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, 2020

☐ 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☑ No ☐

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, 2020, was approximately $11,231,617,436.

As of January 29, 2021, 93,943,645 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, 2020 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 I 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 neuroscience-focused, biopharmaceutical company dedicated to discovering, developing and delivering life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. Our diverse portfolio includes United States Food and Drug Administration, or FDA, approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis* , uterine fibroids* and clinical programs in multiple therapeutic areas. For nearly three decades, we have specialized in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. *(*in collaboration with AbbVie Inc.)*

Product Pipeline

Exclusive and Partnered Commercial Products

The following table summarizes our exclusive and partnered commercial products and is followed by detailed descriptions of each product:

* Mitsubishi Tanabe Pharma has commercialization rights in East Asia. ‡ Under License from BIAL.

† AbbVie has global commercialization rights.

INGREZZA (valbenazine)

We launched INGREZZA in the U.S. in May 2017, after receiving FDA approval for INGREZZA as the first FDA-approved drug for the treatment of tardive dyskinesia in April 2017. INGREZZA provides a once-daily dosing treatment option for tardive dyskinesia and has two dosing options (40 mg and 80 mg capsules), with 40 mg taken for the first seven days of treatment and an option to take 40 mg or 80 mg thereafter, depending on the patient's dosing needs.

In February 2021, Mitsubishi Tanabe Pharmaceutical Company, or MTPC, reported positive top-line results from the J-KINECT Phase III study, designed to evaluate the efficacy and safety of valbenazine in tardive dyskinesia. Detailed results from this trial will be presented at a future medical conference. With positive data in hand, a marketing authorization with the Ministry of Health and Welfare is planned for 2021 in Japan. In addition, MTPC submitted filings for marketing authorizations in South Korea, Thailand, Singapore, Indonesia, and Malaysia in 2020.

Tardive dyskinesia is defined by hyperkinetic involuntary movements which arise after months or years of treatment with dopamine receptor blocking agents, such as antipsychotics used for treating schizophrenia, bipolar disorder and depression, and certain treatments for nausea, vomiting and gastric emptying in patients with gastroparesis. While the prevalence rates of tardive dyskinesia can vary greatly in accordance with the population being studied, it is estimated that over 500 thousand individuals are affected by tardive dyskinesia in the U.S. alone (Kantar Health).

INGREZZA net product sales totaled $993.1 million, $752.9 million and $409.6 million for 2020, 2019 and 2018, respectively, and represented the significant majority of our total net product sales for 2020 and all of our net product sales for 2019 and 2018.

ONGENTYS (opicapone)

We launched ONGENTYS in the U.S. in September 2020, after receiving FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients in April 2020. We acquired the U.S. and Canada rights to ONGENTYS from BIAL – Portela & Ca, S.A., or BIAL, in the first quarter of 2017.

ONGENTYS is a novel, once-daily, peripherally acting, highly selective Catechol-O-methyltransferase, or COMT, inhibitor utilized as an adjunct therapy to levodopa/carbidopa in patients with Parkinson’s disease experiencing motor fluctuations. COMT inhibitors are utilized to prolong the duration of effect of levodopa, the primary treatment option for Parkinson’s disease patients, during periods of the day where the effects of levodopa wear off and motor symptoms worsen, also referred to as “off-time.” Parkinson’s disease is a chronic and progressive movement disorder that affects approximately 1 million individuals in the U.S. alone.

ORILISSA (elagolix)

AbbVie Inc., or AbbVie, launched ORILISSA in the U.S. and Canada in August and November 2018, respectively, after receiving FDA and Health Canada approval for ORILISSA for the management of moderate to severe endometriosis pain in women in July and October 2018, respectively. Discovered and developed through Phase II clinical studies by us, we out-licensed the global rights to elagolix to AbbVie in 2010.

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.

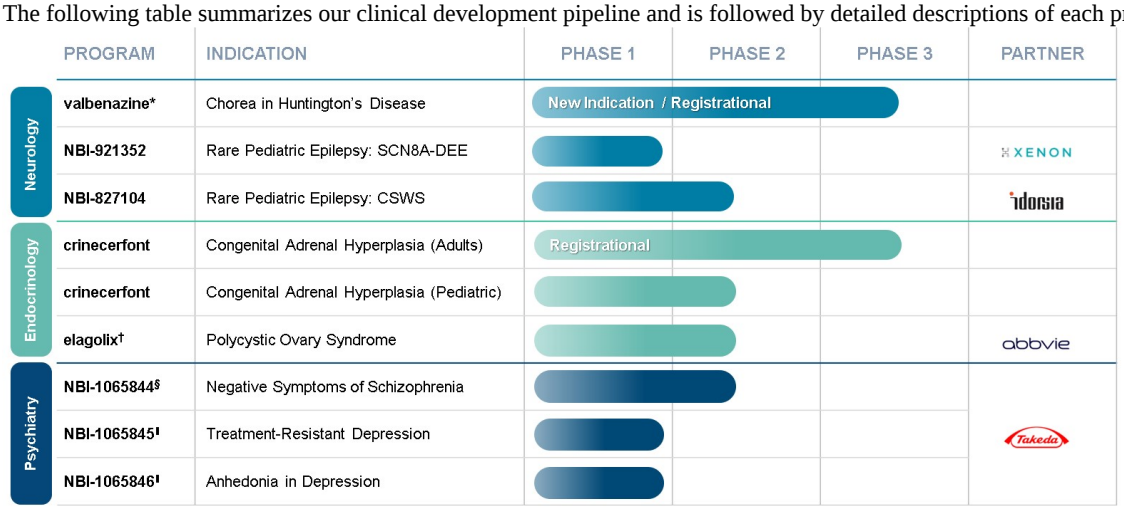
ORIAHNN (elagolix, estradiol, and norethindrone acetate; elagolix)

AbbVie launched ORIAHNN in the U.S. in June 2020, after receiving FDA approval for ORIAHNN as the first FDA-approved non-surgical, oral medication option for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women in May 2020. We out-licensed the global rights to elagolix to AbbVie in 2010.

Uterine fibroids are benign hormonally responsive tumors that form in the wall of the uterus with a prevalence rate of at least 25% (American College of Obstetricians and Gynecologists) and are 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).

Clinical Development Pipeline

The following table summarizes our clinical development pipeline and is followed by detailed descriptions of each program:



SCN8A-DEE = SCN8A Developmental and Epileptic Encephalopathy
CSWS = Epileptic Encephalopathy with Continuous Spike and Wave During Sleep
Neurocrine Biosciences has global rights unless otherwise noted.
* Mitsubishi Tanabe Pharma has commercialization rights in East Asia. † AbbVie has global commercialization rights. § Takeda has co-commercialization option following the ongoing Phase II. ‖ Takeda has co-commercialization rights with option to opt out following certain development milestones.

Neurology

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 tardive dyskinesia, 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.

We are currently conducting the KINECT-HD study, a Phase III, randomized, placebo-controlled, double-blind, multi-center Phase III clinical study to evaluate the efficacy, safety and tolerability of valbenazine for the treatment of chorea in 120 patients with Huntington's disease, or HD, with Phase III top-line data expected in the fourth quarter of 2021.

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).

NBI-921352 (XEN901) – 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.

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.

In October 2020, the FDA requested additional non-clinical data to support the IND we submitted in August 2020 in support of a Phase II clinical study for NBI-921352 in patients with SCN8A-DEE. Based on feedback received in January 2021, we plan to initiate a Phase II clinical study in adolescent patients (aged 12 years and older) with SCN8A-DEE in the third quarter of 2021, and the study protocol will be amended to include younger pediatric patients (aged 2-11 years) with SCN8A-DEE as soon as the FDA has reviewed and approved additional non-clinical information. We are also advancing clinical plans to initiate a Phase II clinical study of NBI-921352 for the treatment of adult focal epilepsy in 2021. In addition, in October 2020, we announced the FDA granted us Rare Pediatric Disease Designation for NBI-921352 for the treatment of SCN8A-DEE.

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.

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

NBI-827104 (ACT-709478) – T-type Calcium Channel Blocker

We acquired the global rights to NBI-827104 from Idorsia Pharmaceuticals Ltd., or Idorsia, in May 2020. NBI-827104 is a potent, selective, orally active and brain penetrating T-type calcium channel blocker, being developed for the treatment of a rare pediatric epilepsy and other potential indications, including essential tremor.

In November 2020, we initiated a Phase II clinical study for NBI-827104 in a rare pediatric epileptic encephalopathy known as Continuous Spike and Wave During Sleep, or CSWS. CSWS typically impacts children initially between the ages of two and four years old and manifests itself via a variety of seizure types, including atypical absence seizures, generalized tonic-clonic seizures and focal seizures that usually occur during sleep. In addition, children with CSWS often present with cognitive, behavioral and developmental regression or delay. Due to the differentiated mechanism of action of this molecule, when compared to non-selective calcium channel inhibitors, treatment with NBI-827104 could lead to an enhanced benefit risk profile for patients with this rare pediatric form of epilepsy. In parallel we are advancing clinical plans to initiate a Proof of Concept clinical study of NBI-827104 for the treatment of essential tremor in 2021.

Endocrinology

crinecerfont (NBI-74788) – CRF1 Antagonist

Crinecerfont is a potent, selective, orally active, corticotropin-releasing factor1, or CRF1, receptor antagonist as demonstrated in a range of in vitro and in vivo assays. CRF1, is a hypothalamic hormone released directly into the hypophyseal portal vasculature which acts on the CRF1 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 CRF1 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 CRF1 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.

Classic CAH is a group of autosomal recessive genetic disorders that affects approximately 30 thousand people in the U.S. and approximately 50 thousand people in the EU, 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. We have been granted orphan drug designation for crinecerfont in the treatment of classic CAH in the U.S. and the EU.

In June 2020, positive data from a completed Phase II, open-label, pharmacokinetic/pharmacodynamic clinical study of crinecerfont in adult patients with classic CAH, which assessed 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, demonstrated meaningful reductions in elevated ACTH and 17-hydroxyprogesterone (17-OHP) levels (by 54% to 75%) at all doses studied, together with a dose-related decrease in androstenedione (A4) levels, ranging from 21% to 64%. At the highest dose of crinecerfont (100 mg twice daily), 75% of patients showed a response of at least 50% reduction from baseline for each of the three hormone markers at day 14. Treatment with crinecerfont was well tolerated with a favorable safety profile with no related serious adverse events reported. Adverse events reported in two or more participants included headache, upper respiratory tract infection, fatigue, contusion, insomnia and nausea.

In July 2020, we initiated the CAHtalyst study, a global registrational Phase III, randomized, double-blind, placebo-controlled clinical study to evaluate the safety and efficacy of crinecerfont in 165 adult patients with classic CAH, followed by an open-label treatment period.

In July 2019, we initiated a Phase IIa proof-of-concept, pharmacokinetic/pharmacodynamic clinical study to evaluate the safety and tolerability of crinecerfont in pediatric patients with classic CAH. We plan to initiate a single global registrational Phase III clinical study for crinecerfont in pediatric patients with CAH in 2021.

elagolix – GnRH Antagonist

The gonadotropin-releasing hormone, or 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 Polycystic Ovary Syndrome, or PCOS.

AbbVie initiated a Phase II clinical study of elagolix in patients with PCOS in mid-2019. The study is designed to evaluate whether there is a potential impact on disordered hormonal dynamics in women with PCOS. We out-licensed the global rights to elagolix to AbbVie in 2010.

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.

Psychiatry

We acquired the global rights to develop and commercialize NBI-1065844 (TAK-831), NBI-1065845 (TAK-653) and NBI-1065846 (TAK-041) from Takeda Pharmaceutical Company Limited, or Takeda, in June 2020.

NBI-1065844 (TAK-831) – DAAO Inhibitor

NBI-1065844 is a potential first-in-class D-Amino Acid Oxidase, or DAAO, inhibitor that has completed multiple Phase I clinical studies and is currently in on-going Phase II clinical studies, including the Phase II INTERACT proof-of-concept clinical study in negative symptoms of schizophrenia, with Phase II top-line data expected in the first quarter of 2021.

According to the World Health Organization, or WHO, 20 million people across the globe are affected by schizophrenia. In the U.S., the prevalence of schizophrenia is estimated to be approximately 0.6% of the population. The negative symptoms associated with schizophrenia describe a lessening or absence of behaviors and functions related to motivation and interest, or verbal and emotional expression. There are currently no approved treatment options in the U.S. for patients with predominant negative symptoms of schizophrenia.

NBI-1065844 is currently designated as a royalty-bearing product for Takeda. Takeda retains a one-time opt-in right for a 50:50 profit share arrangement upon achievement of a certain development event.

NBI-1065845 (TAK-653) – AMPA Potentiator

NBI-1065845 is a potential first-in-class Alpha-Amino-3-Hydroxy-5-Methyl-4-Isoxazole Propionic Acid, or AMPA, potentiator with the potential to be developed for treatment-resistant depression. NBI-1065845 has completed multiple Phase I clinical studies. We plan to initiate a Phase II clinical study of NBI-1065845 in treatment-resistant depression in 2021.

According to the WHO, major depressive disorder, or MDD, is one of the leading causes of disability. While there are a number of marketed treatments for MDD, approximately 1/3 of patients do not benefit from them. There is a significant need to develop new therapies with improved, faster onset of efficacy that are well tolerated.

NBI-1065845 is currently designated as a 50:50 profit share product with Takeda. Takeda retains a one-time opt-out right to convert the designation to a royalty-bearing product dependent on a certain development event.

NBI-1065846 (TAK-041) – G Protein-Coupled Receptor 139 Agonist

NBI-1065846 is a potential first-in-class G Protein-Coupled Receptor 139, or GPR139, agonist with the potential to be developed for the treatment of anhedonia in depression. NBI-1065846 has completed multiple Phase I clinical studies. We plan to initiate a Phase II clinical study of NBI-1065846 in anhedonia in 2021.

Anhedonia is a psychological condition characterized by the inability to experience pleasure. In patients with depression, anhedonia often does not improve with current treatments and predicts lack of functional improvement.

