# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
**For the fiscal year ended December 31, 2019**

☐ 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 No.) |
| **12780 El Camino Real, San Diego, California** | **92130** |
| (Address of principal executive offices) | (Zip Code) |

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

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

| **Common Stock, $0.001 par value** | **NBIX** | **Nasdaq Global Select Market** |
|---|---|---|
| (Title of each class) | (Trading Symbol) | (Name of each exchange on which registered) |

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

**None**

(Title of class)

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

Large accelerated filer ☑ 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 registrant's common stock held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2019, was approximately $5,752,910,928.

As of January 31, 2020, 92,292,392 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to the registrant's annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days following the end of the registrant's fiscal year ended December 31, 2019 are incorporated by reference into Part III of this Form 10-K.

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

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

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

Our late-stage pipeline includes opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients, elagolix for the treatment of heavy menstrual bleeding, or HMB, associated with uterine fibroids in women, valbenazine for the treatment of chorea in adult patients with Huntington’s disease, or HD, and NBIb-1817 (VY-AADC) for the treatment of advanced Parkinson’s disease patients with motor fluctuations that are refractory to medical management. Our product candidates for uterine fibroids and advanced Parkinson’s disease are partnered with AbbVie and Voyager Therapeutics, Inc., or Voyager, respectively.

In the third quarter of 2019, the FDA accepted our new drug application, or NDA, for opicapone for the treatment of Parkinson’s disease with a Prescription Drug User Fee Act, or PDUFA, target action date of April 26, 2020. Also, in the third quarter of 2019, the FDA accepted AbbVie’s NDA for elagolix for the treatment of uterine fibroids with a PDUFA target action date in the second quarter of 2020.

Our early-stage clinical pipeline includes crinecerfont (NBI-74788) for the treatment of congenital adrenal hyperplasia, or CAH, elagolix for the treatment of polycystic ovary syndrome, or PCOS, in women and a vesicular monoamine transporter 2, or VMAT2, inhibitor with potential use in the treatment of neurologic and psychiatric disorders. Our product candidate for PCOS is partnered with AbbVie.

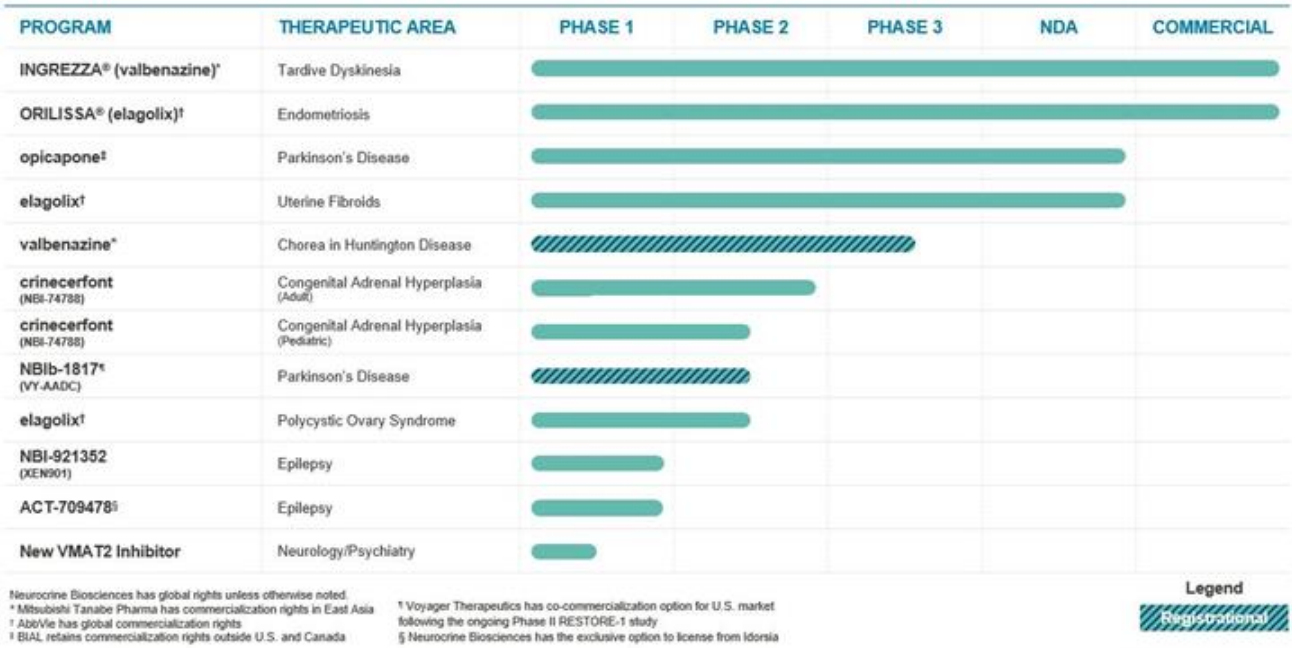
In December 2019, we entered into a license and collaboration agreement with Xenon Pharmaceuticals Inc, or Xenon, a clinical-stage biopharmaceutical company. Pursuant to the terms of the agreement, we acquired an exclusive license to NBI-921352 (XEN901), a clinical-stage candidate with potential in epilepsy.

In January 2020, we announced a collaboration and optional licensing agreement with Idorsia Pharmaceuticals Ltd, or Idorsia, granting us an option to license ACT-709478, a potent, selective, orally active and brain penetrating T-type calcium channel blocker, in clinical development for the treatment of a rare pediatric epilepsy. The option also includes a research collaboration to discover, identify and develop additional novel T-type calcium channel blockers.

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

**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:




***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 tardive dyskinesia.* 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 FDA-approved drug 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.

*Valbenazine as an investigational treatment for chorea associated with Huntington disease*. HD is a hereditary progressive neurodegenerative disorder, in which neurons within the brain break down, resulting in motor, cognitive and psychiatric symptoms. Symptoms generally appear between the ages of 30 to 50 and worsen over a 10 to 25-year period. Many patients with HD experience chorea, a troublesome involuntary movement disorder, in which patients develop abnormal, abrupt or irregular movements. Chorea can affect various body parts, and interfere with speech, swallowing, posture and gait. HD is estimated to affect approximately 30,000 adults in the U.S., with more than 200,000 at risk of inheriting the disease (NORD).

We are currently conducting KINECT-HD, a multi-center randomized, double-blind, placebo-controlled Phase III study to evaluate the efficacy, safety and tolerability of valbenazine for the treatment of chorea in patients with HD.

***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.

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 the second quarter of 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.

In the second and third quarter of 2018, respectively, AbbVie announced FDA and Health Canada approval of ORILISSA for the management of endometriosis with associated moderate to severe pain in women. AbbVie began commercialization of ORILISSA in the U.S. in the third quarter of 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.

In the third quarter of 2019, the FDA accepted AbbVie's NDA for elagolix for the treatment of HMB associated with uterine fibroids in women with a PDUFA target action date in the second quarter of 2020.

*Polycystic Ovary Syndrome.* PCOS is one of the most common hormonal disorders among women of reproductive age, affecting approximately 3.5 million women in the U.S. PCOS occurs when the ovaries or adrenal glands produce more male hormones (androgens) than normal. Women with PCOS experience irregular menstrual periods, infertility, pelvic pain, weight gain, acne and excess hair growth on the face, chest, stomach and thighs. There is no cure for PCOS, and treatment options are limited. If left untreated, PCOS can lead to certain cancers, diabetes and coronary artery disease. AbbVie initiated a Phase II study of elagolix in patients with polycystic ovary syndrome in mid-2019. The study is designed to evaluate whether there is a potential impact on disordered hormonal dynamics in women with PCOS.

***opicapone – Catechol-O-methyltransferase Inhibitor***

Catechol-O-methyltransferase, or 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 disease and extending the on-time period.

In the first quarter of 2017, we entered into an exclusive license agreement with BIAL – Portela & Ca, S.A., or BIAL, for the development and commercialization of 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 one million people in the U.S. 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 disease 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 disease and management consists of controlling the motor symptoms primarily through administration of levodopa therapies. While this improves the control of Parkinson's disease 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 the third quarter of 2016, BIAL announced the European Medicines Agency's, or EMA's, approval of 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.

In the third quarter of 2019, the FDA accepted our NDA for opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients with a PDUFA target action date of April 26, 2020. FDA approval of opicapone for Parkinson's disease would trigger a milestone payment of $20.0 million, payable by us to BIAL.

***crinecerfont (NBI-74788) – Corticotropin-Releasing Factor Receptor$_1$ Antagonist***

Corticotropin-releasing factor$_1$, or 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, or GPCR, in the anterior pituitary to stimulate the release of adrenocorticotropin hormone, or 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 Congenital Adrenal Hyperplasia.* 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.

Crinecerfont 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 crinecerfont in healthy volunteers in 2017. Based on the positive results of the Phase I study, we initiated a Phase II clinical study of crinecerfont in adult patients with classic CAH, which was designed to be an open-label, pharmacokinetic/pharmacodynamic study assessing key pharmacodynamic biomarkers including ACTH, 17-hydroxyprogesterone (17-OHP), androgen, and cortisol levels collected the morning following bedtime dosing on Day 1 and Day 14.

In the first quarter of 2019, positive interim results from the ongoing Phase II study demonstrated a reduction of at least 50% from baseline in 17-hydroxyprogesterone (17-OHP) and ACTH levels in more than 50% of CAH patients treated with crinecerfont for 14 days. Meaningful reductions were also observed in other biomarkers, including androstenedione. Crinecerfont was shown to be well tolerated with no serious adverse events reported to date. We plan to start a global registration study in mid-2020 for crinecerfont in adult patients with CAH.

In the third quarter of 2019, we initiated an adaptive, Phase II proof-of-concept study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of crinecerfont in pediatric patients with classic CAH.

We have been granted orphan drug designation for crinecerfont in the treatment of classic CAH in the U.S. and the EU 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.

***NBIb-1817 – AADC Gene Replacement Therapy***

NBIb-1817 is an investigational gene therapy designed to deliver the AADC gene directly into neurons of the putamen where dopamine receptors are located, bypassing the substantia nigra neurons and enabling the neurons of the putamen to produce the AADC enzyme to convert levodopa into dopamine. With this approach, NBIb-1817 has the potential to durably enhance the conversion of levodopa to dopamine and provide clinically meaningful improvements by restoring motor function in patients and improving symptoms following a single administration.

NBIb-1817 is currently being evaluated in the Phase II RESTORE-1 study in patients who have been diagnosed with Parkinson's disease for at least four years, are not responding adequately to oral medications, and have at least three hours of OFF-time during the day, as measured by a validated self-reported patient diary. Based upon feedback received from the FDA, we plan to implement an amended protocol for the RESTORE-1 study by mid-2020. Further, we plan to start the RESTORE-II registration study in the second half of 2020.

We are developing NBIb-1817 with Voyager as part of a strategic collaboration announced in January 2019.

***NBI-921352 – Nav1.6 Sodium Channel Inhibitor***

NBI-921352 is a potent, highly selective Nav1.6 sodium channel inhibitor being developed to treat pediatric patients with SCN8A-DEE and other potential indications, including adult focal epilepsy.

SCN8A-DEE is a rare, extremely severe, single-gene epilepsy caused by mutations in the SCN8A gene that activates Nav1.6, the most highly expressed sodium channel in the excitatory pathways of the central nervous system, or CNS. Children born with SCN8A-DEE typically start experiencing seizures between birth and 18 months of age, and most have multiple seizures per day. Other symptoms include learning difficulties, muscle spasms, low or high muscle tone, poor coordination, developmental delay, and features similar to autism. An estimated 10% of people with SCN8A are reported to have experienced sudden unexpected death in epilepsy. The prevalence of SCN8A-DEE is estimated to be 1% of all developmental and epileptic encephalopathies (Larsen et al, Neurology 2015, 84, 480). As SCN8A mutations were discovered only recently (i.e., in 2012), the number of SCN8A-DEE cases is expected to increase as awareness of and access to genetic surveillance increases. SCN8A-DEE is generally refractory to anti-epilepsy treatments.

The safety, tolerability and pharmacokinetics of NBI-921352 have been evaluated in a randomized, double-blind, placebo-controlled Phase I study using a powder-in-capsule formulation of NBI-921352 in healthy adult subjects. Xenon has developed a pediatric-specific, granule formulation of NBI-921352, and completed juvenile toxicology studies to support pediatric development activities. We plan to file an investigational new drug application, or IND, in mid-2020 to initiate a Phase II clinical study for NBI-921352 in pediatric patients with SCN8A-DEE.

We are developing NBI-921352 with Xenon as part of a strategic collaboration announced in December 2019.

***ACT-709478 – T-type Calcium Channel Blocker***

ACT-709478 is a potent, selective, orally active and brain penetrating T-type calcium channel blocker for potential use in certain forms of generalized epilepsy.

In January 2020, we announced a collaboration and optional licensing agreement with Idorsia, granting us an option to license ACT-709478, in clinical development for the treatment of a rare pediatric epilepsy. The option also includes a research collaboration to discover, identify and develop additional novel T-type calcium channel blockers.

***New VMAT2 Inhibitor***

We have filed an IND and completed dosing in the single ascending dose and multiple 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. Studies assessing the initial safety, tolerability, and pharmacokinetics of this compound are ongoing.

***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 8% (MAbs. 2019 Feb-Mar; 11(2): 265–296) 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 integrates 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.

**Business Strategy**

Our mission is to improve the lives of patients living with serious and under-addressed neurological and endocrine-related diseases and disorders. The following are the key elements of our business strategy:

*Commercializing Our Product Portfolio.* 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, including symptomatic disease modifying and curative treatments. 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.

*Discovering Novel Medicines to Address Unmet Patient Needs.* We seek to identify and validate new medicines on novel targets for internal development or collaboration. 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 Commercial Products, Drug Development Candidates and Technologies.* We plan to continue to selectively acquire rights to programs at all stages of development and commercial products to take advantage of our drug development and commercial capabilities.

**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. Under the terms of the agreement, AbbVie is responsible for all development, marketing and commercialization costs. 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.

*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. BIAL will be entitled to 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.

*Voyager.* We entered into a collaboration and license agreement with Voyager, a clinical-stage gene therapy company, which became effective in March 2019. The agreement is focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platform. The four programs consist of the following: NBIb-1817 for Parkinson's disease, the Friedreich's ataxia program and two undisclosed programs.

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

In June 2019, we entered into an amendment to the collaboration and license agreement with Voyager. Under the terms of the amendment, we obtained rights outside the U.S. to the Friedreich's ataxia program in connection with the early return of those rights to Voyager pursuant to a restructuring of Voyager's gene therapy relationship with Sanofi Genzyme.

We may terminate the collaboration and license agreement with Voyager upon 180 days written notice to Voyager prior to the first commercial sale of any collaboration product or upon 1 year after the date of notice if such notice is provided after the first commercial sale of any collaboration product. Unless terminated earlier, the agreement will continue in effect until the expiration of the last to expire royalty term with respect to any collaboration product or the last expiration or termination of any exercised co-development and co-commercialization rights by Voyager as provided for in the agreement.

*Xenon.* In December 2019, we entered into a license and collaboration agreement with Xenon, a clinical-stage biopharmaceutical company. Pursuant to the terms of the agreement, we acquired an exclusive license to NBI-921352, a clinical stage selective Nav1.6 sodium channel inhibitor with potential in SCN8A-DEE and other forms of epilepsy. We also acquired an exclusive license to pre-clinical compounds for development, including selective Nav1.6 and dual Nav1.2/1.6 inhibitors. The agreement also includes a multi-year research collaboration to discover, identify and develop additional Nav1.6 and Nav1.2/1.6 inhibitors. Unless earlier terminated, the term of the license and collaboration agreement will continue on a product-by-product and country-by-country basis until expiration of the royalty term for such product in such country. Upon the expiration of the royalty term for a particular product and country, the exclusive license granted by Xenon to us with respect to such product and country will become fully paid, royalty free, perpetual and irrevocable. We may terminate the license and collaboration agreement by providing at least 90 days' written notice, provided that such unilateral termination will not be effective for certain products until we have used commercially reasonable efforts

to complete certain specified clinical studies. Either party may terminate the agreement in the event of a material breach in whole or in part, subject to specified conditions.

*Mitsubishi Tanabe Pharma Corporation.* In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation , or MTPC, for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. Under the terms of the agreement, MTPC 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 study to be performed by us. 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. MTPC may terminate the agreement at its discretion upon 180 days' written notice to us. In such event, all INGREZZA product rights for Japan and other select Asian markets would revert to us.

In November 2019, we initiated the KINECT-HD study, a placebo-controlled Phase III study of valbenazine in adult Huntington's disease patients with chorea.

*Idorsia*. In January 2020, we announced a collaboration and optional licensing agreement with Idorsia, granting us an option to license ACT-709478, a potent, selective, orally active and brain penetrating T-type calcium channel blocker, in clinical development for the treatment of a rare pediatric epilepsy. The option also includes a research collaboration to discover, identify and develop additional novel T-type calcium channel blockers.

**Intellectual Property**

We actively seek to protect our products and product candidates and related inventions and improvements that we consider important to our business. We own a portfolio of U.S and non-U.S. patents and patent applications and have licensed rights to a number of U.S. and non-U.S. patents and patent applications. Our owned and licensed patents and patent applications cover or relate to our products and product candidates, including certain formulations, used to treat particular conditions and methods of administration, drug delivery technologies and delivery profiles and methods of manufacturing.

We own or have licensed rights to the following U.S. patents relating to INGREZZA and our other products and product candidates in our pipeline (in addition to non-U.S. patents and certain patents covering our early-stage product candidates):

- INGREZZA, our highly selective VMAT2 inhibitor for the treatment of TD, is covered by three issued U.S. patents that are listed in the FDA's Orange Book: U.S. Patent No. 8,039,627, which expires in 2029 (not including a potential patent term extension of up to an additional two years), U.S. Patent No. 8,357,697, which expires in 2027, and U.S. Patent No. 10,065,952, which expires in 2036.
- ORILISSA, our small molecule GnRH antagonist for the treatment of endometriosis, is covered by six issued U.S. patents that are listed in the FDA's Orange Book: U.S. Patent Nos. 6,872,728, 7,179,815 and 7,462,625 expire in 2021 (not including potential patent term extensions of up to an additional five years) while U.S. Patent Nos. 7,056,927, 7,176,211 and 7,419,983 expire in 2024 (not including potential patent term extensions of up to an additional 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 an additional five years).
- Crinecerfont, our CRF1 antagonist for the treatment of CAH, is covered by U.S. Patent No. 6,586,456, which expires in 2020, and U.S. Patent No. 8,420,679, which expires in 2022 (both patents are expected to expire prior to marketing approval for crinecerfont and thus be ineligible for patent term extension).
- NBIb-1817, our AADC gene therapy for the treatment of Parkinson's disease, is covered by patent applications that have an earliest priority date in 2017. The terms of any patents that may issue from these patent applications should be capable of continuing until 2038 in most jurisdictions without taking into account any patent term adjustment or extension regime.
- NBI-921352, an inhibitor of the Nav1.6 voltage-gated sodium channel for the treatment of epilepsy, is covered by U.S. Patent No. US 10,246,453 which expires in 2037 (not including a potential patent term extension of up to an additional five years).
- ACT-709478, an inhibitor of T-type calcium channels for the treatment of epilepsy, is covered by U.S. Patent No. US 9,932,314 which expires in 2035 (not including a potential patent term extension of up to an additional five years).
- Our new VMAT2 inhibitor for the treatment of neurological and psychiatry disorders is covered by a patent application that has an earliest priority date in 2017. The terms of any patent that may issue from this patent application should be capable of continuing until 2038 in most jurisdictions without taking into account any patent term adjustment or extension regime.

In addition to the potential patent term extensions referenced above, the products and product candidates in our pipeline may be subject to additional terms of exclusivity that we might obtain by virtue of later filed patent applications.

Separately, the U.S., the European Union, or 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, which is measured from the date of marketing approval by the FDA or corresponding foreign regulatory authority. This period of exclusivity is generally five years in the U.S., six years in Japan and ten years in the EU, except that for biologics such as NBIb-1817, this period of exclusivity in the U.S. is twelve years under the Biologics Price Competition and Innovation Act. In addition, if granted orphan drug designation, certain of our product candidates, including crinecerfont, may also be eligible for market exclusivity in the U.S. and EU for seven years and ten years, respectively.

**Manufacturing and Supply**

We currently rely on, and intend to continue to rely on, third-party manufacturers for the production of INGREZZA and our product candidates. In addition, we rely on third-party service providers to perform a variety of functions related to the packaging, storage and distribution of INGREZZA. We believe our outsource manufacturing strategy enables us to direct our financial resources to the maximization of our opportunity with INGREZZA, investment in our internal R&D programs and expansion of our clinical pipeline through business development opportunities.

Raw materials, active pharmaceutical ingredients, or API, and other supplies required for the production of INGREZZA and our product candidates are procured from various third-party manufacturers and suppliers in quantities adequate to meet our needs. Continuing adequate supply of such raw materials and API is assured through our long-term commercial supply and manufacturing agreements with multiple manufacturers and our continued focus on the expansion and diversification of our third-party manufacturing relationships. Our third-party manufacturers, suppliers and service providers may be subject to routine current Good Manufacturing Practice, or cGMP, inspections by the FDA or comparable agencies in other jurisdictions. We depend on our third-party partners for continued compliance with cGMP requirements and applicable foreign standards.

**Marketing, Sales and Distribution**

Our specialty sales force for INGREZZA in the U.S. consists of approximately 250 experienced sales professionals primarily focused on educating health care professionals who treat patients with TD, including psychiatrists, neurologists, physician’s assistants and nurse practitioners.

