2025 Annual Report

NEUROCRINE® BIOSCIENCES

A Leading Biopharmaceutical Company Built on Strong Enterprise-Wide Momentum and Disciplined Strategic Diversification

COMMERCIAL

INGREZZA® (valbenazine) capsules

Tardive Dyskinesia & Chorea Associated with Huntington's Disease

Crenessity® (crinecerfont)

Classic Congenital Adrenal Hyperplasia

RESEARCH & DEVELOPMENT

Therapeutic Area Diversification:

- NEUROLOGY
- ENDOCRINOLOGY
- PSYCHIATRY
- IMMUNOLOGY

Psychiatry pipeline to deliver multiple first- and best-in-class medicines this decade

Redesigned R&D organization delivering diverse, high-quality candidates, enabling repeatable value creation opportunities

CRF-based therapies offer third growth horizon in endocrinology and metabolic disease

STRONG FINANCIAL POSITION

$2.7–2.8B
NET SALES
2026 INGREZZA Annual Guidance

~$301M
NET SALES
2025 CRENESSITY Sales in First Full Year

~$2.5B
CASH AND INVESTMENTS
as of 12/31/2025

Strong Balance Sheet

Durable Cash Flows

Attractive P&L Profile

"In 2026, we are focused on delivering strong, sustainable growth for INGREZZA® (valbenazine) and CRENESSITY® (crinecerfont) while advancing our pipeline anchored by Phase 3 programs, including osavampator in major depressive disorder and direclidine in schizophrenia. We expect this building momentum will create value for all stakeholders as Neurocrine is well positioned to improve the lives of even more patients in the years ahead."

Kyle W. Gano, Ph. D.
Chief Executive Officer

Neurocrine Well-Positioned to Drive Sustainable Growth and Value

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

or

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

For the transition period from _____to_____

Commission file number 0-22705

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0525145**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

6027 Edgewood Bend Court
San Diego, CA 92130
(858) 617-7600

(Address, including zip code, and telephone number of Registrant's principal executive offices)

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, $0.001 par value	NBIX	Nasdaq Global Select Market

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

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

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

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

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

Indicate by check mark 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 ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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, 2025, was $9.52 billion.

As of February 4, 2026, 100,363,463 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, 2025 are incorporated by reference into Part III of this Form 10-K.

TABLE OF CONTENTS

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 “aim,” “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.

PART I

Item 1. Business

Overview

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs. We are dedicated to discovering, developing, and commercializing life-changing treatments for patients with under-addressed neurological, psychiatric, endocrine, and immunological disorders.

Our portfolio of products includes U.S. Food and Drug Administration (FDA) approved treatments for tardive dyskinesia (TD), chorea associated with Huntington's disease, classic congenital adrenal hyperplasia due to 21-hydroxylase deficiency (CAH), and endometriosis and uterine fibroids in collaboration with AbbVie Inc. In addition, we have a diversified portfolio of multiple compounds in mid- to late-phase development across our core therapeutic areas and an expanding early-phase pipeline that includes a range of modalities including small molecules, peptides, proteins, antibodies, conjugates, and gene therapies.

We launched INGREZZA® (valbenazine) in the U.S. as the first FDA-approved drug for the treatment of TD in May 2017 and for the treatment of chorea associated with Huntington's disease in August 2023 and launched CRENESSITY® (crinecerfont) in the U.S. as a first-in-class FDA-approved treatment of CAH in December 2024.

We estimate that TD affects approximately 800,000 people in the U.S., that approximately 90% of the 40,000 people in the U.S. affected by Huntington's disease will develop chorea, and that CAH affects at least 20,000 people in the U.S. Key elements of our commercial strategy include maximizing the opportunities in INGREZZA and CRENESSITY through consistent and effective commercial execution, continued development of valbenazine as the best-in-class treatment for new patient populations, and to lead the evolving understanding of vesicular monoamine transporter 2 (VMAT2) biology and its role in disease. INGREZZA net product sales were $2.51 billion for 2025, $2.31 billion for 2024, and $1.84 billion for 2023 and accounted for a significant portion of our total net product sales during each of these years. CRENESSITY net product sales were $301.2 million for 2025 during its first full-year of launch.