NBI-1065846 is currently designated as a 50:50 profit share product with Takeda. Takeda retains a one-time opt-out right to convert the designation to a royalty-bearing product dependent on a certain development event.

Research Programs

We invest in research and development in order to address 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).

Business Strategy

Our mission is to improve the lives of patients living with serious and under-addressed neurological, neuro-endocrinology and psychiatry 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 tardive dyskinesia. In April 2020, we received FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients. We market INGREZZA and ONGENTYS in the U.S. The commercial launch of INGREZZA occurred in May 2017 and ONGENTYS occurred in September 2020. 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, primarily psychiatrists and neurologists. 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 ongoing 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:

Takeda. In June 2020, we entered into an exclusive license agreement with Takeda, which became effective in July 2020, to develop and commercialize certain compounds in Takeda’s early to mid-stage psychiatry pipeline. Specifically, Takeda granted us an exclusive license to the following seven assets: (i) NBI-1065844 (TAK-831) for schizophrenia, (ii) NBI-1065845 (TAK-653) for treatment-resistant depression, (iii) NBI-1065846 (TAK-041) for anhedonia (which together with the NBI-1065845 are referred to as the Phase II Ready Assets), and (iv) four non-clinical stage assets, or the Non-Clinical Assets.

NBI-1065844 is deemed a royalty-bearing product under the license agreement pursuant to which we will be responsible for all costs and expenses associated with the development, manufacture, and commercialization of such asset, subject to certain exceptions, and Takeda will be eligible to receive development and commercial milestones and royalties with respect to such asset, or a Royalty-Bearing Product, and Takeda will retain the right to opt-in to a profit sharing arrangement pursuant to which we and Takeda will equally share in the operating profits and losses related to such asset, subject to certain exceptions, in lieu of receiving milestones and royalties, or a Profit-Share Product. Subject to specified conditions, Takeda may elect to exercise such opt-in right for NBI-1065844 before we initiate a Phase III clinical trial. Each of the Phase II Ready Assets is deemed a Profit-Share Product and Takeda will retain the right to opt-out of the profit-sharing arrangement for such asset pursuant to which such asset would become a Royalty-Bearing Product. Takeda may elect to exercise such opt-out rights with respect to a Phase II

Ready Asset immediately following the completion of the second Phase II clinical trial for such Phase II Ready Asset. In addition, under certain circumstances related to the development and commercialization activities to be performed by us, Takeda may elect to opt-out of the profit-sharing arrangement for a Profit-Share Product before the initiation of a Phase III clinical trial for such product.

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

Unless earlier terminated, the license agreement will continue on a licensed product-by-licensed product and country-by-country basis until the date on which, (i) for any Royalty-Bearing Product, the royalty term has expired in such country; and (ii) for any Profit-Share Product, for so long as we continue to develop, manufacture, or commercialize such licensed product. We may terminate the license agreement for convenience in its entirety or in one or more (but not all) of the United States, Japan, the European Union, and the United Kingdom, or the Major Markets, on 6 months' written notice to Takeda (i) with respect to all licensed products prior to the first commercial sale of the first licensed product for which first commercial sale occurs, or (ii) with respect to all licensed products in one or more given target classes, as defined in the agreement, prior to the first commercial sale of the first licensed product in such target class(es) for which first commercial sale occurs. We may terminate the license agreement for convenience in its entirety or in one or more (but not all) of the Major Markets on 12 months' written notice to Takeda (i) with respect to all licensed products following the first commercial sale of the first licensed product for which first commercial sale occurs, or (ii) with respect to all licensed products in one or more given target classes following the first commercial sale of the first licensed product in such target class(es) for which first commercial sale. Takeda may terminate the license agreement, subject to specified conditions, (i) if we challenge the validity or enforceability of certain Takeda intellectual property rights or (ii) on a target class-by-target class basis, in the event that we do not conduct any material development or commercialization activities with respect to any licensed product within such target class for a specified continuous period. Subject to a cure period, either party may terminate the license agreement in the event of any material breach, solely with respect to the target class of a licensed product to which such material breach relates, or in its entirety in the event of any material breach that relates to all licensed products.

Idorsia. We acquired the global rights to NBI-827104 from Idorsia in May 2020. NBI-827104 is a potent, selective, orally active and brain penetrating T-type calcium channel blocker, being developed for the treatment of a rare pediatric epilepsy and other potential indications, including essential tremor. The agreement also included a research collaboration to discover and identify additional novel T-type calcium channel blockers as development candidates. Under the terms of the agreement, we are responsible for all manufacturing, development and commercialization costs of any collaboration product. We may terminate the collaboration and licensing agreement, in its entirety or with respect to a particular compound or development candidate, by providing 90 days' written notice to Idorsia. Further, in the event a party commits a material breach and fails to cure such material breach within 90 days after receiving written notice thereof, the non-breaching party may terminate the agreement in its entirety immediately upon written notice to the breaching party.

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

We will be solely responsible, at our sole cost and expense, for all development and manufacturing of the compounds and any pharmaceutical product that contains a compound, subject to Xenon's right to elect to co-fund the development of one product in a major indication and thus receive a mid-single digit percentage increase in royalties owed on the net sales of such product in the 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.

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.

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.

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

BIAL. We acquired the U.S. and Canada rights to ONGENTYS from BIAL in the first quarter of 2017. We launched ONGENTYS in the U.S. in September 2020, after receiving FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients in April 2020.

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

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

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

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

MTPC. In March 2015, we entered into a collaboration and license agreement with 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.

AbbVie. In June 2010, we entered into an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation GnRH antagonists, or collectively the GnRH Compounds, for women's and men's health.

AbbVie received approval of ORILISSA for the management of moderate to severe endometriosis pain in women from the FDA in July 2018 and Health Canada in October 2018. In May 2020, AbbVie received approval from the FDA for ORIAHNN for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women.

Under the terms of the agreement, AbbVie is responsible for all third-party 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.

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 tardive dyskinesia, is covered by eight issued U.S. patents that are listed in the FDA's Orange Book and are set to expire between 2027 and 2037. There is also a potential patent term extension of up to an additional two years for U.S. Patent No. 8,039,627, which is currently set to expire in 2029 and is the earliest patent covering valbenazine, the active pharmaceutical ingredient contained in INGREZZA. In Japan and certain other East Asian markets, we are actively pursuing most of the patents corresponding to those listed in the FDA's Orange Book entry for INGREZZA.
- ONGENTYS, a highly selective COMT inhibitor for Parkinson's disease, is covered by nine issued U.S. patents that are listed in the FDA's Orange Book and set to expire between 2026 to 2035 (not including a potential patent term extension of up to an additional four years for one of these patents).
- ORILISSA, our small molecule GnRH antagonist for the treatment of endometriosis pain, is covered by eight issued U.S. patents that are listed in the FDA's Orange Book and are set to expire between 2021 to 2036 (not including a potential patent term extension of up to an additional five years for one of the patents currently set to expire either in 2021 or 2024).
- ORIAHNN, containing our small molecule GnRH antagonist for the treatment of menstrual bleeding associated with uterine fibroids, is covered by six issued U.S. patents that are listed in the FDA's Orange Book and are set to expire between 2021 to 2024 (not including a potential patent term extension of up to an additional five years for one of the patents).
- Valbenazine, our highly selective VMAT2 inhibitor under further clinical development for the treatment of chorea in Huntington's disease, is covered by at least six of the issued U.S. patents that are listed in the FDA's Orange Book entry for INGREZZA and are set to expire between 2027 and 2036 . There is also a potential patent term extension of up to an additional two years for U.S. Patent No. 8,039,627, which is currently set to expire in 2029.

- Crinecerfont, our CRF1 antagonist for the treatment of CAH, is covered by U.S. Patent No. 10,905,690, which expires in 2035 (not including a potential patent term extension of up to an additional five years).
- NBI-1065844, a DAAO inhibitor for the treatment of negative symptoms of schizophrenia, is covered by U.S. Patent No. 9,290,456, among others, which expires in 2032 (not including a potential patent term extension of up to an additional five years).
- NBI-827104, an inhibitor of T-type calcium channels for the treatment of CSWS epilepsy, is covered by U.S. Patent No. US 9,932,314, among others, which expires in 2035 (not including a potential patent term extension of up to an additional five years).
- NBI-921352, an inhibitor of the Nav1.6 voltage-gated sodium channel for the treatment of SCN8A-DEE epilepsy, is covered by U.S. Patent No. US 10,246,453, among others, which expires in 2037 (not including a potential patent term extension of up to an additional five years).
- Elagolix, our small molecule GnRH antagonist under further development for the treatment of polycystic ovary syndrome, is covered by six of the issued U.S. patents that are listed in the FDA's Orange Book entry for ORILISSA and are set to expire between 2021 to 2024 (not including a potential patent term extension of up to an additional five years for one of the patents).
- NBI-1065845, a positive allosteric modulator of AMPA for the treatment of treatment-resistant depression is covered by U.S. Patent No. 8,778,934, among others, which expires in 2031 (not including a potential patent term extension of up to an additional five years).
- NBI-1065846, a GPR139 agonist for the treatment of anhedonia in depression, is covered by U.S. Patent No. 9,556,130, among others, which expires in 2035 (not including a potential patent term extension of up to an additional five years).

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 future patent issuances.

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, 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. 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. In addition, under the terms of our agreement with BIAL, we rely on BIAL and its suppliers to supply all drug product for the commercialization of ONGENTYS.

We believe our outsource manufacturing strategy enables us to direct our financial resources to the maximization of our opportunities with INGREZZA and ONGENTYS, investment in our internal R&D programs and expansion of our clinical pipeline through business development opportunities.

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 sales force in the U.S. consists of approximately 250 experienced sales professionals focused on educating health care professionals, including psychiatrists and neurologists, who treat patients with tardive dyskinesia and Parkinson's disease.

For INGREZZA, our customers in the U.S. consist of a limited network of specialty pharmacy providers that deliver INGREZZA to patients by mail and a specialty distributor that distributes INGREZZA primarily to closed-door pharmacies and government facilities. For ONGENTYS, our customers in the U.S. consist primarily of wholesale distributors. We rely on third-party service providers to perform a variety of functions related to the packaging, storage and distribution of INGREZZA and ONGENTYS.

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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their privacy and security regulations, which impose certain obligations, including the adoption of administrative, physical and technical safeguards to protect individually identifiable health information on covered entities subject to HIPPA (i.e., health plans, healthcare clearinghouses and certain healthcare providers) and their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information as we as their covered subcontractors.

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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable entities to report ownership and investment interests held by the physicians and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists, and certified nurse-midwives.

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 investigational new drug, or 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 also closely monitor the conduct of our trials and 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, 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. The FDA generally has a six-month review goal of priority NDAs.

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 to ensure that the benefits of the drug outweigh its risks. The risk evaluation and mitigation strategy could include medication guides, physician communication plans, assessment plans, and/or additional 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 for its intended use 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.

In the EU, there are currently two potential tracks for seeking marketing approval for a product not authorized in any EU member state: a decentralized procedure and a centralized procedure. In the decentralized procedure, identical applications for marketing authorization are submitted simultaneously to the national regulatory agencies. Regulatory review is led by one member state (the reference-member state), and its assessment—based on safety, quality and efficacy—is reviewed and approved (assuming there are no concerns that the product poses a serious risk to public health) by the other member states from which the applicant is seeking approval (the concerned-member states). The decentralized procedure leads to a series of single national approvals in all relevant countries. In the centralized procedure, which is required of all products derived from biotechnology, a company submits a single marketing authorization application to the European Medicines Agency, or EMA, which conducts an evaluation of the dossier, drawing upon its scientific resources across Europe. If the drug product is proven to fulfill the requirements for quality, safety and efficacy, the EMA's Committee for Medicinal Products of Human Use, or CHMP, adopts a positive opinion, which is transmitted to the European Commission for final decision on grant of the marketing authorization. While the EC generally follows the CHMP's opinion, it is not bound to do so. Subsequent commercialization is enabled by country-by-country reimbursement approval.

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 strategy 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.

There remain legal and political challenges to certain aspects of the ACA. Since January 2017, the Trump administration signed several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress 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". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a 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. The

U.S. Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. It is also unclear how such litigation 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 2030, except for a temporary suspension from May 1, 2020 through May 31, 2021 due to the COVID-19 pandemic, 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 Congressional hearings 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. Both the U.S. House of Representatives and the Senate Finance Committee passed legislation in 2019 to reform pharmaceutical pricing in a variety of meaningful ways, and we expect legislative efforts to reform drug pricing to continue in 2021.

At the federal level, the Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to drug pricing that sought to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. This rule is undergoing legal challenge.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. This rule has been stayed until 2023 while pending litigation is heard in the courts.

On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. Two additional lawsuits in other jurisdictions are challenging the legality of this rule.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 tardive dyskinesia in adults in August 2017 and is marketed by Teva Pharmaceutical Industries, and several clinical development-stage programs targeting tardive dyskinesia and related movement disorders. Additionally, there are a number of commercially available medicines used to treat tardive dyskinesia off-label, such as Xenazine® (tetrabenazine) and generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin.

Parkinson's Disease. ONGENTYS competes with two other FDA-approved COMT inhibitors and their generic equivalents. Additionally, there are a number of alternative adjunctive treatment options (FDA-approved and in clinical development) for Parkinson's patients which compete with ONGENTYS, including various L-dopa preparations, dopamine agonists, MAO-B inhibitors and others. In terms of potential future competition, there are several programs in late-stage clinical development.

Endometriosis and Uterine Fibroids. ORILISSA and ORIAHNN each compete with several FDA-approved products for the treatment of endometriosis, uterine fibroids, infertility, and central precocious puberty. Additionally, there is also competition from surgical intervention, including hysterectomies and ablations. Separate from these options, there are many programs in clinical development which serve as potential future competition. Lastly, there are numerous medicines used to treat the symptoms of disease (vs. endometriosis or uterine fibroids directly) which may also serve as competition: oral contraceptives, NSAIDs and other pain medications including opioids.

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 clinical development-stage programs targeting CAH and several companies developing medicinal treatments for CAH.