Our customers in the U.S. consist of a limited network of specialty pharmacy providers, which delivers INGREZZA to patients by mail, and a specialty distributor, which distributes INGREZZA primarily to closed-door pharmacies and government facilities. For 2019, our two largest customers accounted for approximately 86% of our gross product sales.

**Government Regulation**

Our business activities 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, tracking, 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. 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 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 designed to ensure our business practices remain compliant.

The federal Anti-Kickback Statute makes it illegal for any person or entity 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.

Federal civil and criminal false claims laws 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 to avoid or decrease an obligation to pay money to the federal government.

The Health Insurance Portability and Accountability Act of 1996, or 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 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.

In addition, we may be subject to HIPPA privacy and security regulations, which require the adoption of administrative, physical and technical safeguards to protect individually identifiable health information.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians, as defined by such law, and teaching hospitals, and applicable entities to report ownership and investment interests held by the physicians and their immediate family members.

Also, many states have similar healthcare statutes or regulations that may be broader in scope and may apply regardless of payor. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

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, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, and additional reporting requirements and regulatory oversight, 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 and for certain products, such as gene therapies, in patients with the target disease.

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 Larger, 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. 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, or BLA, for approval to commence commercial sales. In most cases, the submission of an NDA or BLA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or 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.

In addition, under the Pediatric Research Equity Act of 2003 as amended and reauthorized, certain applications or supplements to an application 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 and BLAs 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 application for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA or BLA 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 or BLA, 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 or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with Good Clinical Practice requirements.

After evaluating the NDA or BLA 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 application 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 order to commercialize our product candidates in each foreign country. 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 or BLA. 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.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons, are life-threatening or chronically debilitating conditions and for which no satisfactory treatment is authorized. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product does not justify maintenance of market exclusivity.

***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 or BLA. 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, or 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. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. 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. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

**Additional Regulation for Gene Therapy Products**

In addition to the regulations discussed above, there are a number of standards that apply to gene therapy. FDA has issued various guidance documents regarding gene therapies, which outline factors that FDA will consider at each of the stages of development and relate to, among other things: the proper preclinical assessment of gene therapies; the chemistry, manufacturing and controls information that should be included in an IND application; the proper design of tests to measure product potency in support of an IND or BLA; and measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies when the risk of such effects is high. For instance, FDA usually recommends that sponsors observe all surviving subjects who receive treatment using gene therapies that are based on adeno-associated virus vectors in clinical trials for potential gene therapy-related delayed adverse events for a minimum five-year period, followed by 10 years of annual queries, either in person or by questionnaire. FDA does not require the long-term tracking to be complete prior to its review of the BLA.

In addition to FDA oversight and oversight by institutional review boards, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

**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. No uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. 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 drug products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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.

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. Legislation enacted in 2017, informally titled 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". In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, 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, among others, 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 2029 unless additional Congressional action is taken.

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 2020 contains further drug price control measures that could be enacted during the 2020 budget process or in other future legislation. Additionally, the current presidential administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs. The U.S. Department of Health and Human Services has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. Although a number of these, and other measures may require additional authorization 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.

**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 products and product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approval and marketing than we do.

Competition may also arise from, among other things, new drug development technologies, new or improved treatment options for preventing or reducing the incidence of disease in diseases our products treat and new small molecule or other classes of therapeutic agents. Such developments by competitors could reduce or eliminate the use of our products or may limit the utility and application of ongoing clinical trials for our product candidates.

Additional information about the competition that our marketed products face is set forth below.

*Tardive Dyskinesia*

INGREZZA competes with AUSTEDO (deutetrabenazine), which was approved by the FDA for the treatment of TD in adults in August 2017 and is marketed by Teva Pharmaceutical Industries, and a number of commercially available medicines used to treat TD off-label, such as tetrabenazine (Xenazine® and generic equivalents), botulinum toxin, and various antipsychotic medications, benzodiazepines and anticholinergics. We are also aware of several clinical development-stage programs that, if successfully developed and approved, may compete with INGREZZA in the TD market.

*Endometriosis*

ORILISSA competes with several FDA-approved products for the treatment of endometriosis, uterine fibroids, infertility, and central precocious puberty. Additionally, there is also competition from surgical interventions. Over 100,000 hysterectomies are performed in

the U.S. annually as a direct result of endometriosis, as well as a significant number of laparoscopic procedures to ablate endometrial explants. Separate from these options, there are many programs in clinical development which serve as potential future competition. Lastly, there are numerous medicines used to treat the symptoms of disease (vs endometriosis directly) which may also serve as competition: oral contraceptives, nonsteroidal anti-inflammatory drugs, or NSAIDs and other pain medications including opioids.

*Parkinson's Disease*

Opicapone would currently compete directly with two FDA-approved COMT inhibitors and their generic equivalents. In addition, there are a number of alternative adjunctive treatment options (FDA-approved and in clinical development) for Parkinson's disease patients which would compete with opicapone, including but not limited to various L-dopa preparations, dopamine agonists, MAO-B inhibitors. We are also aware of several programs in late-stage clinical development that may compete with opicapone.

*Congenital Adrenal Hyperplasia*

For CAH, high doses of corticosteroids are the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive ACTH levels. In the U.S. alone, there are more than two dozen companies manufacturing steroid-based products. In addition, there are several companies developing medicinal treatments for CAH.

*Epilepsy*

Our investigational therapies may in the future compete with numerous approved products and development-stage programs being pursued by several companies.

*Gene Therapy*

Our investigational gene therapies may in the future compete with numerous approved products and development-stage programs being pursued by several companies.

**Employees**

As of December 31, 2019, we had approximately 700 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.

**Corporate Information**

We were originally incorporated in California in January 1992 and reincorporated in Delaware in May 1996. Our principal executive offices are located at 12780 El Camino Real, San Diego, California 92130. Our telephone number is (858) 617-7600.

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, or SEC, website at *www.sec.gov*. Additionally, copies of our Annual Report will be made available, free of charge, upon written request. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K.

**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 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 experience in marketing and selling pharmaceutical products began with INGREZZA's approval in 2017, when we hired our sales force and established our distribution and reimbursement capabilities, all of which are necessary to successfully commercialize INGREZZA. We have continued to invest in our commercial infrastructure and distribution capabilities in the past three years, including our sales force expansion in late 2018. While our team members and consultants have experience marketing and selling pharmaceutical products, we may face difficulties related to managing the rapid growth of our personnel and infrastructure, and there can be no guarantee that we will be able to maintain the personnel, systems, arrangements and capabilities necessary to successfully commercialize INGREZZA 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.

***If physicians and patients do not continue to accept INGREZZA or do not accept 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 healthcare payor coverage and adequate reimbursement for the products;
- public perception regarding any gene therapy products we may develop;
- the success of existing competitor products addressing our target markets or the emergence of equivalent or superior products; and
- the cost-effectiveness of the products.

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

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

Our ability to commercialize any products successfully, including INGREZZA, 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.

***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. In addition, to date the FDA has granted regulatory approval for only a very limited number of gene therapy products. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals on a timely basis or at all;

- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical to commercialize or fail to achieve market acceptance.

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

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

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

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

- the FDA or similar foreign regulatory authority may not allow an IND application or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA may require additional preclinical studies as a condition of the initiation of Phase I clinical studies, or additional clinical studies for progression from Phase I to Phase II, or Phase 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;
- the FDA may not accept the data from any trial or trial site outside of the U.S.;
- 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 crinecerfont (NBI-74788) program for the treatment of congenital adrenal hyperplasia, or CAH. Additionally, any of these events described above could result in suspension of a program and/or obviate any filings for necessary regulatory approvals.

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

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

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

Our strategy for fully developing and commercializing ORILISSA 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 MTPC to develop and commercialize INGREZZA in Japan and other select Asian markets. We will rely on MTPC to achieve certain development, regulatory and commercial milestones which, if achieved, could generate significant future revenue for us. Our collaboration with MTPC 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.

Effective in March 2019, we entered into a collaboration and license agreement with Voyager for the research, development and commercialization of four programs, including NBIb-1817 (VY-AADC) for Parkinson's disease, the Friedreich's ataxia program and two undisclosed programs. In December 2019, we entered into a license and collaboration agreement with Xenon, pursuant to which we acquired an exclusive license to NBI-921352 (XEN901), a clinical-stage selective Nav1.6 sodium channel inhibitor with potential in SCN8A development and epileptic encephalopathy, or SCN8A-DEE, and other forms of epilepsy. We also acquired an exclusive license to pre-clinical compounds for development, including selective Nav1.6 and Nav1.2/1.6 inhibitors. Voyager and Xenon could take actions that may be adverse to us, or they could halt, slow, or deprioritize their development and commercialization efforts under the collaborations. We could also experience disagreements or delays involving the determination of additional programs. In any such instances, our ability to commercialize any product candidate related to the Voyager and Xenon collaborations could be delayed or prohibited.

In 2019, we acquired an option from Idorsia to license ACT-709478, a potent, selective, orally-active, and brain penetrating T-type calcium channel blocker. The option is exercisable by us following the acceptance by the FDA of the IND for ACT-709478 for the treatment of a rare pediatric epilepsy. Idorsia is solely responsible for the development and filing of the IND for ACT-709478, and we cannot predict if the FDA will accept the NDA, or if the FDA does accept the NDA, if we will exercise our option to license ACT-709478.

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

***We are substantially dependent on BIAL for the development and commercialization of opicapone, including the receipt of regulatory approval for opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients.***

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. In June 2019, we submitted an NDA with the FDA for opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients. The FDA has indicated that the Prescription Drug User Fee Act target action date, on which the FDA is expected to complete its review of the opicapone NDA for Parkinson's disease, is April 26, 2020. Our strategy for developing and commercializing opicapone, including the receipt of regulatory approval for opicapone, is dependent upon maintaining our current collaboration with BIAL. Under the terms of our agreement with BIAL, although we are responsible for the management of all opicapone development and commercialization activities, we depend on BIAL and its suppliers to supply all drug product and investigation medicinal product for the development and commercialization of opicapone. BIAL relies on third-party contract manufacturers to produce opicapone. These contract manufacturers may encounter difficulties in achieving volume production, quality control, or quality assurance. As a result, these contract manufacturers may not be able to adequately produce opicapone in commercial quantities when required, which may impact our ability to deliver opicapone on a timely basis. In addition, we and BIAL 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. Because of our substantial reliance on BIAL, any failure by BIAL to timely or fully comply with its obligations under our agreement, any disagreement with BIAL, or any decision by BIAL to not devote sufficient time and resources to our collaboration, could substantially delay and/or prohibit our ability to develop and commercialize opicapone.

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

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

Gene therapy remains a novel technology, with few gene therapy products approved to date in the U.S. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. As part of our collaboration and license agreement with Voyager, a Phase II clinical trial of NBIb-1817 is being conducted. There is no guarantee that this program or other collaboration gene therapy product candidates will not be placed on clinical hold by the FDA, as has been the case for many gene therapy clinical programs. Even if we are able to successfully complete clinical development of a gene therapy product and obtain commercial approval, the success of our collaboration with Voyager will depend upon physicians who specialize in the treatment of genetic diseases targeted by gene therapy product candidates, prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion related to gene therapy products may delay or impair the development and commercialization of our gene therapy product candidates or demand for any gene therapy products we develop.

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

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

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

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be harmed.

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

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

Competition may also arise from, among other things:

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

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

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

- With respect to INGREZZA for TD, we compete with Teva Pharmaceutical Industries, which received FDA approval for AUSTEDO to treat TD in August 2017, and several clinical development-stage programs targeting TD and related movement disorders. Additionally, there are a number of commercially available medicines used to treat TD off-label, such as Xenazine (tetrabenazine) and generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin.
- In endometriosis, ORILISSA competes with several FDA-approved products for the treatment of endometriosis, uterine fibroids, infertility, and central precocious puberty. Additionally, there is also competition from surgical interventions. Approximately 130,000 hysterectomies are performed in the U.S. annually as a direct result of endometriosis, as well as a significant number of laparoscopic procedures to ablate endometrial explants. Separate from these options, there are many programs in clinical development which serve as potential future competition. Lastly, there are numerous medicines used to treat the symptoms of disease (vs. endometriosis directly) which may also serve as competition: oral contraceptives, NSAIDs and other pain medications including opioids.

- With respect to opicapone for Parkinson's disease, there are currently two FDA-approved COMT inhibitors. Opicapone would compete directly with these two drugs and their generic equivalents. Additionally, there are a number of alternative adjunctive treatment options (FDA-approved and in clinical development) for Parkinson's patients which would compete with opicapone, including various L-dopa preparations, dopamine agonists, MAO-B inhibitors and others. In terms of potential future competition, there are several programs in late-stage clinical development.
- As for congenital adrenal hyperplasia, or CAH, high doses of corticosteroids are the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive ACTH levels. In the U.S. alone, there are more than two dozen companies manufacturing steroid-based products. Additionally, there are several companies developing medicinal treatments for CAH.
- Our investigational therapies for potential use in epilepsy may in the future compete with numerous approved products and development-stage programs being pursued by several companies.
- Our development programs using Voyager's proprietary gene therapy platform (NBIb-1817 for Parkinson's disease and the Friedreich's ataxia program) may in the future compete with development-stage programs being pursued by numerous companies.

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

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

***We currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA 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 and opicapone. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products, including INGREZZA and opicapone. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations, including current Good Manufacturing Practice regulations. Our third-party manufacturers, including BIAL and its suppliers, might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. In addition, the manufacture of gene therapy products, which will be necessary under our collaboration and license agreement with Voyager, is technically complex and necessitates substantial expertise and capital investment. Our reliance on contract manufacturers also exposes us to the following risks:

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

***We currently depend on a limited number of third-party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA, 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, or API, and the finished product in sufficient quantities while meeting detailed product specifications on a repeated basis. Manufacturers of pharmaceutical products may encounter difficulties in production, such as difficulties with production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state, and non-U.S. regulations. We depend on a limited number of suppliers for the production of INGREZZA and its API. If our third-party suppliers for INGREZZA encounter these or any other manufacturing, quality or compliance difficulties, we may be unable to meet commercial demand for INGREZZA, which could materially and

adversely affect our ability to successfully commercialize INGREZZA. 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 API for any reason, it would take a significant amount of time and expense to qualify a new supplier. The FDA and similar international regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in pharmaceutical products. The loss of a supplier could require us to obtain regulatory clearance and to incur validation and other costs associated with the transfer of the API or product manufacturing processes. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to meet FDA or a similar international regulatory body's requirements for approval, there could be a shortage of INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA. If BIAL is unable or refuses to supply us with opicapone drug product for any reason, or does not meet FDA or international regulators' requirements for approval, we have limited opportunity to qualify a new supplier. This could materially and adversely affect our ability to obtain regulatory approval for opicapone or successfully commercialize opicapone.

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

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

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

We do not and will not have access to all information regarding elagolix, including potentially material information about commercialization plans, medical information strategies, clinical trial design and execution, safety reports from clinical trials, safety reports, regulatory affairs, process development, manufacturing and other areas known by AbbVie. In addition, we have confidentiality obligations under our agreement with AbbVie. Thus, our ability to keep our shareholders informed about the status of elagolix will be limited by the degree to which AbbVie keeps us informed and allows us to disclose such information to the public. If AbbVie fails to keep us informed about commercialization efforts related to elagolix, or the status of the clinical development or regulatory approval pathway of other product candidates licensed to it, we may make operational and/or investment decisions that we would not have made had we been fully informed, which may materially and adversely affect our business and operations.

***We are subject to ongoing obligations and continued regulatory review for INGREZZA, 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, 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, changes in the product's label, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- product injunctions or the imposition of civil or criminal penalties.

The 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 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.

***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. Pursuant to our collaboration and license agreement with Voyager, Voyager can terminate the agreement if we challenge the validity or enforceability of certain Voyager intellectual property rights or if we commit a material breach in whole or in part of the agreement and do not cure such breach within the agreed upon cure period. Pursuant to our collaboration and license agreement with Xenon, Xenon can terminate the agreement if we commit a material breach in whole or in part or the agreement and do not cure such breach within the agreed upon cure period. In addition, if we were to violate any of the terms of our licenses, we could become subject to damages. Likewise, if we were to lose our rights under a license to use proprietary research tools, it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations. We also face the risk that our licensors could, for a number of reasons, lose patent protection or lose their rights to the technologies we have licensed, thereby impairing or extinguishing our rights under our licenses with them.

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

To date, we have sold $517.5 million aggregate principal amount of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

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

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

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

As of December 31, 2019, the conditional conversion feature of the 2024 Notes had been triggered, allowing holders of 2024 Notes to convert their 2024 Notes at any time during the period beginning on January 2, 2020 and ending at the close of business on March 31, 2020. The future conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of our common stock during the prescribed measurement periods, and as a result, it is possible that holders of 2024 Notes will continue to 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 2024 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.

***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. At December 31, 2019, we had an accumulated deficit of $1.1 billion as a result of historical operating losses.

In April 2017, we received FDA approval of INGREZZA for TD, 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 continue to 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, 2019, our future operating results and profitability may fluctuate from period to period due to the factors described above, and we will need to generate significant revenues to achieve and maintain profitability and positive cash flow on a sustained basis. We may not be able to generate these revenues, and we may never achieve profitability on a sustained basis in the future. Our failure to maintain or increase profitability on a sustained basis could negatively impact the market price of our common stock.

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

At December 31, 2019, we had approximately 700 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.

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

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to seasonality of commercial sales of INGREZZA, 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. 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, 2019, our future operating results and profitability may fluctuate from period to period, and even if we become profitable on a quarterly or annual basis, we may not be able to sustain or increase our profitability. Moreover, as our company and our market capitalization have grown, our financial performance has become increasingly subject to quarterly and annual comparisons with the expectations of securities analysts or investors. The failure of our financial results to meet these expectations, either in a single quarterly or annual period over a sustained period time, could cause our stock price to decline.

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

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

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

Our net operating loss, or NOL, carryforwards generated in tax years ending on or prior to December 31, 2017, are only permitted to be carried forward for 20 years under applicable 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 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 twelve months, the price of our common stock has ranged from approximately $120 per share to approximately $72 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;
- whether the FDA approves opicapone for the treatment of Parkinson's disease and elagolix for the treatment of uterine fibroids, both of which have a PDUFA target action date in the second quarter of 2020, or if the FDA fails to meet such targeted action dates;
- 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.

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

We have entered into distribution agreements with a limited number of specialty pharmacy providers and a specialty distributor, and all of our product sales are to these customers. Two of these customers represented approximately 86% of our product revenue for the year ended December 31, 2019 and a significant majority of our accounts receivable balance at December 31, 2019. If any of these significant customers becomes subject to bankruptcy, is unable to pay us for our products or is acquired by a company that wants to terminate the relationship with us, or if we otherwise lose any of these significant customers, our revenue, results of operations and cash flows would be adversely affected. Even if we replace the loss of a significant customer, we cannot predict with certainty that such transition would not result in a decline in our revenue, results of operations and cash flows.

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

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

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

- the commercial success of INGREZZA 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;
- whether the FDA approves opicapone for the treatment of Parkinson's disease and elagolix for the treatment of uterine fibroids, both of which have a PDUFA target action date in the second quarter of 2020;
- 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, 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 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 federal and state legislation imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers are required to provide certain information regarding the drug product provided to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding distribution of the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, notification and purchaser license verification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

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

- an annual, nondeductible fee on any entity that manufactures, or imports, specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, the Centers for Medicare and Medicaid Services, or CMS, published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a U.S. District Court Judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, 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 ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the current presidential administration's budget proposal for the 2020 fiscal year contains further drug price control measures that could be enacted during the 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, or HHS, has solicited feedback on certain of these measures and, additionally, has implemented others under its existing authority. 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.

***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 or drug pricing; 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. While our interactions with healthcare professionals, including our speaker programs and other arrangements, such as our contributions to patient assistance programs, have been structured to comply with these laws and related guidance, it is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. If our operations or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages,

reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

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

***We could face liability if a regulatory authority determines that we are promoting INGREZZA, 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. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of our products, including INGREZZA, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations. If the FDA or any other governmental agency initiates an enforcement action against us, or if we are the subject of a *qui tam* suit brought by a private plaintiff on behalf of the government, and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

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

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

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

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

The use of any of our potential products in clinical trials, and the sale of any approved products, including INGREZZA, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have product liability insurance coverage for our clinical trials in the amount of $35.0 million per occurrence and $35.0 million in the aggregate. In addition, we have product liability insurance related to the sale of INGREZZA in the amount of $35.0 million per occurrence and $35.0 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability from any current or future clinical trials or approved products. A successful product liability claim, or series of claims, brought against us would decrease our cash reserves and could cause our stock price to fall. Furthermore, regardless of the eventual outcome of a product liability claim, any product liability claim against us may decrease demand for our approved products, including INGREZZA, damage our reputation, result in regulatory investigations that could require costly recalls or product modifications, cause clinical trial participants to withdrawal, result in costs to defend the related litigation, decrease our revenue, and divert management's attention from managing our business.

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

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

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

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect and store confidential and sensitive electronic information on our networks and in our data centers. This information includes, among other things, our intellectual property and proprietary information, the confidential information of our collaborators and licensees, and the personally identifiable information of our employees. It is

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

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

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. For example, the EU's General Data Protection Regulation, or GDPR, imposes strict obligations on the processing of personal data, including personal health data, and the free movement of such data. The GDPR applies to any company established in the EU as well as any company outside the EU that processes personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, obligations relating to: processing health and other sensitive data; obtaining consent of individuals; providing notice to individuals regarding data processing activities; responding to data subject requests; taking certain measures when engaging third-party processors; notifying data subjects and regulators of data breaches; implementing safeguards to protect the security and confidentiality of personal data; and transferring personal data to countries outside the EU, including the 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.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the U.S. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA, which went into effect on January 1, 2020, requires covered companies to provide new disclosures to California consumers, and provides such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

**Item 1B.** ***Unresolved Staff Comments***

None.