Commercial Products

Product	Indication	Major Markets
INGREZZA® (valbenazine) capsules	Tardive Dyskinesia Chorea Associated with Huntington's Disease	U.S., Japan, Select Asian Markets [1]
Crenessity® (crinecerfont)	Classic Congenital Adrenal Hyperplasia	U.S.
Orilissa® elagolix tablets 150 mg 200 mg	Endometriosis	U.S. [2]
Oriahnn® elagolix, estradiol and norethindrone acetate capsules and elagolix capsules 300 mg/1 mg/0.5 mg and 300 mg	Uterine Fibroids	U.S. [2]

(1) INGREZZA is marketed as DYSVAL® (valbenazine) in Japan and REMLEAS® (valbenazine) in other select Asian markets, where Tanabe Pharma Corporation (formerly Mitsubishi Tanabe Pharma Corporation) retains commercialization rights.

(2) AbbVie retains global commercialization rights to elagolix.

Commercial Operations

We sell INGREZZA exclusively in the U.S. through a limited specialty network. Our customers include select specialty pharmacy providers, wholesale distributors, and specialty distributors. This focused distribution model allows us to closely manage product supply and support services. In addition, we sell CRENESSITY in the U.S. through a single specialty pharmacy provider, reflecting the product's rare disease focus and the need for high-touch distribution. We rely on third-party logistics providers for packaging, warehousing, and shipment of our products, leveraging their expertise to ensure timely delivery and broad patient access.

Our commercial reach is powered by a specialized sales force of approximately 600 professionals across the U.S. focused on neurology, psychiatry, long-term care, and rare diseases. In October 2025, we announced the planned expansion of the INGREZZA and CRENESSITY sales teams to maximize our commercial momentum. We expect this expansion, which we anticipate completing by the end of the first quarter of 2026, will boost our reach and frequency with prescribers, accelerating INGREZZA's penetration in both community and institutional settings and supporting the growth trajectory of CRENESSITY in the endocrinology and rare disease community. Importantly, a larger sales force and enhanced infrastructure also position us for potential upcoming product launches from our diversified pipeline, which includes late-stage candidates in major depressive disorder (osavampator) and schizophrenia (direclidine). We believe these investments in commercial capabilities will translate into sustained revenue growth and shareholder value, as we drive current product performance and prepare to bring new therapies to market.

Manufacturing and Supply

We currently rely on, and intend to continue to rely on, third-party manufacturers for the production of INGREZZA, CRENESSITY, and our product candidates. Raw materials, active pharmaceutical ingredients (API), and other supplies required for the production of INGREZZA, CRENESSITY, and our product candidates are sourced from various third-party manufacturers and suppliers in quantities adequate to meet our needs. We believe that continuing adequate supply of such raw materials and API is assured through long-term commercial supply and manufacturing agreements with multiple manufacturers and a continued focus on the expansion and diversification of our third-party manufacturing relationships.

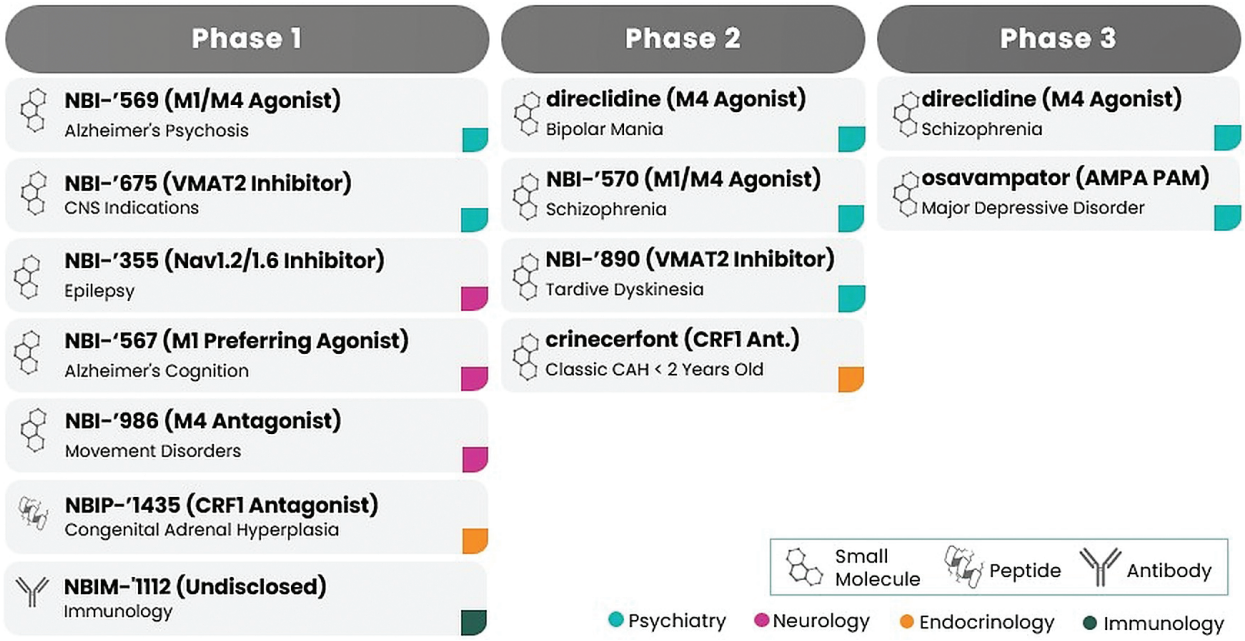
We believe our outsourced manufacturing strategy enables us to direct our financial resources to maximize our commercial opportunities with INGREZZA and CRENESSITY, invest in our internal research and development programs, and expand our clinical pipeline through business development opportunities.