Epilepsy. Our investigational treatments for potential use in epilepsy may in the future compete with numerous approved anti-seizure medications, or ASMs, and development-stage programs being pursued by several other companies. Commonly used ASMs, among others, include phenytoin, levetiracetam, brivaracetam, cenobamate, carbamazepine, clobazam, lamotrigine, valproate, oxcarbazepine, topiramate, lacosamide, perampanel and cannabidiol. There are currently no FDA-approved treatments specifically indicated for the early infantile epileptic encephalopathies SCN8A-DEE and EE-CSWS; however, a number of different ASMs are currently used in these patient populations.

Schizophrenia. The investigational treatment NBI-1065844 for the negative symptoms of schizophrenia may in the future compete with off-label antipsychotic and antidepressant medicines, including cariprazine, clozapine, fluoxetine, citalopram, sertraline, and amisulpride. In addition, there are several development-stage programs being pursued by other companies, including pimavanserin, roluperidone, RO6889450 and sodium benzoate. Currently, there are no-FDA approved treatments specifically indicated for the negative symptoms of schizophrenia.

Other. Our investigational treatments for potential use in endocrinology, neurology, and psychiatry, as well as our investigational gene therapies, may in the future compete with numerous approved products and development-stage programs being pursued by several other companies.

Human Capital

Our Employees. We have grown to a team of over 845 employees as of December 31, 2020, all of whom were employed in the U.S. Our highly qualified and experienced team which includes scientists, physicians and professionals across sales, marketing, manufacturing, regulatory, finance and other important functions are critical to our success. We also leverage temporary workers to provide flexibility for our business needs. During 2020, we added 191 new employees to our team.

We expect to continue to add additional employees in 2021 with a focus on expanding our expertise and bandwidth in clinical and preclinical research and development. We continually evaluate our business needs and opportunities

and balance in house expertise and capacity with external expertise and capacity. Currently, we rely on third-party contract manufacturers.

Our Culture. The success of our human capital management investments is evidenced by our low employee turnover, a number which is regularly reviewed by our Board of Directors as part of their oversight of our human capital strategy. In recognition of our efforts, in 2020, we were named to the Fortune Best Small and Medium Workplaces 2020 list ranking Number 8 across the country. We were also named a Great Place to Work Certified company and were recognized on Great Place to Work's Best Workplace for Parents 2020 list.

Employee Engagement, Talent Development & Benefits. We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. As part of our promotion and retention efforts, we also invest in ongoing leadership development through programs as well as offer tuition reimbursement. In addition, we regularly conduct an employee survey to gauge employee engagement and identify areas of focus.

Diversity & Inclusion. Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values.

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.

Summary Risk Factors

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

- We may not be able to successfully commercialize INGREZZA, ONGENTYS, or any of our product candidates if they are approved in the future.
- If physicians and patients do not continue to accept INGREZZA or do not accept ONGENTYS, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.
- Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products that could limit our product revenues and delay sustained profitability.

- Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have significant sales and marketing efforts or manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.
- Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.
- Our clinical studies may be delayed for safety or other reasons, or fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval. For example, the FDA has placed a clinical hold on the RESTORE-1 study, a Phase II, randomized, placebo-surgery controlled, double-blind, multi-center clinical study of NBIb-1817 in Parkinson's disease patients, following our submission of an IND safety report related to the observation of MRI abnormalities in some study participants. The clinical implications of this observation are currently unknown and are being evaluated. On February 2, 2021, we notified Voyager of our termination of the NBIb-1817 for Parkinson's disease program. The effective date of the termination will be August 2, 2021.
- We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.
- Use of our approved products or those of our collaborators could be associated with side effects or adverse events.
- We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced.
- We currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA, ONGENTYS or any of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed, and our costs may rise.
- We currently depend on a limited number of third-party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA or ONGENTYS, could materially and adversely affect our ability to successfully commercialize INGREZZA or ONGENTYS.
- If we are unable to retain and recruit qualified scientists or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts or impact our commercialization of INGREZZA, ONGENTYS or any product candidate approved by the FDA.
- We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, or violate the terms of these licenses, we could lose our rights to those technologies and drug candidates or be forced to pay damages.
- Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations.
- We have a history of losses and expect to increase our expenses for the foreseeable future, and we may not be able to sustain profitability.
- We have recently increased the size of our organization and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.
- Our customers are concentrated and therefore the loss of a significant customer may harm our business.
- If we cannot raise additional funding, we may be unable to complete development of our product candidates or establish commercial and manufacturing capabilities in the future.
- Health care reform measures and other recent legislative initiatives could adversely affect our business.

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

Risks Related to Our Company

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

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

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

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

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

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

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

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

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

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

and the price of prescription drugs through various means may reduce our potential revenues. These payors' efforts could decrease the price that we receive for any products we may develop and sell in the future.

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

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the 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. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, gene therapy treatments, which we are developing pursuant to our collaboration and license agreement with Voyager, face additional uncertainty related to pricing and reimbursement. As an example, there are a limited number of gene therapy products currently approved for coverage and reimbursement by the Centers for Medicare & Medicaid Services, or CMS.

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

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

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

depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, we may face several challenges or disruptions upon a return back to the workplace if and when the COVID-19 pandemic subsides, including re-integration challenges by our employees and distractions to management related to such transition. These and similar, and perhaps more severe, disruptions in our operations due to the COVID-19 pandemic could negatively impact our business, operating results and financial condition.

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

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

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

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

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

All of our product candidates are currently in research or clinical development with the exceptions of INGREZZA, which has been approved by the FDA for tardive dyskinesia, ONGENTYS, which has been approved by the FDA for Parkinson's disease, ORILISSA (partnered with AbbVie), which has been approved by the FDA for the management of moderate to severe endometriosis pain in women, and ORIAHNN (partnered with AbbVie), which has been approved by the FDA for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. Only a small number of research and development programs ultimately result in commercially successful drugs. In addition, to date the FDA has granted regulatory approval for only a very limited number of gene therapy products and the clinical development of a gene therapy product may result in unforeseen adverse events. For example, the FDA has placed a clinical hold on the RESTORE-1 study, a Phase II, randomized, placebo-surgery controlled, double-blind, multi-center clinical study of NBIb-1817 in Parkinson's disease patients, following our submission of an IND safety report related to the observation of MRI abnormalities in some study participants. The clinical implications of this observation are currently unknown and are being evaluated. On February 2, 2021, we notified Voyager of our termination of the NBIb-1817 for Parkinson's disease program. The effective date of the termination will be August 2, 2021.

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 and the outcomes are uncertain.

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

- the FDA or similar foreign regulatory authority may not allow an IND application or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA may require additional preclinical studies as a condition of the initiation of Phase I clinical studies, or additional clinical studies for progression from Phase I to Phase II, or Phase II to Phase III, or for NDA approval;
- the product candidate may not prove to be effective or as effective as other competing product candidates;
- we may discover that a product candidate may cause harmful side effects or results of required toxicology or other studies may not be acceptable to the FDA;
- the results may not replicate the results of earlier, smaller trials;
- the FDA or similar foreign regulatory authorities may require use of new or experimental endpoints that may prove insensitive to treatment effects;
- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- the results may not be statistically significant;
- patient recruitment and enrollment may be slower or more difficult than expected;
- the FDA may not accept the data from any trial or trial site outside of the US;
- patients may drop out of the trials;
- unforeseen disruptions or delays may occur, caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic; and
- regulatory requirements may change.

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

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

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

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

We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates. For example, we collaborate with AbbVie for the manufacture and commercialization of two of our commercial products, ORILISSA and ORIAHNN, and for the continued development of elagolix. We collaborate with MTPC for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. We also rely on BIAL for the commercial supply of ONGENTYS. In addition, we collaborate with Xenon for the development of NBI-921352, Idorsia for the development of NBI-827104 and Takeda for the development of NBI-1065844.

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

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

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

We may not be able to successfully commercialize ONGENTYS.

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

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

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

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

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

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

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

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

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

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

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

Competition may also arise from, among other things:

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

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

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

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

- With respect to ONGENTYS for Parkinson's disease, there are currently two other FDA-approved COMT inhibitors. ONGENTYS competes directly with these two drugs and their generic equivalents. Additionally, there are a number of alternative adjunctive treatment options (FDA-approved and in clinical development) for Parkinson's patients which compete with ONGENTYS, including various L-dopa preparations, dopamine agonists, MAO-B inhibitors and others. In terms of potential future competition, there are several programs in late-stage clinical development.
- As for CAH, high doses of corticosteroids are the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive ACTH levels. In the U.S. alone, there are more than two dozen companies manufacturing steroid-based products. Additionally, there are several clinical development-stage programs targeting CAH and several companies developing medicinal treatments for CAH.
- Our investigational treatments for potential use in epilepsy may in the future compete with numerous approved anti-seizure medications, or ASMs, and development-stage programs being pursued by several other companies. Commonly used ASMs, among others, include phenytoin, levetiracetam, brivaracetam, cenobamate, carbamazepine, clobazam, lamotrigine, valproate, oxcarbazepine, topiramate, lacosamide, perampanel and cannabidiol. There are currently no FDA-approved treatments specifically indicated for the early infantile epileptic encephalopathies SCN8A-DEE and EE-CSWS; however, a number of different ASMs are currently used in these patient populations.
- The investigational treatment NBI-1065844 for the negative symptoms of schizophrenia may in the future compete with off-label antipsychotic and antidepressant medicines, including ciraprazine, clozapine, fluoxetine, citalopram, sertraline, and amisulpride. In addition, there are several development-stage programs being pursued by other companies, including pimavanserin, roluperidone, RO6889450 and sodium benzoate. Currently, there are no-FDA approved treatments specifically indicated for the negative symptoms of schizophrenia.
- Our investigational treatments for potential use in endocrinology, neurology, and psychiatry, as well as our investigational gene therapies, may in the future compete with numerous approved products and development-stage programs being pursued by several other companies.

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

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

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

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

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the commercialization of our products. We have limited experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Establishing internal commercial manufacturing capabilities would require significant time and resources, and we may not be able to timely or successfully establish such capabilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes, including INGREZZA and ONGENTYS. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products, including INGREZZA and ONGENTYS. The

manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations, including current Good Manufacturing Practice regulations. Our third-party manufacturers, including BIAL and its suppliers, might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. In addition, the manufacture of gene therapy products, which will be necessary under our collaboration and license agreement with Voyager, is technically complex and necessitates substantial expertise and capital investment. Our reliance on contract manufacturers also exposes us to the following risks:

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

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

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

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

materially and adversely affect our ability to successfully commercialize INGREZZA. If BIAL is unable or refuses to supply us with ONGENTYS drug product for any reason, or does not meet FDA or international regulators' requirements for approval, we have limited opportunity to qualify a new supplier. This could materially and adversely affect our ability to successfully commercialize ONGENTYS.

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

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, changes in the product's label, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products; and
- product injunctions or the imposition of civil or criminal penalties.

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

If we are unable to retain and recruit qualified scientists or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts or impact our commercialization of INGREZZA, ONGENTYS or any product candidate approved by the FDA.

We are highly dependent on the principal members of our management and scientific staff. The loss of any of these people could impede the achievement of our objectives, including the successful commercialization of INGREZZA, ONGENTYS or any product candidate approved by the FDA. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future, along with personnel with experience marketing and selling pharmaceutical products, is critical to our success. We may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists and individuals with experience marketing and selling pharmaceutical products. We may face particular retention challenges in light of the recent rapid growth in our personnel and infrastructure and the perceived impact of those changes upon our corporate culture. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy and our commercialization strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

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

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

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

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. If we were to default on our obligations under any of our licenses, we could lose some or all of our rights to develop, market and sell products covered by these licenses. For example, BIAL may terminate our license agreement, pursuant to which we have rights to commercialize ONGENTYS, if we fail to use commercially reasonable efforts to comply with specified obligations under the license agreement, or if we otherwise breach the license agreement. In addition, several of our collaboration and license agreements allow our licensors to terminate such agreements if we challenge the validity or enforceability of certain intellectual property rights or if we commit a material breach in whole or in part of the agreement and do not cure such breach within the agreed upon cure period. In addition, if we were to violate any of the terms of our licenses, we could become subject to damages. Likewise, if we were to lose our rights under a license to use proprietary research tools, it could adversely affect our existing collaborations or adversely affect our ability to form new collaborations. We also face the risk that our licensors could, for a number of reasons, lose patent protection or lose their rights to the technologies we have licensed, thereby impairing or extinguishing our rights under our licenses with them.

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

In May 2017, we sold $517.5 million aggregate principal amount of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes. In November 2020, we entered into separate, privately negotiated transactions with certain

holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. At December 31, 2020, $381.3 million aggregate principal amount of the 2024 Notes remained outstanding. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

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

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

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

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

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

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

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

profitability on a sustained basis in the future. Our failure to maintain or increase profitability on a sustained basis could negatively impact the market price of our common stock.

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

At December 31, 2020, we had approximately 845 full-time employees. Although we have substantially increased the size of our organization, we may need to add additional qualified personnel and resources, especially now that we have a commercial sales force. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates.

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

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

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

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

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

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

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to seasonality and timing of customer purchases and commercial sales of INGREZZA, impact of the commercial launch of ONGENTYS and ORIAHNN, royalties from out-licensed products, the impact of Medicare Part D coverage, our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing, contract research payments, fluctuations in our effective tax rate, and disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic. A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect financial results in a quarter. While we were profitable for the year ended December 31, 2020, our future operating results and profitability may fluctuate from period to period, and even if we become profitable on a quarterly or annual basis, we may not be able to sustain or increase our profitability. Moreover, as our company and our market capitalization have grown, our financial performance has become increasingly subject to quarterly and annual comparisons with the expectations of

securities analysts or investors. The failure of our financial results to meet these expectations, either in a single quarterly or annual period over a sustained period time, could cause our stock price to decline.