**Item 2.** ***Properties***

We lease our corporate headquarters, which are located in San Diego, California, and consist of 141,000 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 37,000 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, and are suitable for the conduct of our business.

**Item 3.** ***Legal Proceedings***

From time to time in the normal course of business, we may be subject to various legal matters such as threatened or pending claims or proceedings. We are not currently a party to any material legal proceedings or claims, nor are we aware of any pending or threatened litigation or claims that could have a material adverse effect on our business, operating results, cash flows or financial condition should such litigation or claim be resolved unfavorably.

**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".

At January 31, 2020, there were approximately 49 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.

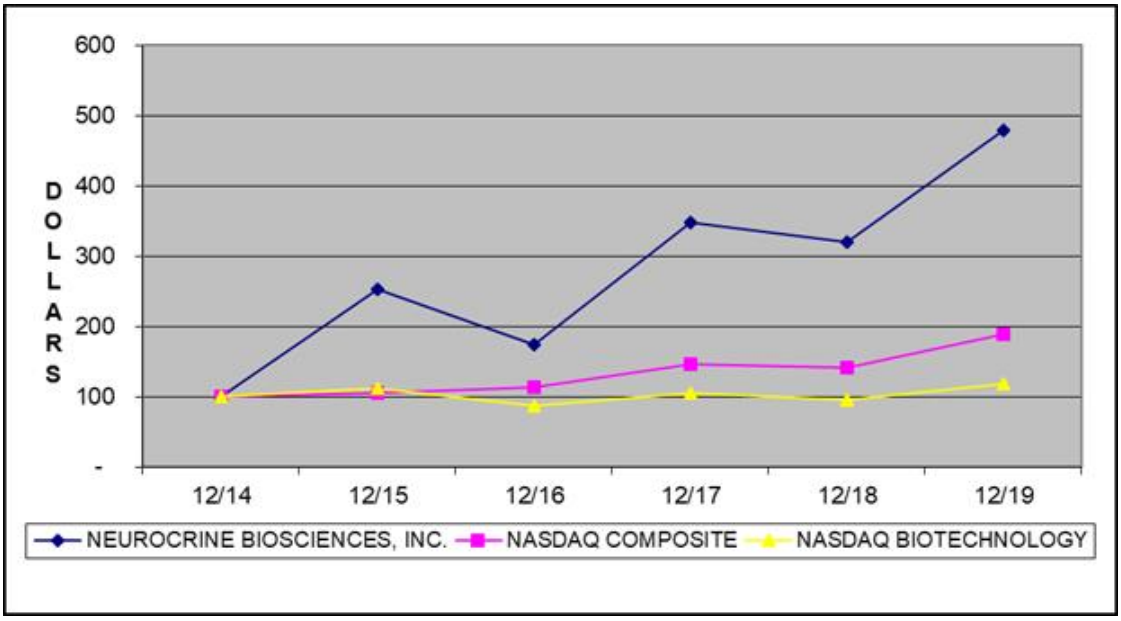
Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

**Recent Sales of Unregistered Securities and Issuer Purchases of Equity Securities**

There were no unregistered sales of our equity securities during 2019. In addition, we did not repurchase any of our equity securities during 2019.

**Stock Performance Graph and Cumulative Total Return***

The graph below shows the cumulative total stockholder return assuming the investment of $100 on December 31, 2014 (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)* | 2019 | 2018 | 2017 | 2016 | 2015 |
|---|---|---|---|---|---|
| **Consolidated Statements of Operations Data** | | | | | |
| Revenues: | | | | | |
| Product sales, net | $ 752,900 | $ 409,608 | $ 116,626 | $ — | $ — |
| Collaboration revenue | 35,187 | 41,632 | 45,000 | 15,000 | 19,769 |
| Total revenues | 788,087 | 451,240 | 161,626 | 15,000 | 19,769 |
| Operating expenses: | | | | | |
| Cost of sales | 7,428 | 4,889 | 1,254 | — | — |
| Research and development | 200,042 | 155,774 | 91,827 | 94,291 | 81,491 |
| Acquired in-process research and development | 154,272 | 4,750 | 30,000 | — | — |
| Sales, general and administrative | 354,062 | 248,932 | 169,906 | 68,081 | 32,480 |
| Total operating expenses | 715,804 | 414,345 | 292,987 | 162,372 | 113,971 |
| Operating income (loss) | 72,283 | 36,895 | (131,361) | (147,372) | (94,202) |
| Other (expense) income: | | | | | |
| Interest expense | (31,963) | (30,530) | (19,523) | — | — |
| Unrealized loss on restricted equity securities | (12,987) | — | — | — | — |
| Investment income and other, net | 19,209 | 15,476 | 8,342 | 6,282 | 5,273 |
| Total other (expense) income | (25,741) | (15,054) | (11,181) | 6,282 | 5,273 |
| Income (loss) before provision for income taxes | 46,542 | 21,841 | (142,542) | (141,090) | (88,929) |
| Provision for income taxes | 9,530 | 730 | — | — | — |
| Net income (loss) | $ 37,012 | $ 21,111 | $ (142,542) | $ (141,090) | $ (88,929) |
| Net income (loss) per share, basic | $ 0.40 | $ 0.23 | $ (1.62) | $ (1.63) | $ (1.05) |
| Net income (loss) per share, diluted | $ 0.39 | $ 0.22 | $ (1.62) | $ (1.63) | $ (1.05) |
| Weighted average common shares outstanding, basic | 91,627 | 90,235 | 88,089 | 86,713 | 84,496 |
| Weighted average common shares outstanding, diluted | 95,732 | 95,386 | 88,089 | 86,713 | 84,496 |
| | | | | | |
| **Consolidated Balance Sheets Data** | | | | | |
| Cash and cash equivalents and marketable securities | $ 970,178 | $ 866,941 | $ 763,290 | $ 350,840 | $ 461,679 |
| Working capital [1] | $ 265,747 | $ 649,544 | $ 500,493 | $ 280,028 | $ 358,359 |
| Total assets | $ 1,306,040 | $ 993,151 | $ 817,591 | $ 365,086 | $ 474,785 |
| Convertible senior notes | $ 408,807 | $ 388,496 | $ 369,618 | $ — | $ — |
| Accumulated deficit | $ (1,132,700) | $ (1,177,755) | $ (1,198,866) | $ (1,056,324) | $ (915,234) |
| Total stockholders' equity | $ 636,923 | $ 480,765 | $ 372,138 | $ 314,877 | $ 424,454 |

(1) At December 31, 2019, the conditional conversion feature of the 2024 Notes had been triggered, allowing holders of 2024 Notes to convert their 2024 Notes at any time during the period beginning on January 2, 2020 and ending at the close of business on March 31, 2020. Accordingly, the 2024 Notes have been classified as a current liability at December 31, 2019.

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

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

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

Our late-stage pipeline includes opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients, elagolix for the treatment of heavy menstrual bleeding, or HMB, associated with uterine fibroids in women, valbenazine for the treatment of chorea in adult patients with Huntington's disease, or HD, and NBIb-1817 (VY-AADC) for the treatment of advanced Parkinson's disease patients with motor fluctuations that are refractory to medical management. Our product candidates for uterine fibroids and advanced Parkinson's disease are partnered with AbbVie and Voyager Therapeutics, Inc., or Voyager, respectively.

In the third quarter of 2019, the FDA accepted our new drug application, or NDA, for opicapone for the treatment of Parkinson's disease with a Prescription Drug User Fee Act, or PDUFA, target action date of April 26, 2020. Also, in the third quarter of 2019, the FDA accepted AbbVie's NDA for elagolix for the treatment of uterine fibroids with a PDUFA target action date in the second quarter of 2020.

Our early-stage clinical pipeline includes crinecerfont (NBI-74788) for the treatment of congenital adrenal hyperplasia, or CAH, elagolix for the treatment of polycystic ovary syndrome, or PCOS, in women and a vesicular monoamine transporter 2, or VMAT2, inhibitor with potential use in the treatment of neurologic and psychiatric disorders. Our product candidate for PCOS is partnered with AbbVie.

In December 2019, we entered into a license and collaboration agreement with Xenon Pharmaceuticals Inc, or Xenon, a clinical-stage biopharmaceutical company. Pursuant to the terms of the agreement, we acquired an exclusive license to NBI-921352 (XEN901), a clinical-stage candidate with potential in epilepsy.

In January 2020, we announced a collaboration and optional licensing agreement with Idorsia Pharmaceuticals Ltd, granting us an option to license ACT-709478, a potent, selective, orally active and brain penetrating T-type calcium channel blocker, in clinical development for the treatment of a rare pediatric epilepsy. The option also includes a research collaboration to discover, identify and develop additional novel T-type calcium channel blockers.

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

### Results of Operations

#### *Revenues*

The following table presents our revenues by category.

| | Year Ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | 2019 | 2018 | 2017 |
| INGREZZA product sales, net | $ 752,900 | $ 409,608 | $ 116,626 |
| Collaboration revenue | 35,187 | 41,632 | 45,000 |
| Total revenues | $ 788,087 | $ 451,240 | $ 161,626 |

***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 $752.9 million for 2019, $409.6 million for 2018 and $116.6 million for 2017.

***Collaboration Revenue***

Collaboration revenue reflects event-based milestones, royalties and license fees earned under our collaboration agreements with AbbVie and Mitsubishi Tanabe Pharma Corporation, or MTPC.

In the third quarter of 2019, we recognized a $20.0 million event-based milestone as revenue upon the FDA's acceptance of AbbVie's NDA submission of elagolix for the treatment of uterine fibroids. In the third quarter of 2018, we recognized a $40.0 million event-based milestone as revenue upon the FDA-approval of AbbVie's ORILISSA for the management of moderate to severe endometriosis pain in women. In the third quarter of 2017, AbbVie's NDA submission for elagolix in endometriosis was accepted as filed by the FDA, resulting in the achievement of a $30.0 million event-based milestone, which we recognized as revenue in the fourth quarter of 2017. We also recognized $15.0 million in development event-based payments as revenue in 2017, resulting from Mitsubishi Tanabe Pharma Corporation's, or MTPC's, initiation of Phase II/III development of INGREZZA in TD in Asia.

We are eligible to receive royalties at tiered percentage rates on any net sales of ORILISSA. We recognized royalty revenues on net sales of ORILISSA of $14.3 million for 2019 and $1.6 million for 2018. We recognized no royalty revenues in 2017.

***Operating Expenses***

*Cost of Sales*

Cost of sales was $7.4 million for 2019, $4.9 million for 2018 and $1.3 million for 2017.

*Research and Development*

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

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

Late stage consists of costs incurred related to product candidates in Phase II registrational studies and onwards. Early stage consists of costs incurred related to product candidates in post-investigational new drug application, or IND, through Phase II non-registrational studies. Research and discovery consists of pre-IND costs. Milestone expenses reflect payments made in connection with our collaborative and other relationships. Payroll and benefits consists of costs incurred for salaries and wages, payroll taxes, benefits, and share-based compensation associated with employees involved in ongoing R&D activities. Share-based compensation may fluctuate from period to period based on factors that are not within our control, such as our stock price on the dates share-based grants are issued.

Facilities and other consists of indirect costs incurred in support of overall R&D activities and non-specific programs, including activities that benefit multiple programs, such as management costs, as well as depreciation, information technology, and facility-based expenses. These costs are not allocated to a specific program or stage.

The following table presents R&D expense by category:

| | Year Ended December 31, | | |
|---|---|---|---|
| ***(in thousands)*** | **2019** | **2018** | **2017** |
| Late stage | $ 43,673 | $ 14,237 | $ 6,423 |
| Early stage | 25,260 | 41,659 | 18,917 |
| Research and discovery | 24,642 | 17,047 | 11,173 |
| Milestone payments | 10,000 | 10,000 | — |
| Payroll and benefits | 71,347 | 61,950 | 42,180 |
| Facilities and other | 25,120 | 10,881 | 13,134 |
| Total R&D expense | $ 200,042 | $ 155,774 | $ 91,827 |

R&D expense was $200.0 million in 2019, $155.8 million in 2018 and $91.8 million in 2017. The increase in R&D expense from 2018 to 2019 was primarily due to funding of development activities in connection with our collaboration with Voyager, ongoing progression of our product candidate pipeline and increased personnel expenses on higher headcount. The increase in R&D expense from 2017 to 2018 was primarily due to the ongoing progression of our product candidate pipeline and increased personnel expenses on higher headcount.

*Acquired In-Process Research and Development*

In-process research and development, or IPR&D, was $154.3 million for 2019, $4.8 million for 2018 and $30.0 million for 2017. In connection with the payment of the upfront fee pursuant to our collaboration and license agreement with Voyager, we recorded a

charge of $113.1 million, accounted for as IPR&D, in the first quarter of 2019. In the second quarter of 2019, we entered into an amendment to the collaboration and license agreement with Voyager, pursuant to which we paid Voyager $5.0 million upfront, accounted for as IPR&D, to obtain outside the U.S. rights to the Friedreich's ataxia program. In connection with the payment of the upfront fee pursuant to our collaboration with Xenon, we recorded a charge of $36.2 million, accounted for as IPR&D, in the fourth quarter of 2019. In the third quarter of 2018, we entered into a research collaboration with Jnana Therapeutics Inc., or Jnana, pursuant to which we paid Jnana $4.8 million upfront, accounted for as IPR&D, to obtain access to their proprietary drug discovery platform. In connection with the payment of the upfront fee pursuant to our exclusive license agreement with BIAL – Portela & Ca, S.A., we recorded a charge of $30.0 million, accounted for as IPR&D, in the first quarter of 2017.

*Sales, General and Administrative*

Sales, general and administrative, or SG&A, expense was $354.1 million in 2019, $248.9 million in 2018 and $169.9 million in 2017. The increase in SG&A expense from 2018 to 2019 was primarily due to the sales force expansion completed in the third quarter of 2018, the national launch of a patient-focused disease state awareness campaign, Talk About TD, and an increase in the Branded Pharmaceutical Drug fee expense. The increase in SG&A expense from 2017 to 2018 was primarily due to our commercial launch for INGREZZA in April 2017 and the subsequent sales force expansion in the third quarter of 2018.

***Other Expense***

Other expense, net, was $25.7 million in 2019, $15.1 million in 2018 and $11.2 million in 2017. The increase in other expense, net, from 2018 to 2019 was primarily due to an unrealized loss of $13.0 million to adjust our equity investments in Voyager and Xenon to fair value as of December 31, 2019. The increase in other expense, net, from 2017 to 2018 was primarily due to higher interest expense resulting from our issuance of $517.5 million of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes, in May 2017.

***Provision for Income Taxes***

Our provision for income taxes was $9.5 million for 2019 and $0.7 million for 2018, reflecting estimated current state income taxes for both periods. We did not have a provision for income taxes for 2017. At December 31, 2019 and 2018, we had full valuation allowances against our net deferred tax assets as realization was uncertain. As a result, our tax expense for both periods varies from the statutory tax rate primarily due to changes in our valuation allowances, net of other permanent book/tax differences, tax credits generated and impacts of changes in tax laws.

***Net Income (Loss)***

Net income was $37.0 million, or $0.39 diluted earnings per share, for 2019 and $21.1 million, or $0.22 diluted earnings per share, for 2018. We incurred a net loss of $142.5 million, or $1.62 net loss per share, for 2017. The change from 2018 to 2019 was primarily the result of increased INGREZZA net product sales, offset by $154.3 million of IPR&D in connection with our collaborations with Voyager and Xenon, ongoing support for the commercial launch of INGREZZA for TD and progression of our clinical pipeline. 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.

**Liquidity and Capital Resources**

At December 31, 2019, our cash, cash equivalents and marketable securities totaled $970.2 million, compared with $866.9 million at December 31, 2018.

Net cash provided by operating activities was $152.1 million for 2019 and $101.4 million for 2018. Net cash used in operating activities was $94.3 million for 2017. The increase in positive cash flow from 2018 to 2019 was primarily driven by increased INGREZZA net product sales, partially offset by incremental INGREZZA investment and upfront payments of $118.1 million and $36.2 million in connection with our collaborations with Voyager and Xenon, respectively. 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 a $40.0 million event-based milestone related to the FDA's approval of ORILISSA.

Net cash used in investing activities was $211.1 million for 2019, $242.9 million for 2018 and $251.3 million for 2017. The change in net cash used in investing activities for all periods presented resulted primarily from timing differences in purchases, sales and maturities of marketable securities and changes in our portfolio-mix between cash equivalents and short-term and long-term investment holdings. Net cash used in investing activities for 2019 also reflects equity investments of $54.7 million in Voyager in the first quarter of 2019 and $14.2 million in Xenon in the fourth quarter of 2019.

Net cash provided by financing activities was $27.3 million for 2019, $29.5 million for 2018 and $516.6 million in 2017. Net cash provided by financing activities for 2019 and 2018 reflected proceeds from stock option issuances. Net cash provided by financing activities for 2017 primarily reflected net proceeds of $502.8 million associated with our issuance of the 2024 Notes in May 2017.

*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, or SEC. We sold no securities under this shelf registration statement in 2019, 2018 or 2017.

*Convertible Senior Notes.* In May 2017, we issued $517.5 million of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes. At December 31, 2019, the conditional conversion feature of the 2024 Notes had been triggered, allowing holders of 2024

Notes to convert their 2024 Notes at any time during the period beginning on January 2, 2020 and ending at the close of business on March 31, 2020.

**Off-Balance Sheet Arrangements**

As of December 31, 2019, 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, or 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 Sales, Net***

Our product sales, net consist of sales of INGREZZA in the U.S. to a limited network of specialty pharmacy providers, which delivers INGREZZA to patients by mail, and a specialty distributor, which distributes INGREZZA primarily to closed-door pharmacies and government facilities. Product sales, net are recognized at the time the customer takes possession of the product.

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, payors and other third parties. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

Our significant categories of sales discounts and allowances are as follows:

*Product discounts* – product discounts are based on payment terms extended to our customers, which include incentives offered for prompt payment. We maintain a reserve for product discounts based on our historical experience, including the timing of customer payments. To date, actual product discounts have not differed materially from our estimates.

*Product returns* – our contracts with customers provide for product returns only if the product is damaged or there has been an error in shipment. Returns based on product expiry are not permitted. To date, product returns have not been significant, and a reserve has not been established.

*Government rebates* – we are obligated to pay rebates for mandated discounts under the Medicaid Drug Rebate Program. The liability for such rebates consist of invoices received for claims from prior quarters that remain unpaid or for which an invoice has not been received and estimated rebates for the current applicable reporting period. Such rebates are primarily estimated based upon actual historical rebates, estimated payor mix, state and federal regulations and related contractual terms and are recorded as a reduction of product sales in the same period the related revenue is recognized. To date, actual government rebates have not differed materially from our estimates.

*Chargebacks* – the difference between the list price, or the price at which we sell INGREZZA product to our customers, and the contracted price, or the price at which our customers sell INGREZZA product to qualified healthcare professionals, is charged back to us by our customers. In addition to actual chargebacks received, we maintain a reserve for chargebacks based on estimated contractual discounts on INGREZZA product inventory levels on hand in our distribution channel. To date, actual chargebacks have not differed materially from our estimates.

*Payor and pharmacy rebates* – we are obligated to pay rebates as a percentage of sales under payor and pharmacy contracts. We estimate these rebates based on actual historical rebates, contractual rebate percentages, sales made through the payor channel and purchases made by pharmacies. To date, actual payor and pharmacy rebates have not differed materially from our estimates.

*Copay assistance* – we offer qualified patients financial assistance with prescription drug co-payments required by insurance. We accrue for copay assistance based on estimated claims and the cost per claim we expect to receive associated with inventory that remains in the distribution channel at period end. To date, actual copay assistance has not differed materially from our estimates.

***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. The fair value of performance-based

restricted stock units, or PRSUs, is estimated based on the closing sale price of our common stock on the date of grant. Expense recognition for PRSUs commences when attainment of the associated performance-based criteria is determined to be probable.

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**

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.

Our in-license, research and clinical development agreements are generally cancelable with written notice within 180 days or less. We may be required to pay up to $4.9 billion in milestone payments, plus sales royalties, in the event that all scientific research, development and commercialization milestones under these agreements are achieved.

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;
- whether the FDA approves opicapone for the treatment of Parkinson's disease and elagolix for the treatment of uterine fibroids, both of which have a PDUFA target action date in the second quarter of 2020;
- 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, funds generated by anticipated INGREZZA net product sales and investment income will be sufficient to satisfy our current and projected funding requirements for at least the next twelve 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, 2019, are as follows:

| *(in millions)* | Total | 2020 | 2021 | 2022 | 2023 | 2024 and Thereafter |
|---|---|---|---|---|---|---|
| 2024 Notes and related interest (1) | $ 569.7 | $ 11.6 | $ 11.6 | $ 11.6 | $ 11.6 | $ 523.3 |
| Operating leases (2) | 160.9 | 8.6 | 10.8 | 13.1 | 13.9 | 114.5 |
| Total contractual obligations | $ 730.6 | $ 20.2 | $ 22.4 | $ 24.7 | $ 25.5 | $ 637.8 |

(1) 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. At December 31, 2019, the conditional conversion feature of the 2024 Notes had been triggered, allowing holders of 2024 Notes to convert their 2024 Notes at any time during the period beginning on January 2, 2020 and ending at the close of business on March 31, 2020. 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. Amounts for the 2024 Notes and related interest in the table above assume that the 2024 Notes will be held until maturity.