Our third-party manufacturers, suppliers, and service providers may be subject to routine current Good Manufacturing Practice (cGMP) inspections by the FDA or comparable agencies in other jurisdictions. We depend on our third-party partners and our quality system oversight of them for continued compliance with cGMP requirements and applicable foreign standards.

Clinical Development Programs

Our research and development pipeline is robust and diversified across neurology, psychiatry, endocrinology, and immunology. This pipeline is fueled by core expertise in key areas of receptor biology developed over three decades. We are leveraging validated biological pathways and novel modalities to advance what we believe are potential first-in-class or best-in-class treatment candidates for patients with serious and under-addressed conditions. Our strategy is to maintain a balanced portfolio by stage of development and across our therapeutic areas of interest – targeting prevalent central nervous system (CNS) disorders such as depression, bipolar, and schizophrenia on one hand, and rare/orphan diseases such as CAH on the other – thereby positioning Neurocrine Biosciences to deliver a steady cadence of innovative medicines for years to come. By harnessing both novel validated mechanisms and our proprietary platforms, we aim to launch, on average, approximately one new medicine every two years, driving long-term value for patients and shareholders.

The following chart summarizes select clinical development programs.



Psychiatry Portfolio Highlights

Our psychiatry pipeline is built on mechanisms with strong biological rationale (glutamate, muscarinic, monoamine modulation) and is aligned with areas of high unmet need in mental illness. We believe the breadth of this portfolio, ranging from late-stage to first-in-human studies, positions us to deliver multiple potential first-in-class or best-in-class treatments in psychiatry over the coming years.

Osavampator (NBI-1065845)

Osavampator is a potential first-in-class alpha-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid (AMPA) receptor potentiator in development for adults with major depressive disorder (MDD) who have inadequate response to oral antidepressant treatment. Approximately one-third of over 16 million people in the U.S. who live with MDD do not achieve adequate relief with existing antidepressants, and osavampator's novel mechanism is being studied for antidepressant effects in these insufficient responders. We have initiated a comprehensive Phase 3 clinical program for osavampator in MDD (with initial topline data expected in 2027), including three acute randomized, double-blind, placebo-controlled studies, a randomized-withdrawal maintenance-of-effect study, and a long-term open-label safety extension, reflecting our confidence in osavampator's potential to elevate the standard of care in MDD. Osavampator was in-licensed from Takeda Pharmaceutical Company Limited (Takeda) in 2020, and we have exclusive worldwide rights to develop and commercialize osavampator, except in Japan, where Takeda has exclusive development and commercialization rights.

