over financial reporting.

Dated: February 7, 2019

/s/ Kevin C. Gorman
Kevin C. Gorman
Chief Executive Officer

EXHIBIT 31.2

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 annual report on Form 10-K of Neurocrine Biosciences, Inc.;

2. Based on my knowledge, this annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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 annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual 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 the internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   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 controls over financial reporting.

Dated: February 7, 2019

/s/ Matthew C. Abernethy
Matthew C. Abernethy
Chief Financial Officer

EXHIBIT 32

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

In connection with the Annual Report on Form 10-K of Neurocrine Biosciences, Inc. (the "Company") for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "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.

February 7, 2019

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

In connection with the Annual Report on Form 10-K of Neurocrine Biosciences, Inc. (the "Company") for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "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.

February 7, 2019

By: /s/ Matthew C. Abernethy
Name: Matthew C. Abernethy
Title: Chief Financial Officer