(2) 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 2029 and 2031 and do not include renewal options. 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.

**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 twelve months. If a 10% change in interest rates were to have occurred on December 31, 2019, 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, 2019 and 2018, 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, 2019 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 6, 2020 expressed an unqualified opinion thereon.

**Adoption of ASU No. 2016-02**

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842), and the related amendments.

**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.

**Critical Audit Matters**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

***Reserves for government rebates related to product sales***

| | |
|---|---|
| *Description of the Matter* | The Company sells drugs to specialty pharmacies and specialty distributors in the US (collectively, "customers"). As described in Note 1 to the consolidated financial statements, the Company recognizes revenues for sales of INGREZZA to its customers after deducting management's estimates of reserves, including drug coverage gap rebates, it will provide under government rebate programs ("government rebates"). Estimated government rebates are presented within accounts payable and accrued liabilities on the consolidated balance sheet.<br><br>Auditing the estimates of government rebates was complex and judgmental due to the level of uncertainty involved in management's assumptions used in the measurement process. In particular, management was required to estimate, for product that remains in the distribution channel at December 31, 2019, the portion of product that is expected to be subject to a government rebate and the applicable contractual government rebate percentage by forecasting the revenue, the payor type underlying the revenue and the applicable rebate amount applicable for the payor type. |
| *How We Addressed the Matter in Our Audit* | We tested the Company's internal controls over management's process for estimating the portion of product that is expected to be subject to a government rebate for product that remains in the distribution channel at December 31, 2019 including controls over management's forecast of revenue and the accuracy of data used in the calculation.<br><br>To test management's estimate of government rebate reserves our audit procedures included, among others, evaluating the methodologies used, testing the significant assumptions discussed above and testing the completeness and accuracy of the underlying data used by the Company in its analyses. Specifically, we compared the significant assumptions to third-party reports used by the Company to estimate product remaining in the distribution channel at December 31, 2019. In addition, we compared the underlying government rebate percentages used in the Company's analyses to those published by the applicable government entity. We assessed the historical accuracy of management's rebate estimates, tested payments of rebates and performed a sensitivity analysis of significant assumptions to evaluate the changes in the rebate allowance that would result from changes in the assumptions. |

/s/ Ernst & Young LLP

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

San Diego, California

February 6, 2020

**NEUROCRINE BIOSCIENCES, INC.**
**CONSOLIDATED BALANCE SHEETS**

| *(in thousands, except per share data)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 112,279 | $ 141,714 |
| Marketable securities | 558,245 | 509,199 |
| Accounts receivable | 126,575 | 57,406 |
| Inventory | 17,288 | 10,864 |
| Other current assets | 16,647 | 18,594 |
| Total current assets | 831,034 | 737,777 |
| Marketable securities | 299,654 | 216,028 |
| Operating lease assets | 74,364 | — |
| Restricted equity securities | 55,868 | — |
| Property and equipment, net | 41,914 | 33,869 |
| Restricted cash | 3,206 | 5,477 |
| Total assets | $ 1,306,040 | $ 993,151 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 141,285 | $ 86,377 |
| Convertible senior notes | 408,807 | — |
| Other current liabilities | 15,195 | 1,856 |
| Total current liabilities | 565,287 | 88,233 |
| Convertible senior notes | — | 388,496 |
| Noncurrent operating lease liabilities | 86,756 | — |
| Other long-term liabilities | 17,074 | 35,657 |
| Total liabilities | 669,117 | 512,386 |
| | | |
| Stockholders’ equity: | | |
| Preferred stock, $0.001 par value; 5,000 shares authorized; no shares issued and outstanding | — | — |
| Common stock, $0.001 par value; 220,000 shares authorized; issued and outstanding shares were 92,272 and 90,797 at December 31, 2019 and 2018, respectively | 92 | 91 |
| Additional paid-in capital | 1,768,118 | 1,660,361 |
| Accumulated other comprehensive income (loss) | 1,413 | (1,932) |
| Accumulated deficit | (1,132,700) | (1,177,755) |
| Total stockholders’ equity | 636,923 | 480,765 |
| Total liabilities and stockholders’ equity | $ 1,306,040 | $ 993,151 |

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, 2019 | 2018 | 2017 |
|---|---|---|---|
| Revenues: | | | |
| Product sales, net | $ 752,900 | $ 409,608 | $ 116,626 |
| Collaboration revenue | 35,187 | 41,632 | 45,000 |
| Total revenues | 788,087 | 451,240 | 161,626 |
| Operating expenses: | | | |
| Cost of sales | 7,428 | 4,889 | 1,254 |
| Research and development | 200,042 | 155,774 | 91,827 |
| Acquired in-process research and development | 154,272 | 4,750 | 30,000 |
| Sales, general and administrative | 354,062 | 248,932 | 169,906 |
| Total operating expenses | 715,804 | 414,345 | 292,987 |
| Operating income (loss) | 72,283 | 36,895 | (131,361) |
| Other (expense) income: | | | |
| Interest expense | (31,963) | (30,530) | (19,523) |
| Unrealized loss on restricted equity securities | (12,987) | — | — |
| Investment income and other, net | 19,209 | 15,476 | 8,342 |
| Total other expense, net | (25,741) | (15,054) | (11,181) |
| Income (loss) before provision for income taxes | 46,542 | 21,841 | (142,542) |
| Provision for income taxes | 9,530 | 730 | — |
| Net income (loss) | 37,012 | 21,111 | (142,542) |
| Unrealized gain (loss) on marketable securities | 3,345 | (82) | (1,532) |
| Comprehensive income (loss) | $ 40,357 | $ 21,029 | $ (144,074) |
| Net income (loss) per share, basic | $ 0.40 | $ 0.23 | $ (1.62) |
| Net income (loss) per share, diluted | $ 0.39 | $ 0.22 | $ (1.62) |
| Weighted average common shares outstanding, basic | 91,627 | 90,235 | 88,089 |
| Weighted average common shares outstanding, diluted | 95,732 | 95,386 | 88,089 |

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 Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| Balance at December 31, 2016 | 86,883 | $ 87 | $ 1,371,432 | $ (318) | $ (1,056,324) | $ 314,877 |
| Net loss | — | — | — | — | (142,542) | (142,542) |
| Unrealized loss on marketable securities | — | — | — | (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 | — | — | 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 loss on marketable securities | — | — | — | (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 |
| Net income | — | — | — | — | 37,012 | 37,012 |
| Unrealized gain on marketable securities | — | — | — | 3,345 | — | 3,345 |
| Share-based compensation expense | — | — | 75,262 | — | — | 75,262 |
| Cumulative-effect adjustment to equity due to adoption of ASU 2016-02 | — | — | — | — | 8,043 | 8,043 |
| Issuance of common stock for vested restricted stock units | 416 | — | — | — | — | — |
| Issuance of common stock for stock option exercises | 981 | 1 | 27,312 | — | — | 27,313 |
| Issuance of common stock for employee stock purchase plan | 78 | — | 5,183 | — | — | 5,183 |
| Balance at December 31, 2019 | 92,272 | $ 92 | $ 1,768,118 | $ 1,413 | $ (1,132,700) | $ 636,923 |

See accompanying notes to consolidated financial statements.

**NEUROCRINE BIOSCIENCES, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

| *(in thousands)* | Year Ended December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| **Cash Flows from Operating Activities:** | | | |
| Net income (loss) | $ 37,012 | $ 21,111 | $ (142,542) |
| Reconciliation of net income (loss) to net cash provided by (used in) operating activities: | | | |
| Share-based compensation expense | 75,262 | 58,068 | 42,522 |
| Depreciation | 7,452 | 4,024 | 2,400 |
| Amortization of debt discount | 18,922 | 17,552 | 10,937 |
| Amortization of debt issuance costs | 1,389 | 1,326 | 848 |
| Net (accretion of discounts) amortization of premiums on investments | (1,965) | 1,449 | 1,756 |
| Change in fair value of restricted equity securities | 12,987 | — | — |
| Other, net | 754 | (409) | (1,445) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (69,169) | (25,113) | (31,127) |
| Inventory | (6,424) | (3,524) | (1,024) |
| Accounts payable and accrued liabilities | 53,955 | 24,223 | 27,338 |
| Other changes in operating assets and liabilities, net | 21,879 | 2,657 | (3,994) |
| Net cash provided by (used in) operating activities | 152,054 | 101,364 | (94,331) |
| | | | |
| **Cash Flows from Investing Activities:** | | | |
| Purchases of marketable securities | (797,169) | (545,962) | (583,408) |
| Sales and maturities of marketable securities | 669,691 | 327,825 | 339,088 |
| Purchase of restricted equity securities | (68,855) | — | — |
| Purchases of property and equipment | (14,748) | (24,812) | (6,940) |
| Proceeds from sales of property and equipment | 8 | 34 | 7 |
| Net cash used in investing activities | (211,073) | (242,915) | (251,253) |
| | | | |
| **Cash Flows from Financing Activities:** | | | |
| Issuance of common stock | 27,313 | 29,530 | 13,865 |
| Proceeds from issuance of convertible senior notes, net | — | — | 502,781 |
| Net cash provided by financing activities | 27,313 | 29,530 | 516,646 |
| Change in cash and cash equivalents and restricted cash | (31,706) | (112,021) | 171,062 |
| Cash and cash equivalents and restricted cash at beginning of period | 147,191 | 259,212 | 88,150 |
| Cash and cash equivalents and restricted cash at end of period | $ 115,485 | $ 147,191 | $ 259,212 |
| | | | |
| **Supplemental Disclosure:** | | | |
| Cash paid for interest | $ 11,644 | $ 11,644 | $ 6,242 |
| Cash paid for income taxes | $ 507 | $ — | $ — |
| Non-cash capital expenditures | $ 953 | $ 2,318 | $ — |

See accompanying notes to consolidated financial statements.

**Note 1. Organization and Summary of Significant Accounting Policies**

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

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

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

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

Our late-stage pipeline includes opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients, elagolix for the treatment of heavy menstrual bleeding, or HMB, associated with uterine fibroids in women, valbenazine for the treatment of chorea in adult patients with Huntington’s disease, or HD, and NBIB-1817 (VY-AADC) for the treatment of advanced Parkinson’s disease patients with motor fluctuations that are refractory to medical management. Our product candidates for uterine fibroids and advanced Parkinson’s disease are partnered with AbbVie and Voyager Therapeutics, Inc., or Voyager, respectively.

In December 2019, we entered into a license and collaboration agreement with Xenon Pharmaceuticals Inc, or Xenon, a clinical-stage biopharmaceutical company. Pursuant to the terms of the agreement, we acquired an exclusive license to NBI-921352 (XEN901), a clinical-stage candidate with potential in epilepsy.

In January 2020, we announced a collaboration and optional licensing agreement with Idorsia Pharmaceuticals Ltd, granting us an option to license ACT-709478, a potent, selective, orally active and brain penetrating T-type calcium channel blocker, in clinical development for the treatment of a rare pediatric epilepsy. The option also includes a research collaboration to discover, identify and develop additional novel T-type calcium channel blockers.

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

***Reclassifications.*** Certain amounts in the consolidated financial statements for 2018 and 2017 have been reclassified to conform with the presentation adopted in the current year period, including an increase of $4.8 million and $30.0 million to acquired in-process research and development for 2018 and 2017, respectively, and a corresponding decrease to research and development in the same periods. These reclassifications had no impact on operating income (loss), net income (loss) or net income (loss) per share**.**

***Use of Estimates.*** The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America, or 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.*** We operate in a single industry segment – the discovery, development and marketing of pharmaceuticals for the treatment of neurological and endocrine-based diseases and disorders. We had no foreign-based operations during any of the years presented.

***Cash Equivalents.*** We consider 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.

***Accounts Receivable.*** Accounts receivable are recorded net of customer allowances for prompt payment discounts, chargebacks and any allowance for doubtful accounts. We estimate the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of our customers and individual customer circumstances. To date, an allowance for doubtful accounts has not been material.

***Marketable Securities.*** Marketable securities consist of investments in certificates of deposit, corporate debt securities and securities of government-sponsored entities. We classify marketable securities as available-for-sale. Marketable securities are recorded at fair value, with unrealized gains and losses included in comprehensive income (loss), until realized. Realized gains and losses are included in investment income and other, net on a specific-identification basis. Marketable securities classified as current have maturities of less than one year. Marketable securities classified as non-current have maturities of one to two years.

We review marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Factors considered in determining whether an impairment is other-than-temporary include the length of time and extent to which the marketable security has been less than the cost basis, the financial condition of the issuer and our intent and ability to hold such marketable security until recovery of the associated amortized cost basis. Based on our evaluation, no such other-than-temporary impairments were identified at December 31, 2019 and 2018. Further, we do not intend to sell our marketable security investments and it is not more likely than not that we will be required to sell these investments before recovery of their amortized cost bases, which may be maturity.

***Restricted Equity Securities.*** Investments in equity securities of certain companies that are subject to holding period restrictions longer than one year are carried at fair value using an option pricing valuation model. The most significant assumptions within the option pricing valuation model are the term of the restrictions and the stock price volatility, which is based upon the historical volatility of similar companies. Unrealized gains and losses on investments in restricted equity securities are included in other expense, net.

***Fair Value of Financial Instruments.*** We record cash equivalents, marketable securities and restricted equity securities at fair value based on a fair value hierarchy that distinguishes between assumptions based on market data (observable inputs) and our own assumptions (unobservable inputs). The hierarchy consists of three levels:

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

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

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

The fair value of marketable securities is determined using proprietary valuation models and analytical tools, which utilize market pricing or prices for similar instruments that are both objective and publicly available, such as matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities and bids and offers.

The fair value of restricted equity securities is determined using an option pricing valuation model. The most significant assumptions within the option pricing valuation model are the term of the restrictions and the stock price volatility, which is based upon the historical volatility of similar companies. Significant changes in any of those inputs in isolation would result in a significantly higher or lower fair value measurement.

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

There were no transfers between levels in the fair value hierarchy during 2019 or 2018.

***Inventory.*** Inventory is valued at the lower of cost or net realizable value. We determine the cost of inventory using the standard-cost method, which approximates actual cost based on the first-in, first-out method. We assess the valuation of our inventory on a quarterly basis and adjust the value for excess and obsolete inventory to the extent management determines that the cost cannot be recovered based on estimates about future demand. Inventory costs resulting from these adjustments are recognized as cost of sales in the period in which they are incurred. When future commercialization is considered probable and the future economic benefit is expected to be realized, based on management's judgment, we capitalize pre-launch inventory costs prior to regulatory approval.

***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 three to seven years. Leasehold improvements are depreciated over the shorter of their estimated useful lives or the remaining lease term. Depreciation expense was $7.5 million for 2019, $4.0 million for 2018 and $2.4 million for 2017.

***Impairment of Long-Lived Assets.*** We review 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, we assess 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, we measure 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.*** We recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. Revenue is recognized using a five-step model: (i) identify 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 revenues when (or as) we satisfy the performance obligation.

*Product Sales, Net*

Our product sales, net consist of sales of INGREZZA in the U.S. to a limited network of specialty pharmacy providers, which delivers INGREZZA to patients by mail, and a specialty distributor, which distributes INGREZZA primarily to closed-door pharmacies and government facilities. Product sales, net are recognized at the time the customer takes possession of the product.

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, payors and other third parties. Our process for estimating reserves established for these variable consideration components does not differ materially from historical practices. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment.

Our significant categories of sales discounts and allowances are as follows:

*Product discounts* – product discounts are based on payment terms extended to our customers, which include incentives offered for prompt payment. We maintain a reserve for product discounts based on our historical experience, including the timing of customer payments. To date, actual product discounts have not differed materially from our estimates.

*Product returns* – our contracts with customers provide for product returns only if the product is damaged or there has been an error in shipment. Returns based on product expiry are not permitted. To date, product returns have not been significant, and a reserve has not been established.

*Government rebates* – we are obligated to pay rebates for mandated discounts under the Medicaid Drug Rebate Program. The liability for such rebates consist of invoices received for claims from prior quarters that remain unpaid or for which an invoice has not been received and estimated rebates for the current applicable reporting period. Such rebates are primarily estimated based upon, actual historical rebates, estimated payor mix, state and federal regulations and related contractual terms and are recorded as a reduction of product sales in the same period the related revenue is recognized. To date, actual government rebates have not differed materially from our estimates.

*Chargebacks* – the difference between the list price, or the price at which we sell INGREZZA product to our customers, and the contracted price, or the price at which our customers sell INGREZZA product to qualified healthcare professionals, is charged back to us by our customers. In addition to actual chargebacks received, we maintain a reserve for chargebacks based on estimated contractual discounts on INGREZZA product inventory levels on hand in our distribution channel. To date, actual chargebacks have not differed materially from our estimates.

*Payor and pharmacy rebates* – we are obligated to pay rebates as a percentage of sales under payor and pharmacy contracts. We estimate these rebates based on actual historical rebates, contractual rebate percentages, sales made through the payor channel and purchases made by pharmacies. To date, actual payor and pharmacy rebates have not differed materially from our estimates.

*Copay assistance* – we offer qualified patients financial assistance with prescription drug co-payments required by insurance. We accrue for copay assistance based on estimated claims and the cost per claim we expect to receive associated with inventory that remains in the distribution channel at period end. To date, actual copay assistance has not differed materially from our estimates.

*Collaboration Revenue*

We have entered into collaboration and licensing agreements under which we license certain rights to our product candidates to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; development, regulatory, and/or commercial milestone payments; and royalties on net sales of licensed products.

*Licenses of intellectual property* – if the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we use judgment to assess the nature of the combined performance obligation to determine whether the combined performance 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. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

*Milestone payments* – at the inception of each arrangement that includes developmental, regulatory or commercial milestone payments, we evaluate whether achieving the milestones is considered probable and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is included in the transaction price. Milestone payments that are not within our control, such as approvals from regulators or where attainment of the specified event is dependent on the development activities of a third party, are not considered probable of being achieved until those approvals are received or the specified event occurs. Revenue is recognized from the satisfaction of performance obligations in the amount billable to the customer.

*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, we recognize 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). 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. To date, actual royalties received have not differed materially from our estimates.

***Concentration of Credit Risk.*** We do not currently have any of our own manufacturing facilities and therefore we depend on an outsourced manufacturing strategy for the production of INGREZZA for commercial use and for the production of our product candidates in clinical trials. We have contracts with one third-party manufacturer approved for the commercial production of

INGREZZA's capsules at two separate sites and two third-party manufacturers approved for the production of INGREZZA's API. Although there are potential sources of supply other than our existing suppliers, any new supplier would be required to qualify under applicable regulatory requirements.

We have entered into distribution agreements with a limited number of specialty pharmacy providers and a specialty distributor, and all of our product sales are to these customers. Our two largest customers represented approximately 86% of our product revenue for 2019 and a significant majority of our accounts receivable balance at December 31, 2019. For 2018 and 2017, our three largest customers represented approximately 93% of our product revenue and substantially all of our accounts receivable balance at December 31, 2018 and 2017.

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents, investments and accounts receivables. We established guidelines to limit our exposure to credit risk by placing investments with high credit quality financial institutions, diversifying our 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, royalty fees on net sales of ORILISSA and adjustments for excess and obsolete inventory to the extent management determines that the cost cannot be recovered based on estimates about future demand.

***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 R&D 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 our independent R&D efforts, as well as efforts associated with collaborations, in-licenses and third-party funded research arrangements.

***Asset Acquisitions.*** We account for acquisitions of an asset or group of assets that do not meet the definition of a business using the cost accumulation method, whereby the cost of the acquisition, including certain transaction costs, is allocated to the assets acquired on the basis of their relative fair values. No goodwill is recognized in an asset acquisition. Intangible assets that are acquired in an asset acquisition for use in R&D activities which have no alternative future use are expensed as in-process research and development, or IPR&D, on the acquisition date. Future costs to develop these assets are recorded to R&D expense as they are incurred.

***Advertising Expense.*** In connection with the FDA approval and commercial launch of INGREZZA in April 2017, we began to incur advertising costs, which are expensed when services are performed, or goods are delivered. We incurred advertising costs related to our marketed product, INGREZZA, of $40.6 million in 2019, $20.5 million in 2018 and $10.1 million in 2017.

***Share-Based Compensation.*** We grant stock options to purchase our common stock to eligible employees and directors and also grant certain employees restricted stock units, or RSUs, and performance-based restricted stock units, or PRSUs. Additionally, we allow employees to participate in an employee stock purchase plan, or ESPP.

We estimate 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 our 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 three to four years; however, certain provisions in our 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 six months. Additionally, we 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 (loss) 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. We issued the 2024 Notes with a combination settlement feature, which we have the ability and intent to use upon conversion of the 2024 Notes, to settle the principal amount of debt for cash and the excess of the principal portion in shares of our common stock. As a result, of the approximately 6.8 million shares underlying the 2024 Notes, only the shares required to settle the excess of the principal portion would be considered dilutive under the treasury stock method. Further, approximately 0.3 million PRSUs were 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.***

***ASU 2016-02.*** In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-02, "Leases (Topic 842)", which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. ASU 2016-02 establishes a right-of-use, or 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 twelve months. ASU 2016-02 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. On January 1, 2019, we adopted ASU 2016-02 using the modified retrospective transition method. Under this transition method, we recognized and measured leases that existed at the application date in our consolidated balance sheet as of January 1, 2019.

Arrangements that are determined to be operating leases at inception are included in operating lease assets, noncurrent operating lease liabilities and other current liabilities in our consolidated balance sheets.

ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As none of our operating leases provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The operating lease ROU asset is adjusted for any prepaid or accrued lease payments and any lease incentives received. Operating lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. We have lease agreements with lease and non-lease components, which we have elected to account for as a single lease component. Further, we have elected to recognize our short-term lease payments in profit or loss on a straight-line basis over the associated lease term and variable lease payments in the period in which the obligation for those payments is incurred. Short-term and variable lease payments were not material for 2019.

In connection with the adoption of ASU 2016-02, we elected 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. We also made accounting policy elections not to apply the recognition requirements under ASU 2016-02 to any of our short-term leases and to account for each separate lease and associated nonlease components as a single lease component for all of our leases.

In preparation for implementation of ASU 2016-02, we finalized key accounting assessments and updated processes to appropriately recognize and present the associated financial information. Based on these efforts, the adoption of ASU 2016-02 resulted in the recognition of (1) ROU assets of $50.0 million and operating lease liabilities of $70.9 million, resulting from leases of office and laboratory space; (2) the derecognition of deferred rent of $20.9 million for certain lease incentives received; and (3) a cumulative-effect adjustment of $8.0 million to the opening balance of the accumulated deficit as of January 1, 2019, resulting from the recognition of an existing deferred gain on sale of real estate. The comparative prior period information continues to be reported under the accounting standards in effect during those periods. Further, we expect the adoption of ASU 2016-02 to be immaterial to our results of operations and cash flows on an ongoing basis.

***ASU 2018-07.*** 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. On January 1, 2019, we adopted ASU 2018-07 using the modified retrospective transition method with no impact on our consolidated financial statements. Further, we expect the adoption of ASU 2018-07 to be immaterial to our financial position, results of operations and cash flows on an ongoing basis.

***Recently Issued Accounting Pronouncements.***

***ASU 2016-13.*** In June 2016, the FASB issued ASU 2016-13, "Measurement of Credit Losses on Financial Instruments". The standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded instead of reducing the amortized cost of the investment. The standard limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. The standard is effective for interim and annual periods beginning after December 15, 2019.

Based on the composition of our investment portfolio, current market conditions and historical credit loss activity, the adoption of ASU 2016-13 is not expected to have a material impact on our consolidated financial position, results of operations or the related disclosures.

**Note 2. License and Collaboration Agreements**

***AbbVie.*** In June 2010, we announced an exclusive worldwide collaboration with AbbVie, to develop and commercialize elagolix and all next-generation gonadotropin-releasing factor, or GnRH, antagonists and collectively, GnRH Compounds, for women’s and men’s health. AbbVie made an upfront payment of $75.0 million and has agreed to make additional development and regulatory event-based payments of up to $480.0 million, of which $135.0 million has been earned as of December 31, 2019, and up to an additional $50.0 million in commercial event-based payments.

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

We evaluated the terms of this agreement under Topic 606 and determined that there is one performance obligation, the exclusive worldwide license with rights to develop, manufacture and commercialize elagolix. At execution, the transaction price included only

the $75.0 million up-front consideration received. None of the development or regulatory milestones were included in the transaction price, as all milestone amounts were fully constrained. As part of our evaluation of the constraint, we considered numerous factors, including that achievement of the milestones is outside of our control and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to AbbVie and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

In the third quarter of 2019, AbbVie submitted a new drug application, or NDA, with the FDA for the approval of elagolix in the treatment of uterine fibroids. The NDA was accepted by the FDA with a Prescription Drug User Fee Act, or PDUFA, target action date in the second quarter of 2020. The FDA's acceptance of the NDA triggered a milestone payment of $20.0 million, which we recognized as revenue in the third quarter of 2019 and received in the fourth quarter of 2019. 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 $40.0 million event-based milestone, which we recognized as revenue in 2018. We also recognized sales-based royalties on AbbVie net sales of ORILISSA of approximately $14.3 million for 2019 and $1.6 million for 2018. In 2017, event-based revenue of $30.0 million was recognized based on AbbVie's new drug application, or NDA, submission for elagolix in endometriosis being accepted by the FDA.

***BIAL – Portela & Ca, S.A.*** In February 2017, we entered into an exclusive license agreement with BIAL – Portela & Ca, S.A., or 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. We paid BIAL an upfront license fee of $30.0 million, which was expensed in 2017 as acquired 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 we conduct an additional Phase III study, resulting in a $10.0 million event-based milestone payment to BIAL, which was expensed as incurred. In the second quarter of 2019, we submitted an NDA with the FDA for opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients. The NDA was accepted by the FDA with a PDUFA target action date of April 26, 2020. The FDA's acceptance of the NDA triggered a milestone payment of $10.0 million, which we expensed as R&D in the second quarter of 2019. We may be required to pay up to an additional $95.0 million in milestone payments associated with the regulatory approval and net sales of opicapone. FDA approval of opicapone for Parkinson's disease would trigger a milestone payment of $20.0 million, payable by us to BIAL. Upon commercialization of opicapone, we agreed to determine certain annual sales forecasts. In the event we fail to meet the minimum sales requirements for a particular year, we 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 we fail to meet the minimum sales requirements for any two years, BIAL may terminate the agreement.

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. 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 our 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, we 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 we fail 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 Neurocrine. In certain circumstances where BIAL elects to terminate the agreement in connection with Neurocrine's change of control, BIAL shall pay us a termination fee. We 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 nine months written notice to BIAL if such notice is given after the first NDA approval in the U.S. If our termination request occurs prior to the first NDA approval in the U.S., we shall pay BIAL a termination fee except under certain conditions specified in the agreement.

***Voyager.*** We entered into a collaboration and license agreement with Voyager, a clinical-stage gene therapy company, which became effective in March 2019. The agreement is focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platform. The four programs consist of the NBIb-1817 (VY-AADC) program for Parkinson's disease, the Friedreich's ataxia program and the rights to two undisclosed programs.

In connection with the agreement, we paid Voyager $115.0 million upfront and purchased $50.0 million of Voyager's common stock at $11.9625 per share, representing approximately 4.2 million shares. Pursuant to the terms of the agreement, Voyager may also be entitled to an additional $1.7 billion in development, regulatory and commercial milestone payments, as well as royalties on net sales of any collaboration product.

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

We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. Our equity investment in Voyager was recorded at a fair value of $54.7 million after considering Voyager's stock price on the date of closing and certain lock-up and voting provisions applicable to the acquired shares. The remaining $113.1 million of the purchase price, which

includes the applicable transaction costs, was expensed as in-process research and development, or IPR&D, in the first quarter of 2019.

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

We may terminate the collaboration and license agreement with Voyager upon 180 days' written notice to Voyager prior to the first commercial sale of any collaboration product or upon one year after the date of notice if such notice is provided after the first commercial sale of any collaboration product. Unless terminated earlier, the agreement will continue in effect until the expiration of the last to expire royalty term with respect to any collaboration product or the last expiration or termination of any exercised co-development and co-commercialization rights by Voyager as provided for in the agreement.

***Xenon.*** In December 2019, we entered into a license and collaboration agreement with Xenon to establish a collaboration under which the parties will identify, research and develop sodium channel inhibitors, including clinical candidate NBI-921352 (XEN901) and three preclinical candidates, which compounds we will have the exclusive right to further develop and commercialize under the terms and conditions set forth in the agreement.

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

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

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

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

***Mitsubishi Tanabe Pharma Corporation.*** During 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation, or MTPC, for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. MTPC made an up-front license fee of $30.0 million and has agreed to make payments up to $85.0 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, MTPC is responsible for all third-party development, marketing and commercialization costs in Japan and other select Asian markets and we would be entitled to a percentage of sales of INGREZZA in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights. Further, the collaboration effort between the parties to advance INGREZZA towards commercialization in Japan and other select Asian markets is governed by joint steering and development committees with representatives from both parties. There are no performance, cancellation, termination or refund provisions in the agreement that would have a material financial consequence to us. We do not directly control when event-based payments will be achieved or when royalty payments will begin. MTPC may terminate the agreement at its discretion upon 180 days' written notice to us. In such event, all INGREZZA product rights for Japan and other select Asian markets would revert to us.

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

To evaluate the appropriate transaction price, we determined that the up-front amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on our best estimate of their relative stand-alone selling prices. For the license, the stand-alone selling price was calculated using an income approach model and included the following key assumptions: the development timeline, revenue forecast, discount rate and probabilities of technical and regulatory

success. The relative selling price of our development activities to initiate a clinical study of INGREZZA for Huntington's chorea was based on an assessment of costs to perform the study, based upon a peer company analysis for similar studies. We believe a change in the assumptions used to determine our stand-alone selling price for the license most likely would not have a significant effect on the allocation of consideration received (or receivable) to the performance obligations.

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

Since inception of the agreement, we have recognized revenue of $20.6 million associated with the delivery of a technology license and existing know-how, and $15.0 million in development event-based payments resulting from MTPC's initiation of Phase II/III development of INGREZZA in tardive dyskinesia, or TD, in Asia. In 2019, we recognized revenue of $0.9 million in connection with our initiation of the KINECT-HD study in November 2019, a placebo-controlled Phase III study of valbenazine in adult Huntington's disease patients with chorea. In accordance with our continuing performance obligations, $9.4 million of the $30.0 million up-front payment is being deferred and will be recognized as revenue over the KINECT-HD study period. No revenue was recognized under the MTPC agreement for 2018. In 2017, we recognized $15.0 million in development event-based payments resulting from MTPC's initiation of Phase II/III development of INGREZZA in TD in Asia.

**Note 3. Marketable Securities**

Available-for-sale debt securities consisted of the following:

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Commercial paper | $ 144,472 | $ 94,572 |
| Corporate debt securities | 521,946 | 544,978 |
| Securities of government-sponsored entities | 191,481 | 85,677 |
| Total marketable securities | $ 857,899 | $ 725,227 |

The following table presents the amortized cost, gross unrealized gain (loss) positions and estimated fair value for available-for-sale debt securities, aggregated by investment category.

| *(in thousands)* | Contractual Maturity (in years) | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Aggregate Estimated Fair Value |
|---|---|---|---|---|---|
| **December 31, 2019:** | | | | | |
| Classified as current assets: | | | | | |
| Commercial paper | Less than 1 | $ 144,460 | $ 27 | $ (15) | $ 144,472 |
| Corporate debt securities | Less than 1 | 270,485 | 557 | (42) | 271,000 |
| Securities of government-sponsored entities | Less than 1 | 142,351 | 422 | — | 142,773 |
| | | $ 557,296 | $ 1,006 | $ (57) | $ 558,245 |
| Classified as non-current assets: | | | | | |
| Corporate debt securities | 1 to 2 | $ 250,499 | $ 515 | $ (68) | $ 250,946 |
| Securities of government-sponsored entities | 1 to 2 | 48,691 | 19 | (2) | 48,708 |
| | | $ 299,190 | $ 534 | $ (70) | $ 299,654 |
| | | | | | |
| **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 |
| | | $ 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 |
| | | $ 216,270 | $ 228 | $ (470) | $ 216,028 |

The following table presents the estimated fair value and gross unrealized loss position for available-for-sale debt securities, aggregated by investment category and length of time that such 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, 2019:** | | | | | | |
| Commercial paper | $ 33,070 | $ (15) | $ — | $ — | $ 33,070 | $ (15) |
| Corporate debt securities | 186,052 | (110) | — | — | 186,052 | (110) |
| Securities of government-sponsored entities | 15,002 | (2) | — | — | 15,002 | (2) |
| | $ 234,124 | $ (127) | $ — | $ — | $ 234,124 | $ (127) |
| **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) |
| | $ 331,622 | $ (792) | $ 245,745 | $ (1,376) | $ 577,367 | $ (2,168) |

**Note 4. Fair Value Measurements**

Investments measured at fair value on a recurring basis consisted of the following:

| | | Fair Value Measurements Using | | |
|---|---|---|---|---|
| *(in thousands)* | Carrying Value | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **December 31, 2019:** | | | | |
| Classified as current assets: | | | | |
| Cash and money market funds | $ 112,279 | $ 112,279 | $ — | $ — |
| Commercial paper | 144,472 | — | 144,472 | — |
| Securities of government-sponsored entities | 142,773 | — | 142,773 | — |
| Corporate debt securities | 271,000 | — | 271,000 | — |
| | 670,524 | 112,279 | 558,245 | — |
| Classified as long-term assets: | | | | |
| Certificates of deposit | 3,206 | 3,206 | — | — |
| Securities of government-sponsored entities | 48,708 | — | 48,708 | — |
| Corporate debt securities | 250,946 | — | 250,946 | — |
| Restricted equity securities | 55,868 | — | — | 55,868 |
| | 1,029,252 | 115,485 | 857,899 | 55,868 |
| Less cash and cash equivalents and restricted cash | (115,485) | (115,485) | — | — |
| Total investments | $ 913,767 | $ — | $ 857,899 | $ 55,868 |
| **December 31, 2018:** | | | | |
| Classified as current assets: | | | | |
| Cash and money market funds | $ 141,714 | $ 141,714 | $ — | $ — |
| Commercial paper | 94,572 | — | 94,572 | — |
| Securities of government-sponsored entities | 20,840 | — | 20,840 | — |
| Corporate debt securities | 393,787 | — | 393,787 | — |
| | 650,913 | 141,714 | 509,199 | — |
| Classified as long-term assets: | | | | |
| Cash and money market funds | 1,500 | 1,500 | — | — |
| Certificates of deposit | 3,977 | 3,977 | — | — |
| Securities of government-sponsored entities | 64,837 | — | 64,837 | — |
| Corporate debt securities | 151,191 | — | 151,191 | — |
| | 872,418 | 147,191 | 725,227 | — |
| Less cash and cash equivalents and restricted cash | (147,191) | (147,191) | — | — |
| Total investments | $ 725,227 | $ — | $ 725,227 | $ — |

A reconciliation of restricted equity securities measured at fair value on a recurring basis follows.

| *(in thousands)* | | |
|---|---|---|
| Balance at December 31, 2018 | $ | — |
| Investments in restricted equity securities | | 68,855 |
| Net unrealized loss recognized on restricted equity securities during the period | | (12,987) |
| Balance at December 31, 2019 | $ | 55,868 |

**Note 5. Convertible Senior Notes**

On May 2, 2017, we completed a private placement of $517.5 million in aggregate principal amount of 2.25% convertible senior notes due 2024, or the 2024 Notes, and entered into an indenture agreement that sets forth the details of all the terms and conditions of the 2024 Notes, or the 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 us.

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

(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 our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than 130% of the conversion price on each applicable trading day;

(ii) during the five business-day period immediately after any 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 our common stock and the conversion rate on each such trading day;

(iii) upon the occurrence of specified corporate events, including a merger or a sale of all or substantially all of our assets; or

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

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

As the conditional conversion feature described under (i) above had been triggered as of December 31, 2019, holders of the 2024 Notes may convert the 2024 Notes at any time during the period beginning on January 2, 2020 and ending at the close of business on March 31, 2020. Accordingly, the 2024 Notes have been classified as a current liability as of December 31, 2019. The future conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of our common stock during the prescribed measurement periods.

Upon conversion, holders will receive the principal amount of their 2024 Notes and any excess conversion value, calculated based on the per share volume-weighted average price, or 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 our common stock or a combination of cash and shares of its common stock, at our option.

It is our intent and policy to settle conversions through combination settlement, which essentially involves repayment of an amount of cash equal to the “principal portion” and delivery of the “share amount” in excess of the principal portion in shares of common stock or cash. In general, for each $1,000 in principal, the “principal portion” of cash upon settlement is defined as the lesser of $1,000, and the conversion value during the 25-day observation period as described in the 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 our common stock. The “share amount” is the cumulative “daily share amount” during the observation period, which is calculated by dividing the daily VWAP into the difference between the daily conversion value (i.e., conversion rate x daily VWAP) and $1,000.

The initial conversion rate for the 2024 Notes is 13.1711 shares of common stock per $1,000 principal amount, which is equivalent to an initial conversion price of approximately $75.92 per share of our common stock. At the initial conversion rate, settlement of the 2024 Notes for shares of our common stock would approximate 6.8 million shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. The initial conversion price of the 2024 Notes represented a premium of approximately 42.5% to the closing sale price of $53.28 per share of our common stock on the Nasdaq Global Select Market on April 26, 2017, the date we priced the private offering of the 2024 Notes.

In the event of conversion, holders would forgo all future interest payments, any unpaid accrued interest and the possibility of further stock price appreciation. Upon the receipt of conversion requests, the settlement of the 2024 Notes will be paid pursuant to the terms of the 2024 Indenture. In the event that all of the 2024 Notes are converted, we would be required to repay the $517.5 million in principal value and any conversion premium in any combination of cash and shares of its common stock (at the Company’s option).

On or after, but not prior to May 15, 2021, we may redeem for cash all or part of the 2024 Notes if the last reported sale price (as defined in the 2024 Indenture) of 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 we provide notice of redemption. The redemption price will equal the sum of (i) 100% of the principal amount

of the 2024 Notes being redeemed, plus (ii) accrued and unpaid interest, including additional interest, if any, to, but excluding, the redemption date. No sinking fund is provided for the 2024 Notes.

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

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

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 seven-year term of the 2024 Notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. At December 31, 2019, the remaining period over which the discount on the liability component will be amortized was approximately 4.4 years.

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

The 2024 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by 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)*** | **2019** | **2018** |
| Principal | $ 517,500 | $ 517,500 |
| Deferred financing costs | (6,937) | (8,326) |
| Debt discount, net | (101,756) | (120,678) |
| Net carrying amount | $ 408,807 | $ 388,496 |

The 2024 Notes were recorded at the estimated value of a similar non-convertible instrument on the date of issuance and accretes to the face value of the 2024 Notes over their seven-year term. The fair value of the 2024 Notes, which was estimated utilizing market quotations from an over-the-counter trading market (Level 2), was $596.8 million at December 31, 2019 and $616.1 million at December 31, 2018.

**Note 6. Other Balance Sheet Details**

Inventory consisted of the following:

| | December 31, | |
|---|---|---|
| ***(in thousands)*** | **2019** | **2018** |
| Raw materials | $ 14,148 | $ 7,855 |
| Work in process | 1,470 | 2,208 |
| Finished goods | 1,670 | 801 |
| Total inventory | $ 17,288 | $ 10,864 |

Property and equipment, net, consisted of the following:

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Tenant improvements | $ 26,342 | $ 19,857 |
| Scientific equipment | 33,483 | 28,163 |
| Computer equipment | 12,460 | 11,152 |
| Furniture and fixtures | 3,188 | 2,968 |
| | 75,473 | 62,140 |
| Less accumulated depreciation | (33,559) | (28,271) |
| Total property and equipment, net | $ 41,914 | $ 33,869 |

Accounts payable and accrued liabilities consisted of the following:

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Accrued employee related costs | $ 38,941 | $ 27,341 |
| Revenue-related reserves for discounts and allowances | 30,634 | 13,586 |
| Accrued development costs | 25,496 | 7,069 |
| Accounts payable and other accrued liabilities | 46,214 | 38,381 |
| Total accounts payable and accrued liabilities | $ 141,285 | $ 86,377 |

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheet that sum to the total of the same such amounts shown in the consolidated statement of cash flows.

| *(in thousands)* | December 31, 2019 | December 31, 2018 |
|---|---|---|
| Cash and cash equivalents | $ 112,279 | $ 141,714 |
| Restricted cash | 3,206 | 5,477 |
| Total cash, cash equivalents and restricted cash | $ 115,485 | $ 147,191 |

**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, 2019 | 2018 | 2017 |
|---|---|---|---|
| Net income (loss) - basic and diluted | $ 37,012 | $ 21,111 | $ (142,542) |
| Weighted average common shares outstanding, basic | 91,627 | 90,235 | 88,089 |
| Effect of dilutive securities: | | | |
| Employee stock purchase program | 25 | 11 | — |
| Stock options | 2,559 | 3,228 | — |
| Restricted stock units | 449 | 564 | — |
| 2024 Notes | 1,072 | 1,348 | — |
| Weighted average common shares outstanding, diluted | 95,732 | 95,386 | 88,089 |
| Net income (loss) per share, basic | $ 0.40 | $ 0.23 | $ (1.62) |
| Net income (loss) per share, diluted | $ 0.39 | $ 0.22 | $ (1.62) |

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, 2019 | 2018 | 2017 |
|---|---|---|---|
| Stock options and restricted stock units | 2,144 | 887 | 7,436 |

**Note 8. Share-Based Compensation**

***Share-Based Compensation Plans.*** In May 2011, we adopted the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan, as amended, or the 2011 Plan, pursuant to which 21 million shares of our 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, non-statutory stock options, restricted stock awards, restricted stock unit awards, or RSUs, stock appreciation rights, performance stock awards, performance-based restricted stock units, or PRSUs, and other forms of equity compensation. In May 2018, we adopted the Neurocrine Biosciences, Inc. ESPP pursuant to which 300,000 shares of our common stock are authorized for issuance. During 2019, we issued 78,000 shares of our common stock under the ESPP. No purchases occurred under the ESPP during 2018.

We previously issued stock options and RSUs under the Neurocrine Biosciences, Inc. Inducement Plan, or the Inducement Plan, to certain employees. Pursuant to the Inducement Plan, we granted 70,000 stock options and 20,000 RSUs in 2018 and 410,000 stock options and 12,500 RSUs in 2017. We did not grant any stock options or RSUs pursuant to the Inducement Plan during 2019. These stock option grants have a four-year vesting period and the RSUs generally have vesting periods of three to four years. We currently have a total of 211,000 stock options and RSUs outstanding under this Inducement Plan.

At December 31, 2019, 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.

We issue new shares upon the exercise of stock options, the issuance of stock bonus awards, and the vesting of RSUs and PRSUs. At December 31, 2019, 7.8 million shares of common stock were reserved for such issuances.