Direclidine (NBI-1117568)

Direclidine is an investigational oral agonist targeting the muscarinic M4 receptor, representing a novel mechanism for the treatment of schizophrenia and bipolar mania. Schizophrenia is a severe, disabling disorder affecting approximately 24 million people globally and more than 3 million people in the U.S., and roughly one-third of patients do not respond adequately to current antipsychotics. Current antipsychotics largely modulate dopamine receptors and can cause significant side effects; by contrast, direclidine's selective stimulation of M4 (a receptor involved in cholinergic neurotransmission) offers a new approach to treating psychosis and has the potential to help these patients and improve outcomes, and may avoid the safety and tolerability issues of commercially available antipsychotics and non-selective muscarinic agonists by not requiring coadministration with a peripheral muscarinic blocker. We have initiated a comprehensive Phase 3 clinical program for direclidine in schizophrenia (with initial topline data expected in 2027), including studies evaluating efficacy in patients experiencing an acute relapse of schizophrenia and long-term safety. In addition, we initiated a Phase 2 study evaluating direclidine in bipolar mania in the fourth quarter of 2025. Direclidine was in-licensed from Nxera Pharma UK Limited (Nxera) in 2021, and we retain global rights.

Early-Stage Psychiatry Programs

Our early-stage psychiatry pipeline is focused on muscarinic receptor modulators and next-generation VMAT2 inhibitors – both areas where we have deep expertise.

We have initiated a Phase 2 study of NBI-1117570, a dual M1/M4 muscarinic agonist intended for schizophrenia and other psychiatric indications. Based on its pharmacologic profile, we are also evaluating long-acting injectable formulations of NBI-1117570 that, if successful, could support development as a potential first-in-class long-acting antipsychotic designed to improve medication adherence (an important factor, as non-adherence is common in schizophrenia).

Another muscarinic agonist, NBI-1117569, is in Phase 1 development. NBI-1117569 targets M1/M4 receptors and is initially aimed at Alzheimer's disease-related psychosis – an area of immense unmet need, as no therapies are specifically approved for this condition. It is estimated that over 6 million Americans live with Alzheimer's, and neuropsychiatric symptoms (such as psychosis) pose significant challenges; our muscarinic agonist programs could represent a new therapeutic class addressing these symptoms without the downsides of antipsychotic off-label use.

Additionally, we have advanced next-generation VMAT2 inhibitors NBI-1065890 into Phase 2 development and NBI-1140675 into Phase 1 development. These compounds are engineered to have increased half-life, potency, and enhanced physiochemical properties relative to INGREZZA that may enable long-acting injectable administration. The aim is to develop long-acting injectable treatments for disorders characterized by abnormal involuntary movements (VMAT2 is the target of INGREZZA, the first FDA-approved drug for the treatment of TD). The new VMAT2 candidates could potentially treat a broader range of CNS conditions – such as additional mood or movement disorders – with less frequent dosing (e.g., monthly injections). These programs underscore our strategy of continual innovation even on proven targets: by delivering superior molecules, we can address patient needs such as convenience and adherence in chronic therapies.

Neurology Portfolio Highlights

Across our neurology pipeline, we focus on precision, mechanism-based approaches to epilepsy and movement disorders. Our programs are anchored in clinically and genetically validated targets, such as sodium channels and muscarinic receptors, where we believe selective modulation of disease-relevant pathways can meaningfully improve outcomes for patients whose conditions are not adequately controlled with existing therapies.

Early-Stage Neurology Programs

Our early-stage neurology programs aim to broaden our impact on neurological diseases.

NBI-1076986 is a selective M4 receptor antagonist in Phase 1 development, being evaluated for potential use in movement disorders such as dystonia. By selectively blocking the M4 muscarinic receptor, NBI-1076986 may normalize motor circuit activity in conditions of excessive cholinergic tone – an approach backed by preclinical models of dystonia and other hyperkinetic states.

NBI-1117567 is an investigational oral M1-preferring muscarinic agonist in Phase 1 development, being evaluated for the potential treatment of Alzheimer's disease, with the goal of improving cognition.

NBI-921355 is an investigational, selective inhibitor of voltage-gated sodium channels $Na_v1.2$ and $Na_v1.6$ in Phase 1 development for the potential treatment of certain types of epilepsy. $Na_v1.2$ and $Na_v1.6$ are predominantly expressed in excitatory neurons, and selective inhibition of these channels is intended to reduce pathological neuronal hyperexcitability while sparing $Na_v1.1$, which is mainly expressed in inhibitory interneurons. This mechanistic profile is designed to offer a more targeted approach than broad-spectrum sodium channel blockers and may translate into improved efficacy and tolerability for people living with epilepsy. If successful, NBI-921355 could provide a differentiated, mechanism-based treatment option for certain epilepsy syndromes that are not adequately controlled with existing antiseizure medications. NBI-921355 was in-licensed from Xenon Pharmaceuticals Inc. in 2019, and we retain global rights.