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

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

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

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

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

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

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

In addition, on December 31, 2020, we determined, based on our facts and circumstances, that it was more likely than not that a substantial portion of our deferred tax assets would be realized and, as a result, substantially all of our valuation allowance against our deferred tax assets was released. Therefore, beginning in 2021, we expect to commence recording income tax expense at an estimated tax rate that will likely approximate statutory tax rates, which would result in a significant reduction in our net income and net income per share.

The price of our common stock is volatile.

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market for these securities has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The COVID-19 pandemic, for example, has negatively affected the stock market and investor sentiment and has resulted in significant volatility. Furthermore, especially as we and our market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts' forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, which is based on assumptions that may be incorrect or that may change from quarter to quarter, the market price of our common stock could decline. Over the course of the last twelve months, the price of our common stock has ranged from approximately $72 per share to approximately $136 per share. The market price of our common stock may fluctuate in response to many factors, including:

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

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

We have entered into agreements for the distribution of INGREZZA with a limited number of specialty pharmacy providers and a specialty distributor, and all of our product sales are to these customers. Two of these customers

represented approximately 86% of our product revenue for the year ended December 31, 2020 and a significant majority of our accounts receivable balance at December 31, 2020. If any of these significant customers becomes subject to bankruptcy, is unable to pay us for our products or is acquired by a company that wants to terminate the relationship with us, or if we otherwise lose any of these significant customers, our revenue, results of operations and cash flows would be adversely affected. Even if we replace the loss of a significant customer, we cannot predict with certainty that such transition would not result in a decline in our revenue, results of operations and cash flows.

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

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

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

- the commercial success of INGREZZA, ONGENTYS, ORILISSA, and/or ORIAHNN;
- debt service obligations on the 2024 Notes;
- continued scientific progress in our R&D and clinical development programs;
- the magnitude and complexity of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- competing technological and market developments;
- the establishment of additional strategic alliances;
- developments related to any future litigation;
- the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and
- the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances and may seek additional funding through public or private sales of our securities, including equity securities. In addition, during the second quarter of 2017, we issued the 2024 Notes and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. At December 31, 2020, $381.3 million aggregate principal amount of the 2024 Notes remained outstanding. Additional equity or debt financing might not be available on reasonable terms, if at all. In addition, disruptions due to the COVID-19 pandemic could make it more difficult for us to access capital. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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

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

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

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

Risks Related to Our Industry

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

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care and to lower drug prices. In the 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 impose obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers are required to provide certain information regarding the drug product provided to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding distribution of the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, notification and purchaser license verification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Additionally, in March 2010, Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was signed into law, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees

on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports, specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There remain legal and political challenges to certain aspects of the ACA. Since January 2017, several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA have been put into place. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a 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. On March 2, 2020, the United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. It is also unclear how such litigation 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 Bipartisan Budget Act of 2018, will remain in effect through 2030, except for a temporary suspension from May 1, 2020 through May 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which

ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it remains unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for the 2021 fiscal year includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump 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. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates and their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state laws that require disclosure of price increases above certain identified thresholds as well as of new commercial launches in the state; state and local laws that require the registration of pharmaceutical sales representatives; state and local "drug take

back" laws and regulations; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

In addition, any sales of our product once commercialized outside the 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, ONGENTYS or any of our product candidates that receives regulatory approval, for "off-label" uses.

A company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the 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 and ONGENTYS, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations. If the FDA or any other governmental agency initiates an enforcement action against us, or if we are the subject of a *qui tam* suit brought by a private plaintiff on behalf of the government, and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

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

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

- obtain patent protection for our products;
- preserve our trade secrets;
- prevent third parties from infringing upon our proprietary rights; and
- operate without infringing upon the proprietary rights of others, both in the 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 and ONGENTYS, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have product liability insurance coverage for our clinical trials in the amount of $45.0 million per occurrence and $45.0 million in the aggregate. In addition, we have product liability insurance related to the sale of INGREZZA and ONGENTYS in the amount of $45.0 million per occurrence and $45.0 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability from any current or future clinical trials or approved products. A successful product liability claim, or series of claims, brought against us would decrease our cash reserves and could cause our stock price to fall. Furthermore, regardless of the eventual outcome of a product liability claim, any product liability claim against us may decrease demand for our approved products, including INGREZZA and ONGENTYS, damage our reputation, result in regulatory investigations that could require costly recalls or product modifications, cause clinical trial participants to withdrawal, result in costs to defend the related litigation, decrease our revenue, and divert management's attention from managing our business.

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

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

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

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

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

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

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

Additionally, the California Consumer Privacy Act, or CCPA, which went into effect in 2020, created new individual privacy rights for California consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. For example, the

CCPA requires covered companies to provide additional disclosures to California consumers, and provides such consumers with new rights, such as the ability to opt out of certain disclosures of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the 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 thousand square feet of laboratory and office space located at 12780 El Camino Real, 88 thousand square feet of office space located at 12790 El Camino Real, 46 thousand square feet of laboratory space located at 10420 Wateridge Circle, and 45 thousand square feet of office space located at 12777 High Bluff Drive.

We believe that our property and equipment are generally well maintained, in good operating condition, and 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 29, 2021, there were approximately 47 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.

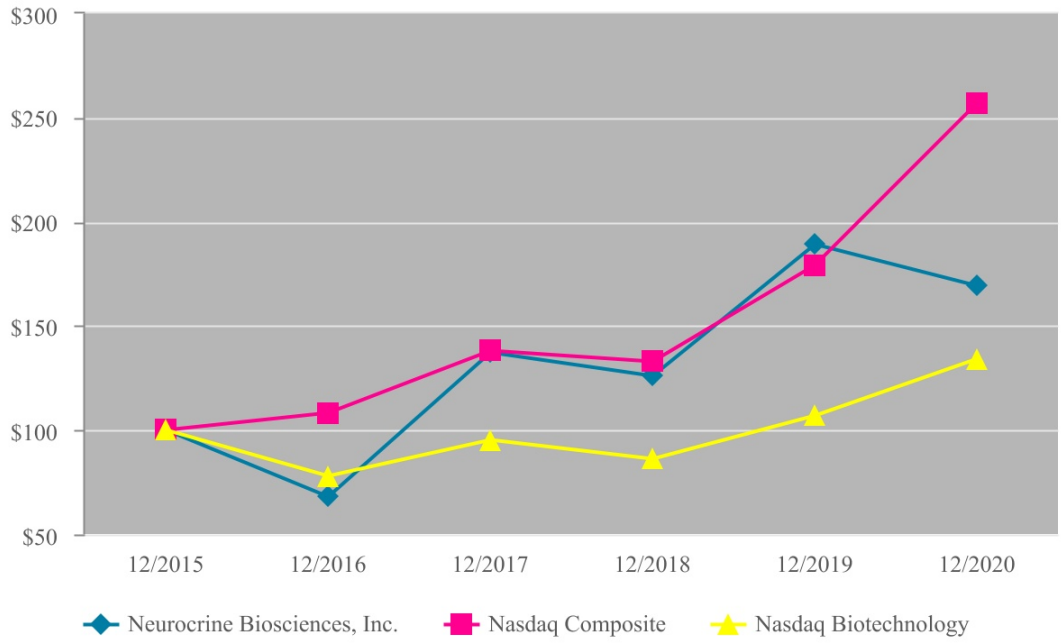
Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities and Issuer Purchases of Equity Securities

There were no unregistered sales of our equity securities during 2020. In addition, we did not repurchase any of our equity securities during 2020.

Stock Performance Graph and Cumulative Total Return*

The graph below shows the cumulative total stockholder return assuming the investment of $100 on December 31, 2015 (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, or 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 millions, except per share data)	2020	2019	2018	2017	2016
Consolidated Statements of Operations Data					
Revenues:					
Product sales, net	$ 994.1	$ 752.9	$ 409.6	$ 116.6	$ —
Collaboration revenue	51.8	35.2	41.6	45.0	15.0
Total revenues	1,045.9	788.1	451.2	161.6	15.0
Operating expenses:					
Cost of sales	10.1	7.4	4.9	1.3	—
Research and development	275.0	200.0	155.8	91.8	94.3
Acquired in-process research and development	164.5	154.3	4.8	30.0	—
Selling, general and administrative	433.3	354.1	248.9	169.9	68.1
Total operating expenses	882.9	715.8	414.4	293.0	162.4
Operating income (loss)	163.0	72.3	36.8	(131.4)	(147.4)
Other (expense) income:					
Interest expense	(32.8)	(32.0)	(30.5)	(19.5)	—
Unrealized loss on restricted equity securities	(17.7)	(13.0)	—	—	—
Loss on extinguishment of convertible senior notes	(18.4)	—	—	—	—
Investment income and other, net	12.6	19.2	15.5	8.3	6.3
Total other (expense) income, net	(56.3)	(25.8)	(15.0)	(11.2)	6.3
Income (loss) before (benefit from) provision for income taxes	106.7	46.5	21.8	(142.5)	(141.1)
(Benefit from) provision for income taxes	(300.6)	9.5	0.7	—	—
Net income (loss)	$ 407.3	$ 37.0	$ 21.1	$ (142.5)	$ (141.1)
Net income (loss) per share, basic	$ 4.38	$ 0.40	$ 0.23	$ (1.62)	$ (1.63)
Net income (loss) per share, diluted	$ 4.16	$ 0.39	$ 0.22	$ (1.62)	$ (1.63)
Weighted average common shares outstanding:					
Basic	93.1	91.6	90.2	88.1	86.7
Diluted	97.8	95.7	95.4	88.1	86.7
Consolidated Balance Sheets Data					
Cash, cash equivalents and debt securities available-for-sale	$ 1,028.1	$ 970.2	$ 866.9	$ 763.3	$ 350.8
Working capital	$ 829.7	$ 265.7	$ 649.5	$ 500.5	$ 280.0
Total assets	$ 1,734.7	$ 1,306.0	$ 993.2	$ 817.6	$ 365.1
Convertible senior notes	$ 317.9	$ 408.8	$ 388.5	$ 369.6	$ —
Accumulated deficit	$ (725.4)	$ (1,132.7)	$ (1,177.8)	$ (1,198.9)	$ (1,056.3)
Total stockholders' equity	$ 1,126.2	$ 636.9	$ 480.8	$ 372.1	$ 314.9

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

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

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

In addition, we have a rapidly expanding pipeline of potential treatments and gene therapies for diseases such as Huntington's disease, or HD, Parkinson's disease, epilepsy, congenital adrenal hyperplasia, or CAH, schizophrenia and depression. Refer to Part I, Item 1, "Business" for more information about our exclusive and partnered commercial products, clinical development pipeline and research programs.

Highlights:

- INGREZZA net product sales for 2020 increased $240.2 million, or 31.9%, to $993.1 million, primarily reflecting strong refill and persistency rates for existing INGREZZA patients.
- We launched ONGENTYS in the U.S. in September 2020, after receiving FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients in April 2020.
- AbbVie launched ORIAHNN in the U.S. in June 2020, after receiving FDA approval for ORIAHNN as the first FDA-approved non-surgical, oral medication option for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women in May 2020. We recognized a $30.0 million event-based milestone as revenue in the second quarter of 2020.
- Completed strategic partnerships with Idorsia Pharmaceuticals Ltd, or Idorsia, and Takeda Pharmaceutical Company Limited, or Takeda, to expand clinical pipeline for epilepsy and psychiatry disorders. Recognized

in-process research and development, or IPR&D, expense for 2020 of $164.5 million, related to upfront payments.

- Total debt outstanding decreased by $136.2 million to $381.3 million after repurchase of approximately 26% of our debt outstanding in December 2020. The total aggregate repurchase price of $186.9 million was paid in cash and resulted in an $18.4 million loss.
- At December 31, 2020, in part because we achieved three years of cumulative pretax income, management determined that there is sufficient positive evidence to conclude that it is more likely than not that deferred tax assets of $319.4 million are realizable. We therefore reduced the valuation allowance accordingly.

Pipeline Highlights:

- Crinecerfont (NBI-74788): In July 2020, we initiated the CAHtalyst study, a global registrational Phase III, randomized, double-blind, placebo-controlled clinical study to evaluate the safety and efficacy of crinecerfont in 165 adult patients with classic CAH, followed by an open-label treatment period.
- NBI-827104 (ACT-709478): In November 2020, we initiated a Phase II clinical study for NBI-827104 in a rare pediatric epileptic encephalopathy known as Continuous Spike and Wave During Sleep.
- INGREZZA: In February 2021, Mitsubishi Tanabe Pharmaceutical Company, or MTPC, reported positive top-line results from the J-KINECT Phase III study, designed to evaluate the efficacy and safety of valbenazine in tardive dyskinesia. Detailed results from this trial will be presented at a future medical conference. With positive data in hand, a marketing authorization with the Ministry of Health and Welfare is planned for 2021 in Japan. In addition, MTPC submitted filings for marketing authorizations in South Korea, Thailand, Singapore, Indonesia, and Malaysia in 2020.
- NBIb-1817 (VY-AADC): On February 2, 2021, we notified Voyager Therapeutics, Inc., or Voyager, of our termination of the NBIb-1817 for Parkinson’s disease program. The effective date of this termination will be August 2, 2021. The termination does not apply to any other development program other than NBIb-1817 for Parkinson’s disease, and our collaboration and license agreement with Voyager will otherwise continue in effect.

COVID-19

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

While we are unable to reliably estimate the duration or extent of any potential business disruption or financial impact during this time, including any impacts on INGREZZA product sales or R&D expense, we remain committed to (1) prioritizing the safety, health and well-being of patients, their caregivers, healthcare providers and our employees; (2) ensuring patients with tardive dyskinesia are well supported and have continued uninterrupted access to INGREZZA, for which we currently do not expect any supply disruption; and (3) advancing ongoing clinical studies. As part of this commitment, we implemented a “Work from Home Policy” in early March 2020 for employees not involved in business-critical activities. For employees involved in business-critical activities, we implemented safety measures designed to comply with federal, state and local guidelines.

Due to the impact of COVID-19, we initially paused enrollment of new patients in several of our clinical trials. Beginning in the third quarter of 2020, we began enrolling patients in our HD and CAH studies. To date, we have not experienced any interruption of our supply of drug products needed to support our ongoing clinical studies, but we expect that completion and data readouts for several of our ongoing and planned studies will be delayed.