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

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

| | Year Ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | 2019 | 2018 | 2017 |
| Sales, general and administrative expense | $ 49,489 | $ 31,847 | $ 27,951 |
| Research and development expense | 25,773 | 26,221 | 14,571 |
| Share-based compensation expense | $ 75,262 | $ 58,068 | $ 42,522 |

***Stock Options.*** The exercise price of our stock options granted is equal to the closing price of our 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:

| | Year Ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | 2019 | 2018 | 2017 |
| Risk-free interest rate | 2.4% | 2.5% | 2.0% |
| Expected volatility of common stock | 54.8% | 59.5% | 58.0% |
| Dividend yield | 0.0% | 0.0% | 0.0% |
| Expected option term | 5.4 years | 4.7 years | 5.7 years |

We estimate 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 our common stock over the most recent period commensurate with the estimated expected term of our 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 our employee stock options. We have never declared or paid dividends and has no plans to do so in the foreseeable future.

Our determination of fair value is affected by our stock price as well as a number of assumptions that require judgment. The weighted-average fair values of stock options granted during 2019, 2018 and 2017 estimated as of the grant date using the Black-Scholes option-pricing model, were $41.74, $43.42 and $25.11, respectively.

A summary of activity related to stock options follows:

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2019 | | 2018 | | 2017 | |
| *(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 | 5,746 | $ 41.38 | 6,356 | $ 28.83 | 6,112 | $ 20.01 |
| Granted | 1,416 | 82.27 | 1,040 | 84.97 | 1,807 | 46.55 |
| Exercised | (983) | 27.95 | (1,592) | 18.95 | (1,353) | 10.41 |
| Canceled | (72) | 75.09 | (58) | 64.67 | (210) | 43.05 |
| Outstanding at December 31 | 6,107 | $ 52.62 | 5,746 | $ 41.38 | 6,356 | $ 28.83 |

Stock options outstanding at December 31, 2019 had a weighted average remaining contractual term of 6.7 years.

For 2019, 2018 and 2017 share-based compensation expense related to stock options was $36.5 million, $35.4 million and $28.2 million, respectively. At December 31, 2019, there was approximately $75.0 million of unamortized compensation cost related to stock options, which we expect to recognize over a weighted average remaining vesting period of approximately 2.4 years. At

December 31, 2019, there were approximately 4.0 million stock options exercisable with a weighted average exercise price of $41.01 and a weighted-average remaining contractual term of 5.8 years. The total intrinsic value, which is the amount by which the exercise price was exceeded by the sale price of our common stock on the date of sale, of stock option exercises during 2019, 2018, and 2017 was $64.3 million, $117.0 million and $61.4 million, respectively. At December 31, 2019, the total intrinsic value of stock options outstanding and exercisable was $335.7 million and $268.2 million, respectively. Cash received from stock option exercises for 2019, 2018 and 2017 was $27.3 million, $29.5 million, and $13.9 million, respectively.

***Restricted Stock Units.*** The fair value of RSUs is based on the closing sale price of our common stock on the date of issuance. For 2019, 2018, and 2017 share-based compensation expense related to RSUs was $30.4 million, $21.9 million, and $13.9 million, respectively. As of December 31, 2019, there was approximately $75.5 million of unamortized compensation cost related to RSUs, which is expected to be recognized over a weighted average remaining vesting period of approximately 2.4 years.

The total intrinsic value of RSUs converted into common shares for 2019, 2018 and 2017 was $36.1 million, $35.5 million, and $14.9 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, 2019 was $147.2 million based on our closing stock price on that date.

A summary of activity related to RSUs follows:

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2019 | | 2018 | | 2017 | |
| *(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 | 1,133 | $ 62.31 | 1,080 | $ 40.30 | 883 | $ 29.33 |
| Granted | 707 | 82.66 | 540 | 85.29 | 588 | 47.21 |
| Cancelled | (56) | 74.49 | (58) | 36.21 | (41) | 40.62 |
| Converted into common shares | (416) | 54.30 | (429) | 59.23 | (350) | 24.19 |
| Outstanding at December 31 | 1,368 | $ 74.77 | 1,133 | $ 62.31 | 1,080 | $ 40.30 |

***Performance-Based Restricted Stock Units.*** We had 0.3 million PRSUs outstanding at both December 31, 2019 and 2018. During 2018, we granted approximately 0.2 million PRSUs that vest based on the achievement of certain pre-defined Neurocrine-specific performance criteria and expire approximately four to five years from the grant date. No PRSUs were granted during 2019 or 2017. The fair value of PRSUs is estimated based on the closing sale price of our common stock on the date of grant. Expense recognition for PRSUs commences when attainment of the performance-based criteria is determined to be probable. We recognized expense of $5.6 million for 2019 and $0.4 million for 2017 related to PRSUs. We recognized no expense related to PRSUs for 2018. At December 31, 2019, total unrecognized estimated compensation expense related to PRSUs was $14.1 million and the total intrinsic value of PRSUs outstanding was $35.5 million based on our closing stock price on that date. The total intrinsic value of PRSUs converted into common shares was $8.8 million for 2017.

***Employee Stock Purchase Plan.*** Under the ESPP, eligible employees may purchase shares of our common stock at a discount semi-annually based on a percentage of their annual compensation. 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 $2.7 million for 2019 and $0.8 million for 2018.

**Note 9. Income Taxes**

Components of income tax expense for continuing operations were as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | 2019 | 2018 | 2017 |
| Current: | | | |
| Federal | $ — | $ (100) | $ — |
| State | 9,530 | 830 | — |
| Total income tax expense | $ 9,530 | $ 730 | $ — |

The provision for income taxes on earnings subject to income taxes differs from the statutory federal rate due to the following:

| *(in thousands)* | December 31, 2019 | 2018 | 2017 |
|---|---|---|---|
| Federal income taxes at 21% for 2019 and 2018 and 35% for 2017 | $ 9,775 | $ 4,587 | $ (49,889) |
| State income tax, net of federal benefit | 4,044 | 361 | (4,013) |
| Tax effect on non-deductible expenses | 855 | 446 | 433 |
| Branded prescription drug fee | 3,707 | — | — |
| Share-based compensation expense | (12,785) | (9,778) | (19,589) |
| Officer compensation | 3,068 | 915 | 2,163 |
| Change in tax rate | (4,143) | (198) | 154,415 |
| Expired tax attributes | 1,228 | 13,874 | 2,998 |
| Research credits | (10,359) | (13,526) | (5,596) |
| Change in valuation allowance | 13,883 | 4,306 | (79,966) |
| Other | 257 | (257) | (956) |
| | $ 9,530 | $ 730 | $ — |

Significant components of our deferred tax assets as of December 31, 2019 and 2018 are listed below.

We assess all available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative book loss incurred over the three-year period ended December 31, 2019. Such objective evidence limits the ability to consider other subjective evidence, such as projections for future growth.

On the basis of this analysis, we recorded a valuation allowance of $346.0 million and $335.2 million at December 31, 2019 and 2018, respectively, to offset the net deferred tax asset below as realization of such asset is uncertain. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as our projections for future growth.

| *(in thousands)* | December 31, 2019 | 2018 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating losses | $ 181,300 | $ 223,800 |
| Research and development credits | 71,900 | 62,200 |
| Capitalized research and development | 28,000 | 34,800 |
| Share-based compensation expense | 22,900 | 17,300 |
| Operating lease assets | 23,300 | 100 |
| Intangible assets | 49,300 | 9,400 |
| Other | 18,500 | 19,100 |
| Total deferred tax assets | 395,200 | 366,700 |
| Deferred tax liabilities: | | |
| Convertible senior notes | (24,100) | (26,400) |
| Operating lease liabilities | (18,200) | — |
| Other | (6,900) | (5,100) |
| Total deferred tax liabilities | (49,200) | (31,500) |
| Net of deferred tax assets and liabilities | 346,000 | 335,200 |
| Valuation allowance | (346,000) | (335,200) |
| Net deferred tax assets | $ — | $ — |

At December 31, 2019, we had federal and state income tax net operating loss carry forwards of approximately $816.2 million and $359.8 million, respectively. The federal net operating losses will begin to expire in 2024, 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, we have federal and California R&D tax credit carry forwards of $73.2 million and $47.5 million, respectively. A portion of the federal R&D tax credit carry forwards expired in 2019. The remaining federal R&D tax credits will continue to expire in 2020, unless previously utilized. The California R&D tax credits carry forward indefinitely.

Additionally, the future utilization of our net operating loss and R&D tax credit carry forwards to offset future taxable income may be subject to annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that could result in the future. No such ownership changes have occurred through December 31, 2019.

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.

Our 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 2019, 2018 or 2017.

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

A summary of activity related to unrecognized tax benefits follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| *(in thousands)* | 2019 | 2018 | 2017 |
| Balance at January 1 | $ 54,775 | $ 37,403 | $ 34,112 |
| Increases related to prior year tax positions | 281 | 6,103 | — |
| Increases related to current year tax positions | 9,519 | 11,726 | 3,291 |
| Expiration of the statute of limitations for the assessment of taxes | (657) | (457) | — |
| Balance at December 31 | $ 63,918 | $ 54,775 | $ 37,403 |

We excluded deferred tax assets that are not more-likely-than-not to be sustained under the technical merits of the tax position. Such unrecognized tax benefits totaled $9.5 million for current year tax positions, as reflected in the table above.

At December 31, 2019, we had $57.9 million of unrecognized tax benefits that, if recognized and realized, would affect the effective tax rate, subject to the valuation allowance. We do not expect a significant change in our unrecognized tax benefits in the next twelve months.

**Note 10. Leases**

In December 2007, we closed the sale of our facility and associated real property for a purchase price of $109.0 million. Concurrent with the sale, we 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 remaining balance was $8.0 million as of December 31, 2018, and which we recognized as a cumulative-effect adjustment to equity upon adoption of Topic 842 on January 1, 2019.

Upon closing of the sale of the facility and associated real property, we entered into an agreement, or the original lease, to lease back our corporate headquarters, comprised of two buildings located in San Diego, California, for a term of twelve years. In 2008 through 2011, we entered into a series of subsequent amendments to the original lease, whereby we vacated one of the two buildings and continued to occupy one building, or the existing premises. In June 2017, we entered into an amendment to the original lease, or the amended lease, whereby we extended its term through December 31, 2029. In August 2019, we entered into an amendment, or the 2019 amendment, to the amended lease, whereby we agreed to lease 80,282 square feet of additional office space, or the expanded premises, in San Diego, California, for a term of twelve years, and to extend the total term of the original lease to a coterminous date of July 31, 2031.

Under the terms of the 2019 amendment, we will take possession of the expanded premises on a tranche-by-tranche basis as office space currently occupied by third-party tenants becomes available through 2021. Commencing on each applicable tranche lease commencement date and continuing throughout the term of the lease, we will be obligated to pay base annual rent (subject to an annual fixed percentage increase) and our then-applicable portion of the operating expenses and taxes attributable to the expanded premises. Additionally, we will continue to be obligated to pay base annual rent (subject to an annual fixed percentage increase), operating expenses, and taxes attributable to the existing premises.

The 2019 amendment includes two options to extend the term of the lease for a period of ten years each. We were not reasonably certain to exercise either of these options at lease commencement. As such, neither option was recognized as part of the associated operating lease ROU asset or liability. In connection with the amended lease, in lieu of a cash security deposit, Wells Fargo Bank, N.A., or Wells Fargo, issued a $3.0 million letter of credit on our behalf, which is secured by a deposit of equal amount.

In May 2018, we entered into an agreement to lease 44,718 square feet of office space in San Diego, California, which commenced on July 1, 2018, for a term of ten years and ten months. Under the terms of the lease, we 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 $4.2 million in tenant improvement allowances and twelve months of rent abatement. In lieu of a cash security deposit, Wells Fargo issued a $1.0 million letter of credit on our behalf, which is secured by a deposit of $0.2 million. We do not have the right to extend the lease or right of first offer for future rental of adjacent office space owned by the landlord.

For 2019, our operating lease cost was $8.1 million, and cash paid for amounts included in the measurement of lease liabilities for operating cash flows from operating leases was $7.7 million. At December 31, 2019, we reported operating lease ROU assets and operating lease liabilities of $74.4 million and $95.0 million, respectively. Further, at December 31, 2019, our operating leases had a weighted average remaining lease term of 11.2 years and a weighted average discount rate of 5.8%.

At December 31, 2019, the approximate future minimum lease payments under operating leases were as follows:

| *(in thousands)* | Operating Leases |
|---|---|
| **Year Ending December 31,** | |
| 2020 | $ 8,558 |
| 2021 | 10,578 |
| 2022 | 10,900 |
| 2023 | 11,232 |
| 2024 | 11,574 |
| Thereafter | 91,271 |
| Total operating lease payments | 134,681 |
| Less accreted interest | (39,643) |
| | 95,038 |
| Less current operating lease liabilities | (8,282) |
| Noncurrent operating lease liabilities | $ 86,756 |

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

**Note 11. Retirement Plan**

We have a 401(k) defined contribution savings plan, or the 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 $4.9 million, $1.8 million, and $1.1 million for 2019, 2018 and 2017, respectively.

**Note 12. Commitments and Contingencies**

We have entered into various collaboration and licensing agreements that provide us with rights to certain know-how, technology and patent rights. Under the terms of these agreements, we may be required to make milestone payments upon achievement of certain development and regulatory activities of up to $4.9 billion and pay royalties on future sales, if any, of commercial products resulting from these agreements.

**Note 13. Selected Quarterly Financial Data (Unaudited)**

A summary of our quarterly results follows:

| *(in thousands, except per share data)* | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| **Year Ended December 31, 2019:** | | | | |
| Total revenues | $ 138,403 | $ 183,580 | $ 222,094 | $ 244,010 |
| Total operating expenses (1) | $ 239,400 | $ 149,119 | $ 131,996 | $ 195,289 |
| Net (loss) income (1) | $ (102,115) | $ 51,338 | $ 53,789 | $ 34,000 |
| Net (loss) income per share, basic (1) | $ (1.12) | $ 0.56 | $ 0.59 | $ 0.37 |
| Net (loss) income per share, diluted (1) | $ (1.12) | $ 0.54 | $ 0.56 | $ 0.35 |
| Weighted average common shares outstanding, basic | 91,056 | 91,389 | 91,859 | 92,182 |
| Weighted average common shares outstanding, diluted | 91,056 | 94,779 | 96,074 | 97,229 |
| | | | | |
| **Year Ended December 31, 2018:** | | | | |
| Total revenues | $ 71,086 | $ 96,905 | $ 151,757 | $ 131,492 |
| Total 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 |
| Net (loss) income per share, diluted | $ (0.47) | $ (0.07) | $ 0.52 | $ 0.19 |
| Weighted average common shares outstanding, basic | 89,526 | 90,100 | 90,555 | 90,742 |
| Weighted average common shares outstanding, diluted | 89,526 | 90,100 | 96,798 | 95,724 |

*(1) In connection with the payment of the upfront fee pursuant to our collaboration and license agreement with Voyager, we recorded a charge of $113.1 million, accounted for as IPR&D, in the first quarter of 2019. In the second quarter of 2019, we entered into an amendment to the collaboration and license agreement with Voyager, pursuant to which we paid Voyager $5.0 million upfront, accounted for as IPR&D, to obtain outside the U.S. rights to the Friedreich's ataxia program. In connection with the payment of the upfront fee pursuant to our collaboration with Xenon, we recorded a charge of $36.2 million, accounted for as IPR&D, in the fourth quarter of 2019.*

**Item 9.** ***Changes 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, 2019. 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, 2019, 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, 2019, 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, 2019, 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, 2019 and 2018, 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, 2019, and the related notes and our report dated February 6, 2020 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 6, 2020

**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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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. Information found on, or accessible through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

**Item 11.** ***Executive Compensation***

Information required by this item will be contained in our Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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 2020 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2019. 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, 2019 and 2018

Consolidated Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019, 2018 and 2017

Consolidated Statements of Cash Flows for the years ended December 31, 2019, 2018 and 2017

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** | | |
|---|---|---|
| 3.1 | Description:<br>Reference: | Certificate of Incorporation, as amended<br>Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on November 5, 2018 |
| 3.2 | Description:<br>Reference: | Bylaws, as amended<br>Incorporated by reference to Exhibit 3.2 of the Company's Quarterly Report on Form 10-Q filed on November 5, 2018 |
| 4.1 | Description:<br>Reference: | Form of Common Stock Certificate<br>Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-03172) |
| 4.2 | Description:<br>Reference: | Indenture, dated as of May 2, 2017, by and between the Company and U.S. Bank National Association, as Trustee<br>Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on May 2, 2017 |
| 4.3 | Description:<br>Reference: | Form of Note representing the Company's 2.25% Convertible Notes due 2024<br>Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on May 2, 2017 |
| 4.4 | Description: | Description of Common Stock of the Company |
| 21.1 | Description: | Subsidiaries of the Company |
| 23.1 | Description: | Consent of Independent Registered Public Accounting Firm |
| 31.1 | Description: | Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934 |
| 31.2 | Description: | Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934 |
| 32*** | Description: | Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 101.INS | Description: | Inline XBRL Instance Document. – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH | Description: | Inline XBRL Taxonomy Extension Schema Document. |
| 101.CAL | Description: | Inline XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF | Description: | Inline XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB | Description: | Inline XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE | Description: | Inline XBRL Taxonomy Extension Presentation Linkbase Document. |
| 104 | Description: | Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101) |

*Collaboration and License Agreements:*

| | | |
|---|---|---|
| 10.1* | Description: | Collaboration Agreement dated June 15, 2010, by and between Abbott International Luxembourg S.a.r.l. and the Company as amended on August 31, 2011 |
| | Reference: | Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2010 |
| 10.2* | Description: | First Amendment to Collaboration and License Agreement Dated August 31, 2011 between the Company and Abbott International Luxemburg S.a.r.l. |
| | Reference: | Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on October 31, 2011 |
| 10.3* | Description: | Collaboration and License Agreement dated March 31, 2015 between Mitsubishi Tanabe Pharma Corporation and the Company |
| | Reference: | Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on April 30, 2015 |
| 10.4* | Description: | License Agreement dated February 9, 2017 between BIAL– Portela & CA, S.A. and the Company |
| | Reference: | Incorporated by reference to Exhibit 99.4 of the Company's Current Report on Form 8-K filed on April 25, 2017 |
| 10.5* | Description: | Collaboration and License Agreement dated January 28, 2019 between Voyager Therapeutics, Inc. and the Company |
| | Reference: | Incorporated by reference to Exhibit 10.5 of the Company's Annual Report on Form 10-K filed on February 7, 2019 |
| 10.6 | Description: | Stock Purchase Agreement dated January 28, 2019 between Voyager Therapeutics, Inc. and the Company |
| | Reference: | Incorporated by reference to Exhibit 10.6 of the Company's Annual Report on Form 10-K filed on February 7, 2019 |
| 10.7 | Description: | Investor Agreement dated January 28, 2019 between Voyager Therapeutics, Inc. and the Company |
| | Reference: | Incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K filed on February 7, 2019 |
| 10.8 | Description: | Amendment No. 1 to Collaboration and License Agreement dated June 14, 2019 between Voyager Therapeutics, Inc. and the Company |
| | Reference: | Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2019 |

*Equity Plans and Related Agreements:*

| | | |
|---|---|---|
| 10.9** | Description: | Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan, as amended |
| | Reference: | Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on May 30, 2018 |
| 10.10** | Description: | 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 |
| | Reference: | Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on June 1, 2015 |
| 10.11** | Description: | Neurocrine Biosciences, Inc. Inducement Plan, as amended |
| | Reference: | Incorporated by reference to Exhibit 10.17 of the Company's Annual Report on Form 10-K filed on February 13, 2018 |
| 10.12** | Description: | 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 |
| | Reference: | Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2015 |
| 10.13** | Description: | Neurocrine Biosciences, Inc. 2018 Employee Stock Purchase Plan dated May 30, 2018 |
| | Reference: | Incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on May 30, 2018 |

*Agreements with Officers and Directors:*

| | | |
|---|---|---|
| 10.14** | Description: | Amended and Restated Employment Agreement effective August 1, 2007 between the Company and Kevin C. Gorman, Ph.D. |
| | Reference: | Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on August 3, 2007 |
| 10.15** | Description: | Form of Amendment to Employment Agreement for executive officers, effective as of December 15, 2010 |
| | Reference: | Incorporated by reference to Exhibit 10.32 of the Company's Annual Report on Form 10-K filed on February 11, 2008 |
| 10.16** | Description: | Employment Agreement dated November 3, 2014 between the Company and Kyle Gano |
| 10.17** | Description: | Employment Agreement dated May 26, 2015 between the Company and Eric Benevich |

| | | |
|---|---|---|
| | Reference: | Incorporated by reference to Exhibit 10.3 of the Company's Annual Report on Form 10-K filed on February 14, 2017 |
| 10.18** | Description: | Employment Agreement effective November 29, 2017 between the Company and Matthew C. Abernethy |
| | Reference: | Incorporated by reference to Exhibit 10.26 of the Company's Annual Report on Form 10-K filed on February 13, 2018 |
| 10.19** | Description: | Form of Indemnity Agreement entered into between the Company and its officers and directors |
| | Reference: | Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on November 1, 2017 |
| 10.20** | Description: | Employment Agreement dated January 8, 2018 between the Company and Eiry W. Roberts, M.D. |
| | Reference: | Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2019 |

*Agreements Related to Real Property:*

| | | |
|---|---|---|
| 10.21 | Description: | Amended and Restated Lease dated November 1, 2011 between the Company and Kilroy Realty, L.P. |
| | Reference: | Incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K filed on January 18, 2012 |
| 10.22 | Description: | First Amendment to Amended and Restated Lease between the Company and Kilroy Realty, L.P., dated June 5, 2017 |
| | Reference: | Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 3, 2017 |
| 10.23 | Description: | Second Amendment to Amended and Restated Lease between the Company and Kilroy Realty, L.P., dated October 12, 2017 |
| | Reference: | Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on November 1, 2017 |
| 10.24 | Description: | 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 |
| | Reference: | 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 |
| 10.25 | Description: | Third Amendment to Amended and Restated Lease between the Company and Kilroy Realty, L.P. dated August 7, 2019 |
| | Reference: | Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on November 4, 2019 |

* 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.
(Registrant)

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

Date: February 6, 2020

By: /s/ *Matthew C. Abernethy*
Matthew C. Abernethy
Chief Financial Officer

Date: February 6, 2020

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kevin C. Gorman and Matthew C. Abernethy, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power of authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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 indicated as of February 6, 2020:

| **Signature** | **Title** |
|---|---|
| /s/ *Kevin C. Gorman*<br>Kevin C. Gorman, Ph.D. | Chief Executive Officer and Director<br>*(Principal Executive Officer)* |
| /s/ *Matthew C. Abernethy*<br>Matthew C. Abernethy | Chief Financial Officer<br>*(Principal Financial and Accounting Officer)* |
| /s/ *William H. Rastetter*<br>William H. Rastetter, Ph.D. | Chairman of the Board of Directors |
| /s/ *Gary A. Lyons*<br>Gary A. Lyons | Director |
| /s/ *George J. Morrow*<br>George J. Morrow | Director |
| /s/ *Leslie V. Norwalk*<br>Leslie V. Norwalk | Director |
| /s/ *Richard F. Pops*<br>Richard F. Pops | Director |
| /s/ *Alfred W. Sandrock, Jr.*<br>Alfred W. Sandrock, Jr., M.D., Ph.D. | Director |
| /s/ *Stephen A. Sherwin*<br>Stephen A. Sherwin, M.D. | Director |
| <br>Shalini Sharp | Director |

# DESCRIPTION OF COMMON STOCK

The following summary description of the common stock of Neurocrine Biosciences, Inc., or we, our or us is based on the provisions of our certificate of incorporation, as amended, as well as our bylaws, as amended, and the applicable provisions of the Delaware General Corporation Law. This information is qualified entirely by reference to the applicable provisions of our certificate of incorporation, as amended, bylaws, as amended, and the Delaware General Corporation Law. Our certificate of incorporation, as amended, and bylaws, as amended, have previously been filed as exhibits with the Securities and Exchange Commission.