Endocrinology Portfolio Highlights

Our endocrinology pipeline underscores our commitment to innovative science with real-world impact. We take on conditions where patients have limited or suboptimal therapeutic options and aim to develop therapies that significantly advance care. We have a legacy of leadership in corticotropin-releasing factor (CRF) biology, which has already yielded CRENESSITY (a CRF type 1 receptor (CRF-1) antagonist) as a first-in-class FDA-approved treatment of CAH – and the first new treatment for CAH in over 70 years. Building on this foundation, we are advancing next-generation compounds targeting the CRF hormone pathways to address endocrine and metabolic diseases.

Early-Stage Endocrinology and Metabolic Programs

NBIP-01435 is an investigational, long-acting CRF-1 receptor antagonist peptide, administered as a subcutaneous injection, and is currently in Phase 1 development for the potential treatment of CAH. CAH is a rare genetic disorder in which cortisol synthesis is impaired, leading to life-threatening adrenal crises and excessive androgen levels from birth. Standard of care relies on supraphysiologic doses of glucocorticoids, which cause multiple well-established complications over time. CRF-1 receptor antagonism offers a novel therapeutic approach: by antagonizing CRF-1, NBIP-01435 aims to reduce the drive to produce excess androgens, thereby allowing more physiologic glucocorticoid dosing and better disease control. In December 2024, the FDA approved our oral CRF-1 receptor antagonist (CRENESSITY) as a first-in-class treatment of CAH, validating this mechanism. NBIP-01435, as a long-acting injectable, could further improve convenience and outcomes for CAH patients by providing sustained CRF-1 antagonism with less frequent dosing. This program represents the first biologic (peptide) to emerge from our internal discovery collaboration (with Sentia Medical Sciences, Inc.) on novel peptide CRF receptor antagonists, highlighting our expansion into biologics to complement our small-molecule portfolio.

NBIP-2118 is a highly innovative program targeting the CRF type 2 receptor (CRF-2) for the treatment of obesity and related metabolic diseases. NBIP-2118 is a CRF-2 selective agonist designed to engage a natural satiety pathway that may induce potent weight loss while preserving lean muscle mass – an issue with some current weight-loss drugs that mainly reduce fat but also muscle. Preclinical studies have shown that activating CRF-2 may enhance metabolism and energy expenditure in a favorable manner. We view NBIP-2118 as a potential first-in-class metabolic therapy, and plan to file an investigational new drug application (IND) with the FDA and advance NBIP-2118 into Phase 1 development in the first half of 2026. Obesity remains a global epidemic with few options that achieve substantial, sustainable, and quality weight loss without surgery. By leveraging the CRF-2 pathway (distinct from glucagon-like peptide-1 and other current targets), NBIP-2118 could potentially differentiate itself in this burgeoning field, including as a monotherapy, as an add-on or in combination with existing therapies, or as a follow-on or maintenance option for patients who do not respond to or do not achieve desired outcomes with current treatments. This CRF-2 agonist initiative also exemplifies our strategy to apply our neuroscience expertise to systemic disorders (like metabolic disease) where neuroendocrine pathways play a key role. Our confidence in this approach is bolstered by our internal know-how of over 30 years studying CRF biology and the success of our first CRF program in CAH.

Research and Discovery Engine and Ongoing Innovation

Underpinning all our programs is a reinvigorated research and discovery engine that we have built to be both innovative and efficient. We have refined our discovery efforts to focus on genetically or clinically validated mechanisms of action, which improves our probability of success in the clinic. At the same time, to maintain our leadership edge, we encourage the pursuit of first-in-class targets. Our goal is to advance at least four new programs into Phase 1 and two programs into Phase 2 each year going forward. This rapid cadence is enabled by internal investments in discovery (including medicinal chemistry, biologics, and translational sciences) and strategic business development when complementary opportunities arise. Our scientists are also leveraging state-of-the-art discovery platforms – from structure-based drug design to human translational models – to generate the next wave of development candidates, particularly in areas such as neurology and immunology.

Our clinical development pipeline is both deep and differentiated, comprising multiple late-stage opportunities with near-term registration potential and a wide base of early-stage programs designed to drive growth into the next decade. We believe our pipeline's breadth, scientific sophistication, and strategic alignment position us to deliver sustainable innovation and therapeutic breakthroughs to relieve suffering for people with great needs.