We continue to believe that existing funds, cash generated from operations, and existing sources of and access to financing are adequate to satisfy our needs for working capital, capital expenditures, debt service requirements and other business development initiatives that we plan to strategically pursue. However, should the COVID-19 pandemic and any associated recession or depression continue for a prolonged period, our results of operations, financial condition, liquidity and cash flows could be materially impacted by lower revenues and profitability and a lower likelihood of effectively and efficiently developing new medicines.

Results of Operations

Revenues

The following table presents revenues by category.

(in millions)	Year Ended December 31, 2020	2019	2018
INGREZZA product sales, net	$ 993.1	$ 752.9	$ 409.6
ONGENTYS product sales, net	1.0	—	—
Collaboration revenues	51.8	35.2	41.6
Total revenues	$ 1,045.9	$ 788.1	$ 451.2

Product Sales, net. Net product sales were $994.1 million for 2020, $752.9 million for 2019 and $409.6 million for 2018.

Collaboration Revenues. Collaboration revenues reflect the achievement of certain event-based milestones, royalties earned at tiered percentage rates on any net sales of ORILISSA and ORIAHNN and license fees earned under our collaboration agreements with AbbVie and MTPC.

In the second quarter of 2020, we recognized a $30.0 million event-based milestone as revenue upon FDA-approval of AbbVie's ORIAHNN for uterine fibroids. 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 new drug application, or NDA, submission of elagolix for uterine fibroids. In the third quarter of 2018, we recognized a $40.0 million event-based milestone as revenue upon FDA-approval of AbbVie's ORILISSA for the treatment of moderate to severe pain associated with endometriosis.

For ORILISSA and ORIAHNN, we recognized royalty revenue of $19.2 million for 2020, $14.3 million for 2019 and $1.6 million for 2018.

Operating Expenses

Cost of Sales. Cost of sales was $10.1 million for 2020, $7.4 million for 2019 and $4.9 million for 2018, primarily reflecting a higher annual volume of INGREZZA product sales since commercial launch in April 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:

(in millions)	Year Ended December 31, 2020	2019	2018
Late stage	$ 55.1	$ 43.7	$ 14.2
Early stage	30.2	25.3	41.7
Research and discovery	43.3	24.6	17.0
Milestone payments	20.0	10.0	10.0
Payroll and benefits	95.4	71.3	62.0
Facilities and other	31.0	25.1	10.9
Total R&D expense	$ 275.0	$ 200.0	$ 155.8

R&D expense was $275.0 million for 2020, $200.0 million for 2019 and $155.8 million for 2018. The increase in R&D expense was primarily the result of increased investment to support advancing our expanded clinical portfolio and increased personnel expenses on higher headcount.

Acquired In-Process Research and Development. IPR&D expense was $164.5 million for 2020, $154.3 million for 2019 and $4.8 million for 2018. For 2020, we recorded IPR&D expense of $46.0 million and $118.5 million in connection with the payments of the upfront fees pursuant to our collaborations with Idorsia and Takeda, respectively. For 2019, we recorded IPR&D expense of $118.1 million and $36.2 million in connection with the payments of the upfront fees pursuant to our collaborations with Voyager and Xenon Pharmaceuticals, Inc., or Xenon. For 2018, we recorded IPR&D expense of $4.8 million in connection with payment of the upfront fee to Jnana to obtain access to Jnana's proprietary drug discovery platform.

Selling, General and Administrative. Selling, general and administrative, or SG&A, expense was $433.3 million for 2020, $354.1 million for 2019 and $248.9 million for 2018. The increase in SG&A expense from 2019 to 2020 was primarily due to increased personnel expenses on higher headcount and continued investment in INGREZZA marketing. 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.

Other Expense

Other expense, net, was $56.3 million for 2020, $25.8 million for 2019 and $15.0 million for 2018. Periodic fluctuations in other expense, net, primarily reflect unrealized losses recognized to adjust our equity investments in Voyager and Xenon Pharmaceuticals Inc. to fair value. For 2020, other expense, net, also reflects an $18.4 million loss on debt extinguishment recognized for the partial repurchase of the 2024 Notes in November 2020.

(Benefit from) Provision for Income Taxes

Our benefit from income taxes was $300.6 million for 2020, compared to a provision for income taxes of $9.5 million for 2019 and $0.7 million for 2018. The benefit from income taxes for 2020 included a $296.3 million benefit related to the release of substantially all of our valuation allowance against our deferred tax assets on December 31, 2020. The decision to release the valuation allowance was made after we determined that it was more likely than not the deferred tax assets, including net operating losses and tax credits, would be realized, and was based on the evaluation and weighting of both positive and negative evidence, such as our achievement of a cumulative three-year income position at December 31, 2020, as well as our consideration of forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration. The provision for income taxes for 2019 and 2018 reflected estimated current state income taxes for both periods. At December 31, 2019 and 2018, we had full valuation allowances against our net deferred tax assets as realization was uncertain. Our tax expense for 2020, 2019 and 2018 varied 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

Net income was $407.3 million, or $4.16 diluted earnings per share, for 2020, $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. The change from 2019

to 2020 was primarily the result of increased INGREZZA net product sales and a non-cash tax benefit of $296.3 million related to the release of substantially all of our valuation allowance against our deferred tax assets on December 31, 2020, offset by $164.5 million of IPR&D in connection with our collaborations with Idorsia and Takeda, ongoing support for the commercial launch of INGREZZA for tardive dyskinesia and progression of our clinical pipeline. 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 tardive dyskinesia and progression of our clinical pipeline.

Liquidity and Capital Resources

Cash, cash equivalents and debt securities available-for-sale totaled $1.0 billion and $970.2 million at December 31, 2020 and 2019, respectively.

Net cash provided by operating activities was $228.5 million for 2020, $147.0 million for 2019 and $101.4 million for 2018. The increase in positive cash flow from 2019 to 2020 was primarily due to increased INGREZZA net product sales partially offset by incremental INGREZZA investment and progression of our clinical pipeline. The increase in positive cash flow from 2018 to 2019 was primarily due to increased INGREZZA net product sales, partially offset by incremental INGREZZA investment and upfront payments of $154.3 million in connection with our collaborations with Voyager and Xenon.

Net cash provided by investing activities was $4.1 million for 2020, compared with net cash used in investing activities of $211.1 million for 2019 and $242.9 million for 2018. Periodic fluctuations in cash flows from investing activities primarily reflect timing differences in purchases, sales and maturities of debt securities available-for-sale and changes in our portfolio-mix. Net cash used in investing activities for 2019 also reflects equity investments of $54.7 million in Voyager and $14.2 million in Xenon.

Net cash used in financing activities was $157.8 million for 2020, primarily reflecting our repurchase of $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash in November 2020, compared to net cash provided by financing activities of $32.4 million for 2019 and $29.5 million in 2018. For 2019 and 2018, periodic fluctuations in cash flows from financing activities reflect proceeds from issuances of our common stock.

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 2020, 2019 or 2018.

Convertible Senior Notes. In May 2017, we completed a private placement of $517.5 million in aggregate principal amount of 2.25% convertible senior notes scheduled to mature on May 15, 2024, unless earlier converted, redeemed, or repurchased. We may not redeem the 2024 Notes prior to May 15, 2021. On or after this date, at our election, we may redeem all, or any portion, of the 2024 Notes under certain circumstances. The 2024 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by us. There are customary events of default with respect to the 2024 Notes, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the 2024 Notes will automatically become due and payable. Amounts for the 2024 Notes and related interest in the table above assume that the 2024 Notes will be held until maturity. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. At December 31, 2020, $381.3 million aggregate principal amount of the 2024 Notes remained outstanding.

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. 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.

Government Rebates. We are obligated to pay rebates for mandated discounts under the Medicaid Drug Rebate Program. The liability for such rebates consists 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, which are primarily based on actual historical rebates, estimated payor mix, state and federal regulations and related contractual terms. Estimated rebates are recorded as a reduction of revenue in the period the related sale is recognized. To date, actual government rebates have 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.

Income Taxes. Our income tax benefit (provision) is computed under the asset and liability method. Significant estimates are required in determining our income tax benefit (provision). Some of these estimates are based on interpretations of existing tax laws or regulations. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts (temporary differences) at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which it is more likely than not that some portion or all of the deferred tax assets, including net operating losses and tax credits, will not be realized. We periodically re-assess the need for a valuation allowance against our deferred tax assets based on various factors including our historical earnings experience by taxing jurisdiction, and forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration. Significant judgment is required in making this assessment and, to the extent that a reversal of any portion of our valuation allowance against our deferred tax assets is deemed appropriate, a tax benefit will be recognized against our income tax provision in the period of such reversal. Prior to 2020, we recorded a valuation allowance that fully offset our deferred tax assets. On December 31, 2020, based on our evaluation of various factors, such as our achievement of a cumulative three-year income position as of December 31, 2020, as well as our consideration of forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration, we released substantially all of our valuation allowance against our deferred tax assets and recorded

a corresponding income tax benefit. We continue to maintain a valuation allowance against our California state deferred tax assets.

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 and enrollment may be slower or more difficult 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 cancellable with written notice within 180 days or less. We may be required to pay up to $8.5 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 FDA-approved for the treatment of tardive dyskinesia; ONGENTYS, which has been FDA-approved as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson’s disease patients; ORILISSA (partnered with AbbVie), which has been FDA-approved for the management of moderate to severe endometriosis pain in women; and ORIAHNN (partnered with AbbVie), which has been FDA-approved for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal 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, ONGENTYS, ORILISSA, and/or ORIAHNN;
- debt service obligations on the 2024 Notes;
- continued scientific progress in our R&D and clinical development programs;
- the magnitude and complexity of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- competing technological and market developments;
- the establishment of additional strategic alliances;
- developments related to any future litigation;
- the impact of the COVID-19 pandemic on our business;
- 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.

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

We may require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, the cost of product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We may seek to access the public or private

equity markets whenever conditions are favorable. For example, we have an effective shelf registration statement on file with the SEC which allows us to issue an unlimited number of shares of our 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. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. At December 31, 2020, $381.3 million aggregate principal amount of the 2024 Notes remained outstanding. 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. In addition, COVID-19 pandemic is currently resulting in disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. 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

The following table presents our contractual obligations at December 31, 2020.

(in millions)	Total	2021	2022	2023	2024	2025 and Thereafter
2024 Notes and related interest [1]	$ 411.5	$ 8.7	$ 8.6	$ 8.6	$ 385.6	$ —
Operating leases [2]	159.6	12.3	14.9	15.5	16.0	100.9
Total contractual obligations	$ 571.1	$ 21.0	$ 23.5	$ 24.1	$ 401.6	$ 100.9

(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. 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. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. At December 31, 2020, $381.3 million aggregate principal amount of the 2024 Notes remained outstanding.

(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 2025 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 1% change in interest rates were to have occurred on December 31, 2020, 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, 2020 and 2019, the related consolidated statements of income and comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 5, 2021 expressed an unqualified opinion thereon.

Adoption of New Accounting Standard

ASU No. 2016-02

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases effective January 1, 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 U.S. (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 sheets.

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, 2020, 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 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, 2020, including controls over management's forecast of revenue and the accuracy of data used in the calculation.

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, 2020. 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 5, 2021

NEUROCRINE BIOSCIENCES, INC.

CONSOLIDATED BALANCE SHEETS

(in millions, except per share data)	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 187.1	$ 112.3
Debt securities available-for-sale (amortized cost $612.4 million at December 31, 2020 and $557.3 million at December 31, 2019)	613.9	558.2
Accounts receivable	157.1	126.6
Inventories	28.0	17.3
Other current assets	30.1	16.6
Total current assets	1,016.2	831.0
Debt securities available-for-sale (amortized cost $226.7 million at December 31, 2020 and $299.3 million at December 31, 2019)	227.1	299.7
Right-of-use assets	82.8	74.3
Equity securities	38.2	55.9
Property and equipment, net	44.6	41.9
Deferred tax assets	319.4	—
Restricted cash	3.2	3.2
Other long-term assets	3.2	—
Total assets	$ 1,734.7	$ 1,306.0
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 168.7	$ 141.3
Convertible senior notes	—	408.8
Other current liabilities	17.8	15.2
Total current liabilities	186.5	565.3
Convertible senior notes	317.9	—
Noncurrent operating lease liabilities	94.4	86.7
Other long-term liabilities	9.7	17.1
Total liabilities	608.5	669.1
Stockholders' equity:		
Preferred stock, $0.001 par value; 5.0 shares authorized; no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, $0.001 par value; 220.0 shares authorized; issued and outstanding shares were 93.5 million and 92.3 million at December 31, 2020 and 2019, respectively	0.1	0.1
Additional paid-in capital	1,849.7	1,768.1
Accumulated other comprehensive income	1.8	1.4
Accumulated deficit	(725.4)	(1,132.7)
Total stockholders' equity	1,126.2	636.9
Total liabilities and stockholders' equity	$ 1,734.7	$ 1,306.0

See accompanying notes to consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS INCOME

AND COMPREHENSIVE INCOME

(in millions, except per share data)	Year Ended December 31, 2020	2019	2018
Revenues:			
Product sales, net	$ 994.1	$ 752.9	$ 409.6
Collaboration revenue	51.8	35.2	41.6
Total revenues	1,045.9	788.1	451.2
Operating expenses:			
Cost of sales	10.1	7.4	4.9
Research and development	275.0	200.0	155.8
Acquired in-process research and development	164.5	154.3	4.8
Selling, general and administrative	433.3	354.1	248.9
Total operating expenses	882.9	715.8	414.4
Operating income	163.0	72.3	36.8
Other (expense) income:			
Interest expense	(32.8)	(32.0)	(30.5)
Unrealized loss on restricted equity securities	(17.7)	(13.0)	—
Loss on extinguishment of convertible senior notes	(18.4)	—	—
Investment income and other, net	12.6	19.2	15.5
Total other expense, net	(56.3)	(25.8)	(15.0)
Income before (benefit from) provision for income taxes	106.7	46.5	21.8
(Benefit from) provision for income taxes	(300.6)	9.5	0.7
Net income	407.3	37.0	21.1
Unrealized gain (loss) on debt securities available-for-sale	0.4	3.4	(0.1)
Comprehensive income	$ 407.7	$ 40.4	$ 21.0
Net income per share, basic	$ 4.38	$ 0.40	$ 0.23
Net income per share, diluted	$ 4.16	$ 0.39	$ 0.22
Weighted average common shares outstanding, basic	93.1	91.6	90.2
Weighted average common shares outstanding, diluted	97.8	95.7	95.4