## Common Stock

*Voting.* Common stockholders are entitled to one vote per share for the election of directors and on all other matters that require stockholder approval, and do not have cumulative voting rights.

*Dividends and Other Distributions.* Subject to any preferential rights of outstanding preferred stock, holders of our common stock are entitled to share ratably in any dividends declared by our board of directors on the common stock and paid out of funds legally available for such dividends.

*Distribution on Dissolution.* Subject to any preferential rights of outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in any assets remaining after payment of liabilities and the liquidation preferences of any outstanding preferred stock.

*Other Rights.* Our common stock does not carry any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock. There are no redemption rights or sinking fund provisions applicable to our common stock.

## Anti-takeover Effects of Provisions of Delaware Law and Charter Documents

*Delaware Anti-Takeover Law*

We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

*Certificate of Incorporation*

Our certificate of incorporation, as amended, (i) provides for a board comprised of three classes of directors with each class serving a staggered three-year term, (ii) authorizes our board of directors to issue preferred stock from time to time, in one or more classes or series, without stockholder approval, (iii) requires the approval of at least two-thirds of the outstanding voting stock to amend certain provisions of our certificate of incorporation, as amended, and our bylaws, as amended, and (iv) does not include a provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. These and other provisions contained in our certificate of incorporation, as amended, and bylaws, as amended, could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices. Such provisions could also limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and could adversely affect the price of our common stock.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar’s address is 59 Maiden Lane, New York, New York 10038.

**Listing on the Nasdaq Global Select Market**

Our common stock is listed on the Nasdaq Global Select Market under the symbol NBIX.

# EMPLOYMENT AGREEMENT

**THIS EMPLOYMENT AGREEMENT** is effective as of the last date signed by the parties hereto (the "Effective Date") and is entered into by and between **NEUROCRINE BIOSCIENCES, INC.**, 12780 El Camino Real, San Diego, California 92130 (hereinafter the "Company"), and Kyle Gano (hereinafter "Executive").

## R E C I T A L S

**WHEREAS,** the Company and Executive wish to set forth in this Agreement the terms and conditions under which Executive is to be employed by the Company on and after the Effective Date hereof;

**NOW, THEREFORE,** the Company and Executive, in consideration of the mutual promises set forth herein, agree as follows:

## ARTICLE 1

## NATURE OF EMPLOYMENT

**1.1 Commencement Date.** Executive's full-time employment with the Company under this Agreement shall be deemed to have commenced as of November 3, 2014 ("Commencement Date") and this Agreement shall continue from the Effective Date until it is terminated by either the Company or Executive pursuant to the terms set forth in Article 6.

**1.2 At-Will Employment.** Executive shall be employed at-will by the Company and therefore either Executive or the Company may terminate the employment relationship and this Agreement at any time, with or without Cause (as defined herein) and with or without advance notice, subject to the provisions of Article 6.

## ARTICLE 2

## EMPLOYMENT DUTIES

**2.1 Title/Responsibilities.** Executive hereby accepts employment with the Company pursuant to the terms and conditions hereof. Executive agrees to serve the Company in the position of Chief Business Development Officer. Executive shall have the powers and duties commensurate with such position, including but not limited to hiring personnel necessary to carry out the responsibilities for such position as set forth in the annual business plan approved by the Board of Directors.

**2.2 Full Time Attention.** Executive shall devote his best efforts and his full business time and attention to the performance of the services customarily incident to such office and to such other services as the President and Chief Executive Officer (hereinafter "CEO") or Board of Directors may reasonably request.

**2.3 Other Activities.** Except upon the prior written consent of the CEO, Executive shall not during the period of employment engage, directly or indirectly, in any other business activity (whether or not pursued for pecuniary advantage) that is or may be competitive with, or that might place him in a competing position to that of the Company or any other corporation or entity that directly or indirectly controls, is controlled by, or is under common control with the Company (an "Affiliated Company"), provided that Executive may own less than two percent (2%) of the outstanding securities of any such publicly traded competing corporation.

**ARTICLE 3**

**COMPENSATION**

**3.1** **Base Salary.** Executive shall receive a Base Salary at an annual rate of $310,000, payable semi-monthly in equal installments in accordance with the Company's normal payroll practices. The CEO shall provide Executive with annual performance reviews, and, thereafter, Executive shall be entitled to such increase in Base Salary as the CEO and the Compensation Committee of the Board of Directors (hereinafter the "Compensation Committee") may from time to time establish in their sole discretion.

**3.2** **Incentive Bonus.** In addition to any other bonus Executive shall be awarded by the Compensation Committee, Executive shall be eligible to receive an annual incentive bonus as determined by the Company's Compensation Committee and CEO based upon the achievement by the Company of annual corporate goals established by the Board of Directors and the achievement of Executive in meeting annual personal goals established by the CEO and the Compensation Committee. Executive's annual incentive bonus at target will be as set forth in the Company's Executive Officer Bonus Plan (the "Target Annual Bonus"); for fiscal year 2014, this target is set at 50% of base pay earned. The Company's annual corporate goals, and if applicable, the Executive's annual personal goals, will be set forth in writing by the CEO and the Compensation Committee within ninety (90) days after the start of the Company's fiscal year. The Compensation Committee in consultation with the independent members of the Board of Directors and the CEO shall, in their sole discretion, determine whether Executive's annual personal goals have been attained. The Compensation Committee in consultation with the independent members of the Board of Directors shall, in its sole discretion, determine whether the annual corporate goals have been attained. Any annual incentive bonus shall be considered earned only if Executive is employed by the Company both on the date that the determination is made as to whether annual personal goals have been met, and on the date that the determination is made as to whether annual corporate goals have been met. These determinations generally will be made within the first quarter following the end of the Company's fiscal year. Except as provided in Article 6 herein, no pro-rata bonus will be considered earned if Executive leaves the Company for any reason prior to the foregoing determination dates. Any annual incentive bonus that is earned shall be paid no later than the fifteenth day of the third month following the end of the Company's fiscal year for which such bonus was earned.

**3.3** **Equity.** Except as provided in Article 6 in the case of certain terminations of employment, this Agreement shall not affect any Stock Awards (as such term is defined below) previously granted by the Company to Executive. Subject to approval by the Company's Compensation Committee, in consultation with the independent members of the Board of Directors, Executive will be eligible to receive additional Stock Awards on terms to be determined by the Compensation Committee at the time of any such grant. The determination whether to grant any additional Stock Award to Executive is in the sole discretion of the Compensation Committee, in consultation with the independent members of the Board of Directors. For all purposes of this Agreement, "Stock Awards" shall mean any rights granted by the Company to Executive with respect to the common stock of the Company, including, without limitation, stock options, stock appreciation rights, restricted stock, stock bonuses and restricted stock units.

**3.4** **Withholdings.** All compensation and benefits payable to Executive under this Agreement shall be subject to all federal, state, local taxes and other withholdings and similar taxes and payments required by applicable law.

**ARTICLE 4**

**EXPENSE ALLOWANCES AND FRINGE BENEFITS**

**4.1** **Vacation.** Executive shall be entitled to participate in the Company's vacation plan pursuant to the terms of that plan.

**4.2** **Benefits.** During Executive's employment hereunder, the Company shall also provide Executive with the health insurance benefits it generally provides to its other senior management employees. As Executive becomes eligible in accordance with criteria to be adopted by the Company, the Company shall provide Executive with the right to participate in and to receive benefit from life, accident, disability, medical, and savings plans and similar benefits made available generally to employees of the Company as such plans and benefits may be adopted by the Company. With respect to long-term disability insurance coverage, the Executive will pay all premiums for such coverage with after-tax dollars, and the Company will reimburse the Executive for the premium costs so paid by the Executive, which reimbursement benefit shall be taxable income, subject to withholding. The amount and extent of benefits to which Executive is entitled shall be governed by the specific benefit plan as it may be amended from time to time. With respect to personal financial and tax planning expenses incurred by Executive (the "Financial Planning Expenses"), the Company will reimburse the Executive for Financial Planning Expenses incurred by the Executive during the 2015 calendar year and each calendar year thereafter, up to a maximum reimbursement benefit of $3,000 each calendar year, which reimbursement benefit shall be taxable income, subject to withholding. Such Financial Planning Expenses shall be reimbursed and accounted for under the expense reimbursement policies and procedures established by the Company (the "Expense Reimbursement Policy"), subject to Executive's timely provision of adequate records and other documentary evidence of having incurred such Financial Planning Expenses in accordance with the terms of the Expense Reimbursement Policy; such reimbursement shall be made promptly, but in no event later than December 31 of the calendar year following the year in which such Financial Planning Expenses were incurred by Executive.

**4.3** **Business Expense Reimbursement.** During the term of this Agreement, Executive shall be entitled to receive proper reimbursement for all reasonable out-of-pocket expenses incurred by him (in accordance with the policies and procedures established by the Company for its senior executive officers) in performing services hereunder. Executive agrees to furnish to the Company adequate records and other documentary evidence of such expense for which Executive seeks reimbursement. Such expenses shall be reimbursed and accounted for under the policies and procedures established by the Company, and such reimbursement shall be made promptly, but in no event later than December 31 of the calendar year following the year in which such expenses were incurred by Executive.

## ARTICLE 5

## CONFIDENTIALITY

**5.1** **Proprietary Information.** Executive represents and warrants that he has previously executed and delivered to the Company the Company's standard Proprietary Information and Inventions Agreement.

**5.2** **Return of Property.** All documents, records, apparatus, equipment and other physical property which is furnished to or obtained by Executive in the course of his employment with the Company shall be and remain the sole property of the Company. Executive agrees that, upon the termination of his employment, he shall return all such property (whether or not it pertains to Proprietary Information as defined in the Proprietary Information and Inventions Agreement), and agrees not to make or retain copies, reproductions or summaries of any such property.

**5.3** **No Use of Prior Confidential Information.** Executive will not intentionally disclose to the Company or use on its behalf any confidential information belonging to any of his former employers or any other third party.

## ARTICLE 6

## TERMINATION

**6.1** **General.** As set forth in Section 1.2 herein, Executive shall be employed on an at-will basis by the Company. Notwithstanding the foregoing, Executive's employment and this Agreement may be terminated in one of six ways as set forth in this Article 6: (a) Executive's Death (Section 6.2); (b) Executive's Disability (Section 6.3); (c) Termination by the Company for Cause (Section 6.4); (d) Termination by the Company without Cause (Section 6.5); (e) Termination by Executive due to a Constructive Termination (Section 6.6); or (f) Voluntary Resignation (Section 6.7).

**6.2** **By Death.** Executive's employment and this Agreement shall terminate automatically upon the death of Executive. In such event:

**(a)** **Stock Awards.** The vesting of all outstanding Stock Awards held by Executive shall be accelerated so that the amount of shares vested under such Stock Awards shall equal that number of shares that would have been vested if Executive had continued to render services to the Company for 12 continuous months after the date of Executive's termination of employment. All Stock Awards held by Executive that are vested at the time of termination (including any accelerated Stock Awards) will be exercisable in accordance with their terms until the earlier of (x) one year after the termination date, or (y) the expiration of the maximum term of the option.

**(b)** **Bonus.** The Company shall pay to Executive's beneficiaries or his estate, as the case may be, a lump sum amount equal to Executive's Target Annual Bonus (as defined in Section 3.2) for the Company's fiscal year in which Executive's death occurs multiplied by a fraction, the numerator of which is the number of full months of employment by Executive in such fiscal year and the denominator of which is 12. Such amount shall be paid as soon as administratively practicable, but in no event later than March 15 following the year in which Executive's death occurred.

**(c)** **Accrued Compensation.** The Company shall pay to Executive's beneficiaries or his estate, as the case may be, any accrued Base Salary, any vested deferred compensation (other than pension plan or profit-sharing plan benefits that will be paid in accordance with the applicable plan), any benefits under any plans of the Company (other than pension and profit-sharing plans) in which Executive is a participant to the full extent of Executive's rights under such plans, any accrued vacation pay and any appropriate business expenses incurred by Executive in connection with his duties hereunder, all to the date of termination (collectively "Accrued Compensation").

**(d)** **No Severance Compensation.** The compensation and benefits set forth in Sections 6.2(a) through (c) herein shall be the only compensation and benefits provided by the Company in the event of Executive's death and no other severance compensation or benefits shall be provided.

**6.3** **By Disability.** If Executive is prevented from performing his duties hereunder by reason of any physical or mental incapacity that results in Executive's satisfaction of all requirements necessary to receive benefits under the Company's long-term disability plan due to a total disability, then, to the extent permitted by law, the Company may terminate the employment of Executive and this Agreement at or after such time. In such event, and if Executive signs the General Release set forth as **Exhibit A** or such other form of release as the Company may require (the "Release") on or within the time period set forth therein, but in no event later than forty-five (45) days after the termination date and allows such Release to become effective (the "Release Effective Date"), then:

**(a)** **Accrued Compensation.** The Company shall pay to Executive all Accrued Compensation (as defined in Section 6.2(c) herein).

**(b)** **Base Salary Continuation.** The Company shall continue to pay Executive's Base Salary, less required withholdings, for a period of 12 months (the "Disability Base Salary Payments") following Executive's separation from service; provided that the Disability Base Salary Payments shall be reduced by any insurance or other payments to Executive under policies and plans sponsored by the Company, even if premiums are paid by Executive. Subject to the provisions of Section 6.11, the Disability Base Salary Payments shall be paid in accordance with the Company's standard payroll practices; provided, however, that any amounts that would otherwise be scheduled to be paid prior to the Release Effective Date shall instead accrue and be paid during the first payroll period following the Release Effective Date, and all other payments shall be made as originally scheduled.

**(c)** **Bonus.** The Company shall pay a lump sum amount equal to Executive's Target Annual Bonus (as defined in Section 3.2) for the Company's then-current fiscal year multiplied by a fraction, the numerator of which is the number of full months of employment by Executive in the current fiscal year and the denominator of which is 12. Such payment shall be made within ten (10) days following the Release Effective Date.

**(d)** **Stock Awards.** The vesting of all outstanding Stock Awards held by Executive shall be accelerated so that the amount of shares vested under such Stock Awards shall equal that number of shares which would have been vested if Executive had continued to render services to the Company for 12 continuous months after the date of Executive's termination of employment.

**(e)** **Health Insurance Benefits.** To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, Executive will be eligible to continue Executive's group health insurance benefits at Executive's own expense. If Executive timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums, and any applicable Company COBRA premiums, necessary to continue Executive's then-current coverage for a period of 12 months after the date of Executive's termination of employment; *provided, however,* that any such payments will cease if Executive voluntarily enrolls in a health insurance plan offered by another employer or entity during the period in which the Company is paying such premiums. Executive agrees to immediately notify the Company in writing of any such enrollment.

Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot provide the foregoing benefit without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof provide to Executive a taxable monthly amount to continue his group health insurance coverage in effect on the date of separation from service (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which Executive incurs a separation from service and shall end on the earlier of (x) the date on which Executive voluntarily enrolls in a health insurance plan offered by another employer or entity during the period in which the Company is paying such amounts and (y) 12 months after the date of Executive's separation from service.

**(f)** **Disability Plans.** Nothing in this Section 6.3 shall affect Executive's rights under any disability plan in which Executive is a participant.

**6.4** **Termination by the Company for Cause.**

**(a)** **No Liability.** The Company may terminate Executive's employment and this Agreement for Cause (as defined below) without liability at any time. In such event, the Company shall pay Executive all Accrued Compensation (as defined in Section 6.2(c) herein), but no other compensation or reimbursement of any kind, including without limitation, any severance compensation or benefits shall be paid, and thereafter the Company's obligations hereunder shall terminate.

**(b)** **Definition of "Cause."** For purposes of this Agreement, "Cause" shall mean one or more of the following:

**(i)** Executive's intentional commission of an act, or intentional failure to act, that materially injures the business of the Company; *provided, however,* that in no event shall any business judgment made in good faith by Executive and within Executive's defined scope of authority constitute a basis for termination for Cause under this Agreement;

**(ii)** Executive's intentional refusal or intentional failure to act in accordance with any lawful and proper direction or order of the Board of Directors, the Chief Executive Officer, or the individual to whom Executive reports.

**(iii)** Executive's material breach of Executive's fiduciary, statutory, contractual, or common law duties to the Company (including any material breach of this Agreement, the Proprietary Information and Inventions Agreement, or the Company's written policies);

**(iv)** Executive's indictment for or conviction of any felony or any crime involving dishonesty; or

**(v)** Executive's participation in any fraud or other act of willful misconduct against the Company;

*provided, however,* that in the event that any of the foregoing events is reasonably capable of being cured, the Company shall provide written notice to Executive describing the nature of such event and Executive shall thereafter have ten (10) business days to cure such event.

**6.5 Termination by the Company without Cause.**

**(a) The Company's Right.** The Company may terminate Executive's employment and this Agreement without Cause (as defined in Section 6.4(b) herein) at any time by giving thirty (30) days advance written notice to Executive.

**(b) Severance Benefits.** If the Company terminates Executive's employment without Cause, and if Executive signs the Release on or within the time period set forth therein (but in no event later than forty-five (45) days after the termination date) and allows such Release to become effective (the "Release Effective Date"), then:

**(i) Accrued Compensation.** The Company shall pay to Executive all Accrued Compensation (as defined in Section 6.2(c) herein).

**(ii) Cash Compensation Amount Payments.** The Company shall pay Executive an amount calculated as follows: [Executive's annual Base Salary + Executive's Target Annual Bonus (as defined in Section 3.2 herein)] multiplied by 1.0 (the "Cash Compensation Amount"). Subject to the provisions of Section 6.11, the Cash Compensation Amount will be paid in equal installments on the Company's standard payroll dates over a period of 12 months following Executive's separation from service; provided, however, that any amounts that would otherwise be scheduled to be paid prior to the Release Effective Date shall instead accrue and be paid during the first payroll period following the Release Effective Date, and all other payments shall be made as originally scheduled.

**(iii) Stock Awards.** The vesting of all outstanding Stock Awards held by Executive shall be accelerated so that the amount of shares vested under such Stock Awards shall equal that number of shares which would have been vested if Executive had continued to render services to the Company for 12 continuous months after the date of Executive's termination of employment.

**(iv) Health Insurance Benefits.** To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, Executive will be eligible to continue Executive's group health insurance benefits at Executive's own expense. If Executive timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums, and any applicable Company COBRA premiums, necessary to continue Executive's then-current coverage for a period of 12 months after the date of Executive's termination of employment; *provided, however,* that any such payments will cease if Executive voluntarily enrolls in a health insurance plan offered by another employer or entity during the period in which the Company is paying such premiums. Executive agrees to immediately notify the Company in writing of any such enrollment.

Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot provide the foregoing benefit without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof provide to Executive a taxable monthly amount to continue his group health insurance coverage in effect on the date of separation from service (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which Executive incurs a separation from service and shall end on the earlier of (x) the date on which Executive voluntarily enrolls in a health insurance plan offered by another employer or entity during the period in which the Company is paying such amounts and (y) 12 months after the date of Executive's separation from service.

**6.6 Termination by Executive due to a Constructive Termination.**

**(a) Executive's Right.** Executive may resign his employment and terminate this Agreement at any time as a result of a Constructive Termination (as defined in Section 6.6(c) herein).

**(b) Severance Benefits.** If Executive resigns his employment and terminates this Agreement as a result of a Constructive Termination, and if Executive signs the Release on or within the time period set forth therein (but in no event later than forty-five (45) days after the termination date) and allows such Release to become effective, then Executive shall receive all of the severance benefits set forth in Section 6.5(b) herein.

**(c)** **Definition of "Constructive Termination."** For purposes of this Agreement, "Constructive Termination" shall mean a resignation of employment and termination of this Agreement by Executive for one or more of the following reasons:

**(i)** Assignment to, or withdrawal from, Executive of any duties or responsibilities that results in a material diminution in such Executive's authority, duties or responsibilities as in effect immediately prior to such change;

**(ii)** A material diminution in the authority, duties or responsibilities of the supervisor to whom Executive is required to report,

**(iii)** A material reduction by the Company of Executive's annual Base Salary;

**(iv)** A relocation of Executive or the Company's principal executive offices if Executive's principal office is at such offices, to a location more than forty (40) miles from the location at which Executive is then performing his duties, except for an opportunity to relocate which is accepted by Executive in writing; or

**(v)** A material breach by the Company of any provision of this Agreement or any other enforceable written agreement between Executive and the Company;

*provided however,* that Executive must first provide the Company with written notice specifying the condition giving rise to a Constructive Termination within ninety (90) days following the initial existence of such condition; and Executive's notice must specify that Executive intends to terminate his employment no earlier than thirty (30) days after providing such notice, and the Company must be given an opportunity to cure such condition within thirty (30) days following its receipt of such notice and avoid paying benefits.

**6.7** **Voluntary Resignation,** Executive may resign his or her employment and terminate this Agreement at any time for any reason other than due to a Constructive Termination (as defined in Section 6.6(c) herein). In such event, the Company shall pay Executive all Accrued Compensation (as defined in Section 6.2(c) herein), but no other compensation or reimbursement of any kind, including without limitation, any severance compensation or benefits shall be paid, and thereafter the Company's obligations hereunder shall terminate.

**6.8** **Change In Control.**

**(a)** **Severance Benefits.** If (i) within six months after the consummation of a Change in Control (as defined in Section 6.8(b) herein), (1) the Company terminates Executive's employment and this Agreement without Cause pursuant to Section 6.5 herein or (2) Executive resigns his employment and terminates this Agreement as a result of a Constructive Termination pursuant to Section 6.6 herein, and (ii) in either event (1) or (2), Executive signs the Release on or within the time period set forth therein, but in no event later than forty-five (45) days after the termination date and allows such Release to become effective (the "Release Effective Date"), then Executive shall receive the following severance benefits in lieu of any severance benefits set forth in Section 6.5(b) or Section 6.6(b) herein:

**(i)** **Accrued Compensation.** The Company shall pay to Executive all Accrued Compensation (as defined in Section 6.2(c) herein).

**(ii)** **CIC Cash Compensation Amount Payment.** The Company shall pay Executive an amount calculated as follows: [Executive's annual Base Salary + Executive's Target Annual Bonus (as defined in Section 3.2 herein)] multiplied by 1.5 (collectively, the "CIC Cash Compensation Amount"). The CIC Cash Compensation Amount will be paid in one lump sum within ten (10) days following the Release Effective Date.

**(iii)** **Cash Payment for Stock Awards.** Within ten (10) days following the Release Effective Date, the Company shall pay Executive a cash amount equal to the value, as of the date of the consummation of the Change in Control, of (1) all Stock Awards that are unvested at the time of termination of employment, and (2) all Stock Awards that are vested at the time of termination of employment and for which the shares subject to such Stock Awards have not yet been issued, including, without limitation, any unexercised stock options, unexercised stock appreciation rights, and unissued shares subject to a restricted stock unit award,

provided, in either case, that such Stock Awards were held by Executive as of the date of consummation of the Change in Control, and all rights of Executive in such Stock Awards and any unvested shares of stock that previously may have been issued thereunder shall be extinguished as a result of such payment, with the result that such Stock Awards shall automatically terminate unexercised and unvested shares of stock previously issued shall automatically be reacquired by the Company or its successor. For purposes of the foregoing cash payment, (1) stock options and stock appreciation rights shall be valued on the basis of the difference between the value of the subject stock for purposes of the transaction constituting the Change of Control and the exercise or base price of the award, and (2) restricted stock, restricted stock units or other full value awards and shares of stock acquired under Stock Awards shall be valued on the basis of the value of the subject stock for purposes of the transaction constituting the Change in Control.

**(iv)** **Health Insurance Benefits.** To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, Executive will be eligible to continue Executive's group health insurance benefits at Executive's own expense. If Executive timely elects continued coverage under COBRA, the Company shall pay Executive's COBRA premiums, and any applicable Company COBRA premiums, necessary to continue Executive's then-current coverage for a period of 18 months after the date of Executive's termination of employment; *provided, however,* that any such payments will cease if Executive voluntarily enrolls in a health insurance plan offered by another employer or entity during the period in which the Company is paying such premiums. Executive agrees to immediately notify the Company in writing of any suchenrollment.

Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot provide the foregoing benefit without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof provide to Executive a taxable monthly amount to continue his group health insurance coverage in effect on the date of separation from service (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall be made regardless of whether Executive elects COBRA continuation coverage and shall commence in the month following the month in which Executive incurs a separation from service and shall end on the earlier of (x) the date on which Executive voluntarily enrolls in a health insurance plan offered by another employer or entity during the period in which the Company is paying such amounts and (y) 18 months after the date of Executive's separation from service.

**(b)** **Definition of "Change in Control."** For purposes of this Agreement, a "Change in Control" shall have occurred if at any time during Executive's employment hereunder, any of the following events shall occur:

**(i)** The Company is merged, or consolidated. or reorganized into or with another corporation or other legal person, and as a result of such merger, consolidation or reorganization less than 50% of the combined voting power of the then-outstanding securities of such corporation or person immediately after such transaction are held in the aggregate by the holders of voting securities of the Company immediately prior to such transaction;

**(ii)** The Company sells all or substantially all of its assets or any other corporation or other legal person and thereafter, less than 50% of thecombined voting power of the then-outstanding voting securities of the acquiring or consolidated entity are held in the aggregate by the holders of voting securities of the Company immediately prior to such sale;

**(iii)** There is a report filed after the date of this Agreement on Schedule 13 D or schedule 14 D-1 (or any successor schedule, form or report), each as promulgated pursuant to the Securities Exchange Act of 1934 (the "Exchange Act") disclosing that any person (as the term "person" is used in Section 13(d)(3) or Section 14(d)(2) of the Exchange Act) has become the beneficial owner (as the term beneficial owner is defined under Rule 13d-3 or any successor rule or regulation promulgated under the Exchange Act) representing 50% or more of the combined voting power of the then-outstanding voting securities of the Company;

**(iv)** The Company shall file a report or proxy statement with the Securities and Exchange Commission pursuant to the Exchange Act disclosing in response to item 1 of Form 8-X thereunder or Item 5(f) of Schedule 14 A thereunder (or any successor schedule, form or report or item therein) that the change in control of the Company has or may have occurred or will or may occur in the future pursuant to any then-existing contract or transaction; or

**(v)** During any period of two (2) consecutive years, individuals who at the beginning of any such period constitute the directors of the Company cease for any reason to constitute at least a majority thereof unless the election to the nomination for election by the Company's shareholders of each director of the Company first elected during such period was approved by a vote of at least two-thirds of the directors of the Company then still in office who were directors of the Company at the beginning of such period.

**(c) Parachute Payments.**

**(i)** If any payment or benefit (including payments or benefits pursuant to this Agreement) that Executive would receive in connection with a Change in Control or otherwise ("Payment") would (1) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"), and (2) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, Executive shall have no rights to any additional payments and/or benefits, and reduction shall occur in the manner that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

**(ii)** In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, Executive will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

**(iii)** The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the event described in Section 280G(b)(2)(A)(i) of the Code will perform the foregoing calculations. If the independent registered public accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting such Change in Control or similar transaction, the Company will appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company will bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder. Any good faith determinations of the independent registered public accounting firm made hereunder will be final, binding and conclusive upon the Company and you.

**6.9 Mitigation.** Except as otherwise specifically provided herein, Executive shall not be required to mitigate the amount of any payment provided under this Agreement by seeking other employment or self-employment, nor shall the amount of any payment provided for under this Agreement be reduced by any compensation earned by Executive as a result of employment by another employer or through self-employment or by retirement benefits after the date of Executive's termination of employment from the Company, except as provided herein.

**6.10 Coordination.** If upon termination of employment, Executive becomes entitled to rights under other plans, contracts or arrangements entered into by the Company, this Agreement shall be coordinated with such other arrangements so that Executive's rights under this Agreement are not reduced, and that any payments under this Agreement offset the same types of payments otherwise provided under such other arrangements, but do not otherwise reduce any payments or benefits under such other arrangements to which Executive becomes entitled.

**6.11** **Application of Section 409A.** Notwithstanding anything to the contrary herein, the following provisions apply to the extent severance benefits provided herein are subject to Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "Section 409A"). Severance benefits shall not commence until Executive has a "separation from service" for purposes of Section 409A. If Executive is a "specified employee" within the meaning of 409A(a)(2)(B)(i) of the Code, any installment payments of Disability Base Salary Payments pursuant to Section 6.3(b) or Cash Compensation Amounts pursuant to Section 6.5(b) or 6.6(b) that are triggered by a separation from service shall be accelerated to the minimum extent necessary so that (a) the lesser of (y) the total cash severance payment amount, or (z) six (6) months of such installment payments are paid no later than March 15 of the calendar year following such termination, and (b) all amounts paid pursuant to the foregoing clause (a) will constitute separate payments for purposes of Section l.409A- 2(b)(2) of the Treasury Regulations and thus will be payable pursuant to the "short-term deferral" rule set forth in Section l.409A-l(b)(4) of the Treasury Regulations. It is intended that if Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code at the time of such separation from service the foregoing provision shall result in compliance with the requirements of Section 409A(a)(2)(B)(i) of the Code because payments to Executive will either be payable pursuant to the "short-term deferral" rule set forth in Section l.409A l(b)(4) of the Treasury Regulations or will not be paid until at least 6 months after separation from service. The severance benefits are intended to qualify for an exemption from application of Section 409A or comply with its requirements to the extent necessary to avoid adverse personal tax consequences under Section 409A, and any ambiguities herein shall be interpreted accordingly.

## ARTICLE 7

## GENERAL PROVISIONS

**7.1** **Governing Law.** The validity, interpretation, construction and performance of this Agreement and the rights of the parties thereunder shall be interpreted and enforced under California law without reference to principles of conflicts of laws. The parties expressly agree that inasmuch as the Company's headquarters and principal place of business are located in California, it is appropriate that California law govern this Agreement.

**7.2** **Assignment; Successors Binding Agreement.**

**(a)** **No Assignment.** Executive may not assign, pledge or encumber his interest in this Agreement or any part thereof.

**(b)** **Assumption by Successor.** The Company will require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company, by operation of law or by agreement in form and substance reasonably satisfactory to Executive, to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place.

**(c)** This Agreement shall inure to the benefit of and be enforceable by Executive's personal or legal representatives, executors, administrators, successors, heirs, distributee, devisees and legatees. If Executive should die while any amount is at such time payable to Executive hereunder, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Agreement to Executive's devisee, legates or other designee or, if there be no such designee, to his estate.

**7.3** **Notice.** For the purposes of this Agreement, notices and all other communications provided for in this Agreement shall be in writing and shall be deemed to have been duly given when delivered or mailed by certified or registered mail, return receipt requested, postage prepaid, addressed to the respective addresses set forth below or to such other address as either party may have furnished to the other in writing in accordance herewith, except that notice of change of address shall be effective only upon receipt.

To the Company:

Neurocrine Biosciences, Inc.
12780 El Camino Real
San Diego, CA 92130
Attn.: President & Chief Executive Officer

To Executive:

_____
_____
_____
_____

**7.4** **Modification; Waiver; Entire Agreement.** This Agreement constitutes the complete, final and exclusive embodiment of the entire agreement between Executive and the Company with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations, including, without limitation, the Prior Employment Agreement which shall have no further force or effect. No provisions of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing signed by Executive and such officer as may be specifically designated by the Board of Directors of the Company. No waiver by either party hereto at any time of any breach by the other party of, or compliance with, any condition or provision of this Agreement to be performed by such other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or any prior or subsequent time.

**7.5** **Validity.** The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

**7.6** **Controlling Document.** Except to the extent described in Section 6.10, in case of conflict between any of the terms and condition of this Agreement and any document herein referred to, the terms and conditions of this Agreement shall control.

**7.7** **Executive Acknowledgment.** Executive acknowledges (a) that he has consulted with or has had the opportunity to consult with independent counsel of his own choice concerning this Agreement, and has been advised to do so by the Company, and (b) that he has read and understands the Agreement, is fully aware of its legal effect, and has entered into it freely based on his own judgment.

**7.8** **Dispute Resolution.** To ensure the rapid and economical resolution of disputes that may arise in connection with Executive's employment, Executive and the Company agree that any and all disputes, claims, or causes of action, in law or equity, arising from or relating to the enforcement, breach, performance, execution, or interpretation of this Agreement, Executive's employment, or the termination of that employment, shall be resolved, to the fullest extent permitted by law pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, by final, binding and confidential arbitration in San Diego, California conducted before a single arbitrator by Judicial Arbitration and Mediation Services, Inc. ("JAMS") or its successor, under the then applicable JAMS rules; *provided, however,* that in no event shall the Arbitrator be empowered to hear or determine any class or collective claim of any type. The JAMS rules can be found online at wwwjamsadr.com. By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or by administrative proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. The Company shall pay all of JAMS' arbitration fees. Nothing in this letter agreement shall prevent either Executive or the Company from obtaining injunctive relief in court if necessary to prevent irreparable harm pending the conclusion of any arbitration. The parties agree that the arbitrator shall award reasonable attorneys' fees, costs, and all other related expenses to the prevailing party in any action brought hereunder, and the arbitrator shall have discretion to determine the prevailing party in an arbitration where multiple claims may be at issue.

**7.9** **Remedies.**

**(a)** **Injunctive Relief.** The parties agree that the services to be rendered by Executive hereunder are of a unique nature and that in the event of any breach or threatened breach of any of the covenants contained herein, the damage or imminent damage to the value and the goodwill of the Company's business will be irreparable and extremely difficult to estimate, making any remedy at law or in damages inadequate. Accordingly, the parties agree that the Company shall be entitled to injunctive relief against Executive in the event of any breach or threatened breach of any such provisions by Executive, in addition to any other relief (including damage) available to the Company under this Agreement or under law.

**(b)** **Exclusive.** Both parties agree that the remedy specified in Section 7.9(a) above is not exclusive of any other remedy for the breach by Executive of the terms hereof.

**7.10** **Counterparts.** This Agreement may be executed in one or more counterparts, all of which taken together shall constitute one and the same Agreement.

Executed by the parties as follows:

| | |
|---|---|
| **EXECUTIVE** | **NEUROCRINE BIOSCIENCES, INC** |
| **By:** /s/ Kyle W. Gano | **By:** /s/ Kevin Gorman |
| **Date:** 11/12/14 | **Date:** 11/10/14 |

**EXHIBIT A**
**GENERAL RELEASE**

Pursuant to the terms of the Employment Agreement between Neurocrine Biosciences, Inc. (the "Company") and --- ("Executive") dated --- (the "Agreement"), the parties hereby enter into the following General Release (the "Release"):

**1.** **Accrued Salary and Vacation.** Executive understands that, on the last date of Executive's employment with the Company, the Company will pay Executive any accrued salary and accrued and unused vacation to which Executive is entitled by law, regardless of whether Executive signs this Release.

**2.** **General Release.** Executive hereby generally and completely releases the Company and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively the "Released Parties") of and from any and all claims, liabilities and obligations, both known and unknown, arising out of or in any way related to events, acts, conduct, or omissions occurring at any time prior to or at the time that Executive signs this Release.

**3.** **Scope of Release.** This general release includes, but is not limited to: (1) all claims arising out of or in any way related to Executive's employment with the Company or the termination of that employment; (2) all claims related to Executive's compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership or equity interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing (including claims based on or arising under the Agreement); (4) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act (as amended) ("ADEA"), the federal Family and Medical Leave Act, the California Labor Code (as amended), the California Family Rights Act, and the California Fair Employment and Housing Act (as amended).

**4.** **ADEA Waiver.** Executive acknowledges that Executive is knowingly and voluntarily waiving and releasing any rights Executive may have under the ADEA, and that the consideration given for the waiver and release in the preceding paragraph is in addition to anything of value to which Executive is already entitled. Executive further acknowledges that Executive has been advised by this writing that: (1) Executive's waiver and release do not apply to any rights or claims that may arise after the date Executive signs this Release; (2) Executive should consult with an attorney prior to signing this Release (although Executive may choose voluntarily not to do so); (3) Executive has twenty-one (21) days to consider this Release (although Executive may choose voluntarily to sign it earlier); (4) Executive has seven (7) days following the date Executive signs this Release to revoke it by providing written notice of revocation to the Company's Chief Executive Officer; and (5) this Release will not be effective until the date upon which the revocation period has expired, which will be the eighth calendar day after the date Executive signs it provided that Executive does not revoke it (the "Effective Date").

**5.** **Section 1542 Waiver.** EXECUTIVE UNDERSTANDS THAT THIS AGREEMENT INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS. Executive acknowledges that Executive has read and understands Section 1542 of the California Civil Code which reads as follows: "A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor." Executive hereby expressly waives and relinquishes all rights and benefits under that section and any law or legal principle of similar effect in any jurisdiction with respect to Executive's respective release of claims herein, including but not limited to Executive's release of unknown and unsuspected claims.

**6.** **Excluded Claims.** Executive understands that notwithstanding the foregoing, the following are not included in the Released Claims (the "Excluded Claims"): (i) any rights or claims for indemnification Executive may have pursuant to any written indemnification agreement to which he is a party, the charter, bylaws, or operating agreements of any of the Released Parties, or under applicable law; or (ii) any rights which are not waivable as a matter of law. In addition, Executive understands that nothing in this release prevents Executive from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, or the California Department of Fair Employment and Housing, except that Executive acknowledges and agrees that Executive shall not recover any monetary benefits in connection with any such claim, charge or proceeding with regard to any claim released herein. Executive hereby represents and warrants that, other than the Excluded Claims, Executive is not aware of any claims he has or might have against any of the Released Parties that are not included in the Released Claims.

**7.** **Executive Representations.** Executive hereby represents that Executive has been paid all compensation owed and for all hours worked; Executive has received all the leave and leave benefits and protections for which Executive is eligible, pursuant to the Family and Medical Leave Act, the California Family Rights Act, or otherwise; and Executive has not suffered any on-the-job injury for which Executive has not already filed a workers' compensation claim.

**8.** **Nondisparagement.** Executive agrees not to disparage the Company, its parent, or its or their officers, directors, employees, shareholders, affiliates and agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation (although Executive may respond accurately and fully to any question, inquiry or request for information as required by legal process).

**9.** **Cooperation.** Executive agrees not to voluntarily (except in response to legal compulsion) assist any third party in bringing or pursuing any proposed or pending litigation, arbitration, administrative claim or other formal proceeding against the other party, or against the Company's parent or subsidiary entities, affiliates, officers, directors, employees or agents. Executive further agrees to reasonably cooperate with the other party, by voluntarily (without legal compulsion) providing accurate and complete information, in connection with such other party's actual or contemplated defense, prosecution, or investigation of any claims or demands by or against third parties, or other matters, arising from events, acts, or failures to act that occurred during the period of Executive's employment by the Company.

**10.** **No Admission of Liability.** The parties agree that this Release, and performance of the acts required by it, does not constitute an admission of liability, culpability, negligence or wrongdoing on the part of anyone, and will not be construed for any purpose as an admission of liability, culpability, negligence or wrongdoing by any party and/or by any party's current, former or future parents, subsidiaries, related entities, predecessors, successors, officers, directors, shareholders, agents, employees and assigns. The parties specifically acknowledge and agree that this Release is a compromise of disputed claims and that the Company denies any liability for any matter released herein.

| **NEUROCRINE BIOSCIENCES, INC.:** | **EXECUTIVE:** |
|---|---|
| **By:** _____ | **By:** _____ |
| **Date:** _____ | **Date:** _____ |

**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. 333-175889, 333-190178, 333-197916, and 333-212871) pertaining to the 2011 Equity Incentive Plan of Neurocrine Biosciences, Inc.,

(3) Registration Statements (Form S-8 Nos. 333-199837, and 333-216067) pertaining to the Inducement Plan of Neurocrine Biosciences, Inc.,

(4) Registration Statements (Form S-8 Nos. 333-205933 and 333-223020) pertaining to the 2011 Equity Incentive Plan and Inducement Plan of Neurocrine Biosciences, Inc.,

(5) Registration Statements (Form S-8 No. 333-226971) pertaining to the 2011 Equity Incentive Plan and 2018 Employee Stock Purchase Plan of Neurocrine Biosciences, Inc., and

(6) Registration Statements (Form S-8 No. 333-234501) pertaining to the 2011 Equity Incentive Plan

of our reports dated February 6, 2020 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, 2019.

/s/ Ernst & Young LLP

San Diego, California
February 6, 2020

**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 6, 2020

/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 6, 2020

/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, 2019 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 6, 2020

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, 2019 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 6, 2020

By: /s/ *Matthew C. Abernethy*
Name: Matthew C. Abernethy
Title: Chief Financial Officer