See accompanying notes to consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in millions)	Common Stock Shares	Common Stock $	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2017	88.8	$ 0.1	$ 1,572.8	$ (1.9)	$ (1,198.8)	$ 372.2
Net income	—	—	—	—	21.1	21.1
Unrealized loss on debt securities available-for-sale	—	—	—	(0.1)	—	(0.1)
Share-based compensation expense	—	—	58.1	—	—	58.1
Issuance of common stock for vested restricted stock units	0.4	—	—	—	—	—
Issuance of common stock for stock option exercises	1.6	—	29.5	—	—	29.5
Balances at December 31, 2018	90.8	$ 0.1	$ 1,660.4	$ (2.0)	$ (1,177.7)	$ 480.8
Net income	—	—	—	—	37.0	37.0
Unrealized gain on debt securities available-for sale	—	—	—	3.4	—	3.4
Share-based compensation expense	—	—	75.3	—	—	75.3
Cumulative-effect adjustment to equity due to adoption of ASU 2016-02	—	—	—	—	8.0	8.0
Issuance of common stock for vested restricted stock units	0.4	—	—	—	—	—
Issuance of common stock for stock option exercises	1.0	—	27.3	—	—	27.3
Issuance of common stock for employee stock purchase plan	0.1	—	5.1	—	—	5.1
Balances at December 31, 2019	92.3	$ 0.1	$ 1,768.1	$ 1.4	$ (1,132.7)	$ 636.9
Net income	—	—	—	—	407.3	407.3
Unrealized gain on debt securities available-for-sale, net of tax	—	—	—	0.4	—	0.4
Share-based compensation expense	—	—	100.0	—	—	100.0
Equity component of repurchased convertible senior notes, net	—	—	(47.5)	—	—	(47.5)
Issuance of common stock for vested restricted stock units	0.5	—	—	—	—	—
Issuance of common stock for stock option exercises	0.6	—	23.5	—	—	23.5
Issuance of common stock for employee stock purchase plan	0.1	—	5.6	—	—	5.6
Balances at December 31, 2020	93.5	$ 0.1	$ 1,849.7	$ 1.8	$ (725.4)	$ 1,126.2

See accompanying notes to consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)	Year Ended December 31, 2020	2019	2018
Cash Flows from Operating Activities:			
Net income	$ 407.3	$ 37.0	$ 21.1
Reconciliation of net income to net cash provided by operating activities:			
Share-based compensation expense	100.0	75.3	58.1
Depreciation	8.6	7.4	4.0
Amortization of debt discount	20.0	18.9	17.6
Amortization of debt issuance costs	1.4	1.4	1.3
Change in fair value of equity securities	17.7	13.0	—
Deferred income taxes (including benefit from valuation allowance release)	(310.7)	—	—
Loss on extinguishment of convertible senior notes	18.4	—	—
Other	3.7	(1.2)	1.0
Changes in operating assets and liabilities:			
Accounts receivable	(30.5)	(69.2)	(25.1)
Inventories	(10.7)	(6.4)	(3.5)
Accounts payable and accrued liabilities	26.9	54.0	24.2
Other assets and liabilities, net	(23.6)	16.8	2.7
Net cash provided by operating activities	228.5	147.0	101.4
Cash Flows from Investing Activities:			
Purchases of debt securities available-for-sale	(735.5)	(797.2)	(545.9)
Sales and maturities of debt securities available-for-sale	750.5	669.7	327.8
Purchases of equity securities	—	(68.9)	—
Purchases of property and equipment	(10.9)	(14.7)	(24.8)
Net cash provided by (used in) investing activities	4.1	(211.1)	(242.9)
Cash Flows from Financing Activities:			
Issuances of common stock under benefit plans	29.1	32.4	29.5
Partial repurchase of convertible senior notes	(186.9)	—	—
Net cash (used in) provided by financing activities	(157.8)	32.4	29.5
Change in cash and cash equivalents and restricted cash	74.8	(31.7)	(112.0)
Cash and cash equivalents and restricted cash at beginning of period	115.5	147.2	259.2
Cash and cash equivalents and restricted cash at end of period	$ 190.3	$ 115.5	$ 147.2
Supplemental Disclosure:			
Non-cash capital expenditures	$ 1.4	$ 1.0	$ 2.3
Right-of-use assets acquired through operating leases	$ 12.8	$ 77.1	$ —
Cash paid for interest	$ 11.6	$ 11.6	$ 11.6
Cash paid for income taxes	$ 15.3	$ 0.5	$ —

See accompanying notes to consolidated financial statements.

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

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.

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, endocrine and psychiatric-based diseases and disorders. We had no foreign-based operations during any of the years presented.

Reclassifications. Certain amounts in prior year periods have been reclassified to conform with the presentation adopted in the current year.

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.

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

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

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

assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security is compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded, limited by the amount that the fair value is less than the amortized cost basis. Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive income or loss, as applicable.

Accrued interest receivables on debt securities available-for-sale totaled $3.7 million at December 31, 2020. We do not measure an allowance for credit losses for accrued interest receivables. For the purposes of identifying and measuring an impairment, accrued interest is excluded from both the fair value and amortized cost basis of the debt security. Uncollectible accrued interest receivables associated with an impaired debt security are reversed against interest income upon identification of the impairment. No accrued interest receivables were written off during 2020, 2019 or 2018.

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

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

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

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

Investments in debt securities available-for-sale are classified as Level 2 and carried at fair value. We estimate the fair value of debt securities available-for-sale by utilizing third-party pricing services. These pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. Such inputs include market pricing based on real-time trade data for similar instruments, issuer credit spreads, benchmark yields, broker/dealer quotes and other observable inputs. We validate valuations obtained from third-party pricing services by understanding the models used, obtaining market values from other pricing sources, and analyzing data in certain instances.

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

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

There were no transfers between levels in the fair value hierarchy during 2020 or 2019.

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 $8.6 million for 2020, $7.4 million for 2019 and $4.0 million for 2018.

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 the 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. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Product Sales, Net. In the U.S., our product sales, net consist of sales of INGREZZA, primarily to specialty pharmacy providers and a specialty distributor, and sales of ONGENTYS, primarily to wholesale distributors. We recognize product sales, net when the customer obtains control of our product, which occurs at a point in time, typically upon delivery of our product to the customer.

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. Such estimates are based on information received from external sources (such as written or oral information obtained from our customers with respect to their period-end inventory levels and sales to end-users during the reporting period), as supplemented by management's judgement. 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 at the time of sale, 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.

Government Rebates. We are obligated to pay rebates for mandated discounts under the Medicaid Drug Rebate Program. The liability for such rebates consists 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 estimates are based on actual historical rebates by state, estimated payor mix, state and federal regulations and relevant contractual terms, as supplemented by management's judgement. Our rebate accrual calculations require us to project the magnitude of our sales, by state, that will be subject to these rebates. There is a significant time-lag in our receiving rebate notices from each state (generally, several months or longer after a sale is recognized). Estimated rebates are recorded as a reduction of revenue in the period the related sale 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 our products to our customers, and the contracted price, or the price at which our customers sell our products 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 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.

Co-payment Assistance. We offer financial assistance to qualified patients 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.

Distributor and Other Fees. In connection with the sales of our products, we pay distributor and other fees to certain customers that provide us with inventory management, data and distribution services, which are generally recorded as a reduction of revenue. To the extent we can demonstrate a separable benefit and fair value for these services, we classify the associated costs in selling, general and administrative expenses. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale.

Product Returns. For INGREZZA, we offer our customers product return rights primarily limited to errors in shipment and damaged product. We do not permit returns of INGREZZA for expiring or expired product. Accordingly, we have limited return risk resulting from INGREZZA product sales and therefore do not record an associated returns allowance. For ONGENTYS, we offer our customers product return rights primarily limited to errors in shipment, damaged product, and expiring or expired product, provided it is within a specified period around the product expiration date, as set forth in the associated distribution agreement. Once product is returned, it is destroyed. Where actual returns history is not available, we estimate the associated returns allowance based on benchmarking data for similar products and industry experience. We record this estimate as a reduction of revenue in the period the related sale is recognized. To date, actual product returns have not differed materially from our estimates.

Collaboration Revenues. 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 Revenues. 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 the associated collaboration products. 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. Financial instruments that potentially subject us to concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. We have established guidelines to limit our exposure to credit risk by diversifying our investment portfolio and by placing investments with high credit quality financial

institutions and maturities that maintain safety and liquidity. To date, we have not experienced any credit losses and do not believe we are exposed to any significant credit risk in relation to these financial instruments.

We are also subject to credit risk from our accounts receivable related to our product sales. Our two largest customers represented approximately 86% of our product revenues for both 2020 and 2019, and the significant majority of our accounts receivable balances at December 31, 2020 and 2019. For 2018, our three largest customers represented approximately 93% of our product revenue and substantially all of our accounts receivable balance at December 31, 2018. To date, we have not experienced any significant losses with respect to the collection of these accounts receivable.

Cost of Sales. Cost of sales includes third-party manufacturing, transportation, freight and indirect overhead costs associated with the manufacture and distribution of INGREZZA and ONGENTYS, royalty fees on net sales of ORILISSA and ORIAHNN, 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, including event based milestones.

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. Advertising costs are expensed when services are performed, or goods are delivered. We incurred advertising costs related to INGREZZA and ONGENTYS of $64.8 million for 2020, $40.6 million for 2019 and $20.5 million for 2018.

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 predefined company-specific performance-based criteria. Expense related to these PRSUs is generally recognized ratably over the expected performance period once the predefined performance-based criteria for vesting becomes probable.

Income Taxes. Our income tax benefit (provision) is computed under the asset and liability method. Significant estimates are required in determining our income tax benefit (provision). Some of these estimates are based on interpretations of existing tax laws or regulations. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts (temporary differences) at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which it is more likely than not that some portion or all of the deferred tax assets, including net operating losses and tax credits, will not be realized. We periodically re-assess the need for a valuation allowance against our deferred tax assets based on various factors including our historical earnings experience by

taxing jurisdiction, and forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration. Significant judgment is required in making this assessment and, to the extent that a reversal of any portion of our valuation allowance against our deferred tax assets is deemed appropriate, a tax benefit will be recognized against our income tax provision in the period of such reversal. Prior to 2020, we recorded a valuation allowance that fully offset our deferred tax assets. On December 31, 2020, based on our evaluation of various factors, such as our achievement of a cumulative three-year income position as of December 31, 2020, as well as our consideration of forecasts of future operating results and utilization of net operating losses and tax credits prior to their expiration, we released substantially all of our valuation allowance against our deferred tax assets and recorded a corresponding income tax benefit. Refer to Note 9 to the consolidated financial statements for more information.

We recognize tax benefits from uncertain tax positions only if it is more likely than not that the tax position will be sustained upon examination by the tax authorities based on the technical merits of the position. An adverse resolution of one or more of these uncertain tax positions in any period could have a material impact on the results of operations for that period.

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

Convertible debt instruments that may be settled entirely or partly in cash (such as the 2024 Notes) may, in certain circumstances where the borrower has the ability and intent to settle in cash, be accounted for under the treasury stock method. We issued the 2024 Notes with a combination settlement feature, which we have the ability and intent to use upon conversion of the 2024 Notes, to settle the principal amount of debt for cash and the excess of the principal portion in shares of our common stock. As a result, of the approximately 5.0 million shares underlying the 2024 Notes at December 31, 2020, only the shares required to settle the excess of the principal portion would be considered dilutive under the treasury stock method. Further, approximately 0.2 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 2016-13. On January 1, 2020, we adopted Accounting Standards Update, or ASU, 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, using the modified retrospective transition method. For debt securities available-for-sale, the standard requires an investor to determine whether a decline in the fair value below the amortized cost basis of the investment is due to credit-related factors. Credit-related impairment is recognized as an allowance for credit loss on the balance sheet with a corresponding adjustment to earnings. Credit losses are limited to the amount by which the investment's amortized cost basis exceeds its fair value and may be subsequently reversed if conditions change. Any impairment that is not credit related is recognized in other comprehensive income or loss, as applicable, net of applicable taxes.

The adoption of ASU 2016-13 did not result in a cumulative-effect adjustment to retained earnings. The comparative prior period information continues to be reported under the accounting standards in effect during those periods.

Recently Issued Accounting Pronouncements.

ASU 2019-12. In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application of Topic 740. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years, with early adoption permitted in any interim period for which financial statements have not yet been made available for issuance. We are currently evaluating the effect ASU 2019-12 will have on our condensed consolidated financial statements and related disclosures.

ASU 2020-06. In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting*

for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments, and amends existing earnings-per-share, or EPS, guidance by requiring that an entity use the if-converted method when calculating diluted EPS for convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years, with early adoption permitted for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. We plan to adopt ASU 2020-06 effective January 1, 2022 and are currently evaluating the effect ASU 2020-06 will have on our consolidated financial statements and related disclosures.

2. License and Collaboration Agreements

Under the terms of the following license and collaboration agreements, we may be required to make milestone payments upon achievement of certain development and regulatory activities of up to $8.5 billion and pay royalties on future sales, if any, of commercial products resulting from these agreements.

Takeda Pharmaceutical Company Limited. We entered into an exclusive license agreement with Takeda Pharmaceutical Company Limited, or Takeda, which became effective in July 2020, to develop and commercialize certain compounds in Takeda's early to mid-stage psychiatry pipeline. Specifically, Takeda granted us an exclusive license to the following seven assets: (i) NBI-1065844 (TAK-831) for schizophrenia, (ii) NBI-1065845 (TAK-653) for treatment-resistant depression, (iii) NBI-1065846 (TAK-041) for anhedonia (which together with the NBI-1065845 are referred to as the Phase II Ready Assets), and (iv) four non-clinical stage assets, or the Non-Clinical Assets.

NBI-1065844 is deemed a royalty-bearing product under the license agreement pursuant to which we will be responsible for all costs and expenses associated with the development, manufacture, and commercialization of such asset, subject to certain exceptions, and Takeda will be eligible to receive development and commercial milestones and royalties with respect to such asset, or a Royalty-Bearing Product, and Takeda will retain the right to opt-in to a profit sharing arrangement pursuant to which we and Takeda will equally share in the operating profits and losses related to such asset, subject to certain exceptions, in lieu of receiving milestones and royalties, or a Profit-Share Product. Subject to specified conditions, Takeda may elect to exercise such opt-in right for NBI-1065844 before we initiate a Phase III clinical trial. Each of the Phase II Ready Assets is deemed a Profit-Share Product and Takeda will retain the right to opt-out of the profit-sharing arrangement for such asset pursuant to which such asset would become a Royalty-Bearing Product. Takeda may elect to exercise such opt-out rights with respect to a Phase II Ready Asset immediately following the completion of the second Phase II clinical trial for such Phase II Ready Asset. In addition, under certain circumstances related to the development and commercialization activities to be performed by us, Takeda may elect to opt-out of the profit-sharing arrangement for a Profit-Share Product before the initiation of a Phase III clinical trial for such product.

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

In connection with the agreement, we paid Takeda $120.0 million upfront, which, including certain transaction related costs, was expensed as in-process research and development, or IPR&D, in the third quarter of 2020. Pursuant to the terms of the agreement, Takeda may also be entitled to receive additional payments of up to $1.9 billion upon the achievement of certain event-based milestones associated with Royalty-Bearing Products, as well as receive royalties on the future net sales of Royalty-Bearing Products. On a country-by-country and product-by-product basis, royalty payments would commence on the first commercial sale of a Royalty-Bearing Product and terminate on the later of (i) the expiration of the last patent covering such Royalty-Bearing Product in such country, (ii) a number of years from the first commercial sale of such Royalty-Bearing Product in such country and (iii) the expiration of regulatory exclusivity for Royalty-Bearing Product in such country.

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

In connection with the exercise of the option, we paid Idorsia $45.0 million upfront, which we expensed as IPR&D in the second quarter of 2020. Further, as part of the research collaboration, we provided Idorsia with an incremental $7.2 million in funding, which we recorded as a prepaid asset and is being expensed over the two-year research collaboration term.

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

Xenon Pharmaceuticals, Inc. In December 2019, we entered into a license and collaboration agreement with Xenon Pharmaceuticals Inc., or Xenon, to identify, research, and develop sodium channel inhibitors, including clinical candidate NBI-921352 (XEN901) and three preclinical candidates, 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 receive additional payments of up to $1.7 billion upon the achievement of certain event-based milestones, as well as receive royalties on the future 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.

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

In connection with the agreement, we paid Voyager $115.0 million upfront and purchased $50.0 million of Voyager's common stock at $11.9625 per share, representing approximately 4.2 million shares. Pursuant to the terms of the agreement, Voyager may also be entitled to receive additional payments of up to $1.7 billion upon the achievement of certain event-based milestones, as well as receive royalties on the future 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 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.

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

BIAL – Portela & Ca, S.A. We acquired the U.S. and Canada rights to ONGENTYS® from BIAL in the first quarter of 2017. We launched ONGENTYS in the U.S. in September 2020, after receiving FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients in April 2020. FDA approval for ONGENTYS for Parkinson's disease resulted in a $20.0 million event-based payment to BIAL, which we expensed as R&D in the second quarter of 2020. We further recognized R&D expense of $10.0 million in each 2019 and 2018 in connection with BIAL's achievement of certain regulatory event-based milestones related to then ongoing development of ONGENTYS. Pursuant to the terms of the agreement, BIAL may also be entitled to receive additional payments of up to $75.0 million upon the achievement of certain event-based milestones.

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

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

***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.

Since inception of the agreement, we have recognized revenue of $19.8 million associated with the delivery of a technology license and existing know-how and $15.0 million associated with the achievement of a certain event-based milestone. We further recognized revenue of $2.7 million in 2020 and $0.9 million in 2019 in connection with the ongoing KINECT-HD study, a placebo-controlled Phase III study of valbenazine in adult Huntington's disease patients with chorea. In accordance with our continuing performance obligations, $6.7 million of the $30.0 million upfront payment received from MTPC is being deferred and will be recognized as revenue over the ongoing study period using an input method according to costs incurred to-date relative to estimated total costs associated with the study.

Pursuant to the terms of the agreement, we may also be entitled to receive additional payments of up to $70.0 million upon the achievement of certain event-based milestones, receive payments for the manufacture of certain pharmaceutical products, as well as receive royalties on the future net sales of any collaboration product 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.

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

AbbVie received approval for ORILISSA for the management of moderate to severe endometriosis pain in women from the FDA in July 2018 and Health Canada in October 2018. In May 2020, AbbVie received FDA approval for ORIAHNN for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. We recognized sales-based royalties on AbbVie net sales of ORILISSA and ORIAHNN of $19.2 million in 2020, $14.3 million in 2019 and $1.6 million in 2018.

FDA approval for ORIAHNN for uterine fibroids resulted in the achievement of a $30.0 million event-based milestone, which we recognized as collaboration revenue in the second quarter of 2020. In 2019, we recognized collaboration revenue of $20.0 million in connection with the FDA's acceptance of AbbVie's NDA submission for the approval of ORIAHNN for uterine fibroids. In 2018, we recognized collaboration revenue of $40.0 million in connection with the FDA's approval for ORILISSA for endometriosis.

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

Under the terms of the agreement, AbbVie is responsible for all third-party 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.

3. Debt Securities

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

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

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

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

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

	Less Than 12 Months		12 Months or Longer		Total	
(in millions)	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Securities of government-sponsored entities	$ 95.0	$ (0.1)	$ —	$ —	$ 95.0	$ (0.1)

At December 31, 2020, our security portfolio consisted of 148 securities related to investments in debt securities available-for-sale, of which 30 securities were in an unrealized loss position.

Our investments in corporate debt securities in an unrealized loss position at December 31, 2020 are of high credit quality (rated A or higher). Unrealized losses on these investments were primarily due to changes in interest rates. We do not intend to sell these investments and it is not more likely than not that we will be required to sell these investments before recovery of their amortized cost basis.

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

	Less Than 12 Months		12 Months or Longer		Total	
(in millions)	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 186.1	$ (0.1)	$ —	$ —	$ 186.1	$ (0.1)

4. Fair Value Measurements

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

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

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

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

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

	Year Ended December 31,		
(in millions)	**2020**	**2019**	**2018**
Beginning balance	$ 55.9	$ —	$ —
Purchases	—	68.9	—
Unrealized loss included in earnings	(17.7)	(13.0)	—
Ending balance	$ 38.2	$ 55.9	$ —

At December 31, 2020, the discount for lack of marketability used in the valuation analysis of equity securities ranged from 15.0% to 34.0% (weighted average of 24.8%). The discount for lack of marketability was weighted by the relative fair value of the instruments. A significant increase (decrease) in the discount for lack of marketability in isolation would result in a significantly lower (higher) fair value measurement. Unrealized gains and losses on equity securities are included in other income (expense), net.

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

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

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

(ii) during the 5 business-day period immediately after any 5 consecutive trading-day period (the measurement period) in which the trading price (as defined in the 2024 Indenture) per $1,000 principal amount of the

2024 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day;

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

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

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

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

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

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

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

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

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

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

We are required to separately account for the liability and equity components of the 2024 Notes, as they may be settled entirely or partially in cash upon conversion in a manner that reflects our economic interest cost. The liability component of the instrument was valued in a manner that reflects the market interest rate for a similar nonconvertible instrument at the date of issuance. The initial carrying value of the liability component of $368.3 million was calculated using a 7.5% assumed borrowing rate. The equity component of $149.2 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the 2024 Notes and was recorded in additional paid-in capital on the consolidated balance sheet at the issuance date. That equity component is treated as a discount on the liability component of the 2024 Notes, which is amortized over the seven-year term of the 2024 Notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. At December 31, 2020, the remaining period over which the discount on the liability component will be amortized was approximately 3.4 years.

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

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

In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. We accounted for the partial repurchase of the 2024 Notes as a debt extinguishment. As a result, we attributed $130.7 million of the aggregate repurchase price to the liability component based on the fair value of the liability component immediately before extinguishment. The fair value of the liability component was calculated at settlement using a discounted cash flow analysis with a discount rate of 3.37%, which was the market rate for similar notes that have no conversion rights. The difference of $56.3 million between the fair value of the aggregate consideration remitted to certain holders of the 2024 Notes and the fair value of the liability component was attributed to the reacquisition of the equity component and recognized as a reduction to additional paid-in capital. The carrying amount of the liability of $112.4 million at settlement was recognized as a reduction to convertible senior notes and resulted in an $18.4 million loss on extinguishment.

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

	December 31,	
(in millions)	**2020**	**2019**
Principal	$ 381.3	$ 517.5
Deferred financing costs	(4.0)	(6.9)
Debt discount, net	(59.4)	(101.8)
Net carrying amount	$ 317.9	$ 408.8

The 2024 Notes were recorded at the estimated value of a similar non-convertible instrument on the date of issuance and accretes to the face value of the 2024 Notes over their seven-year term. The fair value of the 2024 Notes, which was estimated utilizing market quotations from an over-the-counter trading market (Level 2), was $514.3 million and $596.8 million at December 31, 2020 and 2019, respectively.

6. Other Balance Sheet Details

Inventories consisted of the following:

	December 31,	
(in millions)	**2020**	**2019**
Raw materials	$ 16.6	$ 14.1
Work in process	2.4	1.5
Finished goods	9.0	1.7
Total inventories	$ 28.0	$ 17.3

Property and equipment, net, consisted of the following:

	December 31,	
(in millions)	**2020**	**2019**
Tenant improvements	$ 29.5	$ 26.3
Scientific equipment	39.2	33.5
Computer equipment	13.9	12.5
Furniture and fixtures	3.7	3.2
	86.3	75.5
Less accumulated depreciation	(41.7)	(33.6)
Total property and equipment, net	$ 44.6	$ 41.9

Accounts payable and accrued liabilities consisted of the following:

	December 31,	
(in millions)	**2020**	**2019**
Accrued employee related costs	$ 38.2	$ 38.9
Revenue-related reserves for discounts and allowances	34.6	30.6
Accrued development costs	32.9	25.5
Accrued Branded Prescription Drug Fee	23.6	4.9
Accounts payable and other accrued liabilities	39.4	41.4
Total accounts payable and accrued liabilities	$ 168.7	$ 141.3

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

	December 31,	
(in millions)	**2020**	**2019**
Cash and cash equivalents	$ 187.1	$ 112.3
Restricted cash	3.2	3.2
Total cash, cash equivalents and restricted cash	$ 190.3	$ 115.5

7. Net Income Per Share

Net income per share was calculated as follows:

	Year Ended December 31,		
(in millions, except per share data)	2020	2019	2018
Net income - basic and diluted	$ 407.3	$ 37.0	$ 21.1
Weighted-average common shares outstanding:			
Basic	93.1	91.6	90.2
Effect of dilutive securities:			
Stock options	2.4	2.6	3.2
Restricted stock units	0.5	0.4	0.6
2024 Notes	1.8	1.1	1.3
Diluted	97.8	95.7	95.4
Net income per share:			
Basic	$ 4.38	$ 0.40	$ 0.23
Diluted	$ 4.16	$ 0.39	$ 0.22

Shares which have been excluded from diluted per share amounts because their effect would have been anti-dilutive were 2.5 million, 2.1 million and 0.9 million for 2020, 2019 and 2018, respectively.

Note 8. Share-Based Compensation

In May 2011, we adopted the 2011 Equity Incentive Plan, as amended, or the 2011 Plan. The 2011 Plan authorized 21 million shares of common stock for issuance and allowed for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, or RSUs, performance stock awards, performance-based restricted stock units, or PRSUs, and certain other awards. During 2020, the 2011 Plan was merged into the 2020 Plan (defined below). As a result, there were no shares of common stock remaining available for future grant under the 2011 Plan.

In May 2018, we adopted the 2018 Employee Stock Purchase Plan, or ESPP, pursuant to which 0.3 million shares of common stock are authorized for issuance. At December 31, 2020, 0.2 million shares of common stock remain available for future grant under the 2018 ESPP.

In May 2020, we adopted the 2020 Equity Incentive Plan, or the 2020 Plan. The 2020 Plan authorized 3.3 million shares of common stock for issuance and allows for the grant of stock options, stock appreciation rights, restricted stock awards, RSUs, performance stock awards, PRSUs and certain other awards. The 2011 Plan was merged into the 2020 Plan and, as a result, all remaining shares in the 2011 Plan were transferred into the 2020 Plan. At December 31, 2020, 8.2 million shares of common stock remain available for future grant under the 2020 Plan.

Share-Based Compensation Expense. The effect of share-based compensation expense on our consolidated statements of income and comprehensive income by line-item follows:

	Year Ended December 31,		
(in millions)	2020	2019	2018
Selling, general and administrative expense	$ 66.3	$ 49.5	$ 31.9
Research and development expense	33.7	25.8	26.2
Total share-based compensation expense	$ 100.0	$ 75.3	$ 58.1

Share-based compensation expense by award-type follows:

	Year Ended December 31,		
(in millions)	2020	2019	2018
Stock options	$ 47.5	$ 36.5	$ 35.4
RSUs	44.2	30.5	21.9
PRSUs	5.3	5.6	—
ESPP	3.0	2.7	0.8
Total share-based compensation expense	$ 100.0	$ 75.3	$ 58.1

At December 31, 2020, unrecognized share-based compensation expense by award-type and the weighted-average period over which such expense is expected to be recognized, as applicable, were as follows:

(dollars in millions)	Unrecognized Expense	Weighted-Average Recognition Period
Stock options	$ 86.2	2.3 years
RSUs	$ 99.5	2.3 years

Stock Options. Typically, stock options have a ten-year term and vest over a three to four-year period. The exercise price of stock options granted is equal to the closing price of our common stock on the date of grant. We estimate the fair value of stock options using the Black-Scholes option-pricing model on the date of grant. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, term and interest rates. The weighted-average grant-date fair values of stock options granted were $45.67, $41.74 and $43.42 for 2020, 2019 and 2018, respectively.

The fair value of each stock option granted was estimated on the date of grant using the Black-Scholes option-pricing valuation model with the following weighted-average assumptions:

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	1.4 %	2.4 %	2.5 %
Expected volatility of common stock	48.5 %	54.8 %	59.5 %
Dividend yield	0.0 %	0.0 %	0.0 %
Expected option term	5.3 years	5.4 years	4.7 years

The weighted-average valuation assumptions were determined as follows:

- The expected volatility of common stock is estimated 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 interest rate for periods within the contractual life of a stock option is based upon observed interest rates appropriate for the expected term of our employee stock options.
- We have not historically declared or paid dividends and do not intend to do so in the foreseeable future.

A summary of activity related to stock options follows:

(in millions, except weighted average data)	Number of Stock Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2019	6.1	$ 52.62		
Granted	1.3	$ 103.44		
Exercised	(0.6)	$ 43.90		
Canceled	—	$ —		
Outstanding at December 31, 2020	6.8	$ 62.98	6.4 years	$ 235.4
Exercisable at December 31, 2020	4.7	$ 49.80	5.5 years	$ 218.2

The total intrinsic value of stock options exercised during 2020, 2019 and 2018 was $40.2 million, $64.3 million and $117.0 million, respectively. Cash received from stock option exercises during 2020, 2019 and 2018 was $23.5 million, $27.3 million and $29.5 million, respectively.

Restricted Stock Units. Typically, RSUs vest over a four-year period. The fair value of RSUs is based on the closing sale price of our common stock on the date of issuance. RSUs may be subject to a deferred delivery arrangement at the election of eligible employees.

A summary of activity related to RSUs follows:

(in millions, except weighted average data)	Number of RSUs	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Unvested at December 31, 2019	1.4	$ 74.77		
Granted	0.7	$ 102.92		
Released	(0.5)	$ 67.86		
Canceled	(0.1)	$ 84.95		
Unvested at December 31, 2020	1.5	$ 89.60	1.3 years	$ 147.5

The total fair value of RSUs that vested during 2020, 2019 and 2018 was $49.7 million, $36.1 million and $35.5 million, respectively.

Performance-Based Restricted Stock Units. PRSUs vest based on the achievement of certain predefined Company-specific performance criteria and expire four to five years from the grant date. 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.

A summary of activity related to PRSUs follows:

(in millions, except weighted average data)	Number of PRSUs	Weighted-Average Grant Date Fair Value	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Unvested at December 31, 2019	0.3	$ 59.62		
Granted	0.2	$ 102.90		
Released	(0.1)	$ 82.04		
Canceled	(0.2)	$ 45.67		
Unvested at December 31, 2020	0.2	$ 102.90	2.2 years	$ 15.8

At December 31, 2020, unrecognized share-based compensation expense for PRSUs was $17.0 million. The total fair value of PRSUs that vested during 2020 was $13.5 million. No PRSUs vested during 2019 or 2018.

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.

Note 9. Income Taxes

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

	Year Ended December 31,		
(in millions)	2020	2019	2018
Current:			
Federal	$ —	$ —	$ (0.1)
State	10.1	9.5	0.8
Total current taxes	10.1	9.5	0.7
Deferred:			
Federal	(287.5)	—	—
State	(23.2)	—	—
Total deferred taxes	(310.7)	—	—
(Benefit from) provision for income taxes	$ (300.6)	$ 9.5	$ 0.7

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

	Year Ended December 31,		
(in millions)	**2020**	**2019**	**2018**
Federal income taxes at 21% for 2020, 2019, 2018	$ 22.4	$ 9.8	$ 4.6
State income tax, net of federal benefit	5.5	4.0	0.4
Non-deductible expenses	0.6	0.8	0.4
Branded prescription drug fee	4.9	3.7	—
Share-based compensation expense	(6.7)	(12.8)	(9.8)
Officer compensation	3.7	3.1	0.9
Change in tax rate	3.3	(4.1)	(0.2)
Expired tax attributes	1.1	1.2	13.9
Research credits	(39.0)	(10.4)	(13.5)
Change in valuation allowance	(296.3)	13.9	4.3
Other	(0.1)	0.3	(0.3)
(Benefit from) provision for income taxes	$ (300.6)	$ 9.5	$ 0.7

Significant components of our deferred tax assets as of December 31, 2020 and 2019 are listed below.

	December 31,	
(in millions)	**2020**	**2019**
Deferred tax assets:		
Net operating losses	$ 111.4	$ 181.3
Research and development credits	109.6	71.9
Capitalized research and development	24.7	28.0
Share-based compensation expense	29.8	22.9
Operating lease assets	25.2	23.3
Intangible assets	86.7	49.3
Other	23.9	18.5
Total deferred tax assets	411.3	395.2
Deferred tax liabilities:		
Convertible senior notes	(13.8)	(24.1)
Operating lease liabilities	(19.9)	(18.2)
Other	(8.4)	(6.9)
Total deferred tax liabilities	(42.1)	(49.2)
Net of deferred tax assets and liabilities	369.2	346.0
Valuation allowance	(49.8)	(346.0)
Net deferred tax assets	$ 319.4	$ —

At December 31, 2020, our deferred tax assets were primarily the result of federal net operating loss carry forwards, capitalized research costs, acquired intangible assets and tax credit carryforwards. At December 31, 2020 and 2019, we recorded a valuation allowance of $49.8 million and $346.0 million, respectively, against our gross deferred tax asset balance.

At each reporting date, management considers new evidence, both positive and negative, that could affect its assessment of the future realizability of our deferred tax assets. At December 31, 2020, in part because we achieved three years of cumulative pretax income, management determined there is sufficient positive evidence to conclude that it is more likely than not deferred tax assets of $319.4 million are realizable. Accordingly, we recorded a net valuation release of $296.3 million on the basis of management's assessment. The remaining valuation allowance of $49.8 million consists primarily of state net operating loss and credit carryforwards for which management cannot conclude it is more likely than not to be realized. The release of the valuation allowance is reported under continuing operations as a benefit to income tax expense.

At December 31, 2020, we had federal and state income tax net operating loss carryforwards of $518.2 million and $340.8 million, respectively. The federal net operating losses will begin to expire in 2028, unless previously utilized.

California net operating losses will begin to expire in 2028 unless previously utilized 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 carryforwards of $92.1 million and $56.4 million, respectively. A portion of the federal R&D tax credit carryforwards expired in 2020. The remaining federal R&D tax credits will continue to expire beginning in 2021, 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 carryforwards to offset future taxable income may be subject to an annual limitation, pursuant to Internal Revenue Code Sections 382 and 383, as a result of ownership changes that could occur in the future. No ownership changes have occurred through December 31, 2020.

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 2020, 2019 or 2018.

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 carryforward 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 millions)	**2020**	**2019**	**2018**
Balance at January 1	$ 63.9	$ 54.8	$ 37.4
(Decrease) increase related to prior year tax positions	(5.7)	0.3	6.1
Increase related to current year tax positions	3.9	9.5	11.7
Settlements related to prior year tax positions	(0.2)	—	—
Expiration of the statute of limitations for the assessment of taxes	(1.1)	(0.7)	(0.4)
Balance at December 31	$ 60.8	$ 63.9	$ 54.8

We excluded those 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 total $3.9 million for current year tax positions, as reflected in the table above.

At December 31, 2020, we had $53.9 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

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

Our operating lease cost was $10.1 million for 2020 and $8.1 million for 2019. Cash paid for amounts included in the measurement of lease liabilities was $8.6 million for 2020 and $7.7 million for 2019.

Our operating leases had a weighted-average remaining lease term of approximately 10.3 years and 11.2 years at December 31, 2020 and 2019, respectively, and a weighted-average discount rate of 5.6% and 5.8% at December 31, 2020 and 2019, respectively.

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

(in millions)	**December 31, 2020**
Year ending December 31, 2021	$ 10.7
Year ending December 31, 2022	12.4
Year ending December 31, 2023	12.7
Year ending December 31, 2024	13.1
Year ending December 31, 2025	13.5
Thereafter	77.5
Total operating lease payments	139.9
Less accreted interest	35.2
Total operating lease liabilities	104.7
Less current operating lease liabilities	10.3
Noncurrent operating lease liabilities	$ 94.4

Note 1: Amounts presented in the table above exclude $19.7 million of non-cancelable future minimum lease payments for operating leases that have not yet commenced.

Note 2: Current operating lease liabilities are included in other current liabilities on the consolidated balance sheets.

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 $6.7 million, $4.9 million, and $1.8 million for 2020, 2019 and 2018, respectively.

Note 12. Selected Quarterly Financial Data (Unaudited)

A summary of our quarterly results follows:

(in millions, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2020:				
Total revenues	$ 237.1	$ 302.4	$ 258.5	$ 247.9
Total operating expenses [(1)]	$ 178.2	$ 225.8	$ 302.8	$ 176.1
Net income (loss) [(1)]	$ 37.4	$ 79.6	$ (57.6)	$ 347.9
Net income (loss) per share, basic [(1)]	$ 0.40	$ 0.86	$ (0.62)	$ 3.72
Net income (loss) per share, diluted [(1)]	$ 0.39	$ 0.81	$ (0.62)	$ 3.58
Weighted average common shares outstanding, basic	92.6	93.0	93.3	93.5
Weighted average common shares outstanding, diluted	97.0	98.2	93.3	97.2
Year Ended December 31, 2019:				
Total revenues	$ 138.4	$ 183.5	$ 222.1	$ 244.1
Total operating expenses [(2)]	$ 239.4	$ 149.1	$ 132.0	$ 195.3
Net (loss) income [(2)]	$ (102.1)	$ 51.3	$ 53.8	$ 34.0
Net (loss) income per share, basic [(2)]	$ (1.12)	$ 0.56	$ 0.59	$ 0.37
Net (loss) income per share, diluted [(2)]	$ (1.12)	$ 0.54	$ 0.56	$ 0.35
Weighted average common shares outstanding, basic	91.1	91.4	91.9	92.2
Weighted average common shares outstanding, diluted	91.1	94.8	96.1	97.2

(1) In connection with the payment of the upfront fee pursuant to our collaboration and license agreement with Idorsia, we recorded a charge of $46.0 million, accounted for as IPR&D, in the second quarter of 2020. In connection with the payment of the upfront fee pursuant to our collaboration with Takeda, we recorded a charge of $118.5 million, accounted for as IPR&D, in the third quarter of 2020.

(2) 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, 2020. 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, 2020, 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, 2020, 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, 2020, 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, 2020 and 2019, the related consolidated statements of income and comprehensive income, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 5, 2021 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 5, 2021

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 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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 2021 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of December 31, 2020. 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, 2020 and 2019

Consolidated Statements of Income and Comprehensive Income for the years ended December 31, 2020, 2019 and 2018

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2020, 2019 and 2018

Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019 and 2018

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: Reference:	Certificate of Incorporation, as amended 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: Reference:	Bylaws Incorporated by reference to Exhibit 3.2 of the Company's Quarterly Report on Form 10-Q filed on November 5, 2018
3.3	Description: Reference:	First Amendment of Bylaws Incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on February 4, 2020
3.4	Description: Reference:	Second Amendment of Bylaws Incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on August 28, 2020
4.1	Description: Reference:	Form of Common Stock Certificate Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-03172)
4.2	Description: Reference:	Indenture, dated as of May 2, 2017, by and between the Company and U.S. Bank National Association, as Trustee 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: Reference:	Form of Note representing the Company's 2.25% Convertible Notes due 2024 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: Reference:	Description of Common Stock of the Company Incorporated by reference to Exhibit 4.4 of the Company's Annual Report on Form 10-K filed on February 7, 2020
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
10.9**	Description:	Exclusive License Agreement dated June 12, 2020 between Takeda Pharmaceutical Company Limited and the Company
	Reference:	Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on August 3, 2020

Equity Plans and Related Agreements:

10.10+	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
10.11+	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
10.12+	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
10.13+	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
10.14+	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
10.15+	Description:	Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan
	Reference:	Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on August 3, 2020
10.16+	Description:	Form of Stock Option Grant Notice and Option Agreement for use under the Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan, and Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement for use under the Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan
	Reference:	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on August 3, 2020

Agreements with Officers and Directors:

10.17+	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
10.18+	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
10.19+	Description:	Employment Agreement dated November 3, 2014 between the Company and Kyle Gano
		Incorporated by reference to Exhibit 10.16 of the Company's Annual Report on Form 10-K filed on February 6, 2020
10.20+	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
10.21+	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
10.22+	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

10.23+	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:

10.24	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
10.25	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
10.26	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
10.27	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
10.28	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

\+ Management contract or compensatory plan or arrangement.

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

** Certain portions of the exhibit have been omitted because the omitted information is not material and would likely cause competitive harm if publicly disclosed.

*** 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 5, 2021

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

Date: February 5, 2021

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 5, 2021:

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

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-8 Nos. 333-175889, 333-190178, 333-197916, and 333-212871) pertaining to the 2011 Equity Incentive Plan of Neurocrine Biosciences, Inc.,

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

(3) 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.,

(4) 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

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

(6) Registration Statements (Form S-8 No. 333-240301) pertaining to the 2020 Equity Incentive Plan

of our reports dated February 5, 2021 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, 2020.

/s/ Ernst & Young LLP

San Diego, California
February 5, 2021

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 5, 2021

/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, 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;

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 5, 2021

/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, 2020 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 5, 2021

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, 2020 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 5, 2021

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