Intellectual Property

We actively seek to protect our products, product candidates, and related inventions and improvements that we consider important to our business. We own a portfolio of U.S. and ex-U.S. patents and patent applications and have also licensed rights to a number of U.S. and ex-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, uses to treat particular conditions, methods of administration, drug delivery technologies and delivery profiles, and methods of manufacturing.

Below is a description of the U.S. and ex-U.S. patents to INGREZZA and CRENESSITY:

- INGREZZA, our highly selective VMAT2 inhibitor approved in the U.S. for the treatment of TD and of chorea associated with Huntington's disease, is covered by 22 issued, FDA Orange Book-listed U.S. patents which are set to expire between 2027 and 2040. Patent term extension corresponding to regulatory approval delay of 552 days has been received for U.S. Patent No. 8,039,627, which now expires in 2031 and covers valbenazine, the active pharmaceutical ingredient contained in INGREZZA. In 2023, we entered into settlement agreements resolving all patent litigation brought by us against the companies that filed ANDAs seeking approval to market generic versions of INGREZZA, and all cases have been dismissed. Pursuant to the terms of the respective settlement agreements, such companies have the right to sell generic versions of INGREZZA in the U.S. beginning March 1, 2038, or earlier under certain circumstances.
- CRENESSITY, a CRF1 receptor antagonist approved in the U.S. for the treatment of CAH in adults and children, is covered by 4 issued, FDA Orange Book-listed U.S. patents which are set to expire between 2035 and 2041 (not including any potential patent term extensions), and pending patent applications, which, if issued, could expire at least as late as 2046. CRENESSITY has been granted seven years of orphan drug exclusivity by the FDA.

We also own, or have licensed rights to, patents covering our other products and earlier stage product candidates. 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 may obtain by future patent issuances.

Separately, the U.S., the EU, and Japan each 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 eight years in the EU, with marketing exclusivity lasting an additional two years, plus another optional year, in the EU, except that for biologics, the period of exclusivity in the U.S. is 12 years under the Biologics Price Competition and Innovation Act. In addition, if granted orphan drug designation, certain of our product candidates may also be eligible for marketing exclusivity in the U.S. for seven years and EU for 10 years.

See Part I, Item 1A. Risk Factors for a discussion of the challenges we may face in obtaining or maintaining patent and/or trade secret protection and Note 15 to the consolidated financial statements for a description of our legal proceedings related to intellectual property matters.

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.

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. Such developments by others (including the development of generic equivalents) may render our product candidates or technologies obsolete or noncompetitive.

- INGREZZA competes with AUSTEDO (deutetrabenazine), marketed by Teva Pharmaceuticals Industries, for the treatment of TD in adults and chorea associated with Huntington's disease. A once-daily dosing of AUSTEDO (AUSTEDO XR) was introduced in February 2023. Additionally, there are a number of commercially available medicines used to treat TD off-label, such as XENAZINE (tetrabenazine) and generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin. In addition, there are several programs in clinical development by other companies targeting Huntington's disease.
- CRENESSITY competes with high dose corticosteroid monotherapy which is the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive adrenocorticotropic hormone levels for patients with CAH. In the U.S. alone, there are more than two dozen companies manufacturing steroid-based products. In addition, there are several programs in clinical development by other companies targeting CAH.
- Our investigational treatments for potential use in schizophrenia and depression may in the future compete with several development-stage programs being pursued by other companies. In addition, there are a number of different anti-psychotic, including the muscarinic agonist COBENFY, and anti-depressant medications currently used in these patient populations.
- Our investigational treatments for potential use in neurology, psychiatry, endocrinology, obesity and related metabolic diseases, and immunology may in the future compete with numerous approved products and development-stage programs being pursued by several other companies.

Collaboration and License Agreements

See Note 11 to the consolidated financial statements for more information on our significant collaboration and license agreements.

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, and equivalent supranational and foreign laws, restrict business practices in the pharmaceutical industry. These laws include, without limitation, federal, state and foreign fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws and industry codes of conduct 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 U.S. federal Anti-Kickback Statute and equivalent foreign laws 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 programs such as a federal healthcare program, such as Medicare or Medicaid in the U.S.

Federal and equivalent foreign civil and criminal false claims laws and the federal civil monetary penalties law and equivalent foreign laws, 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 (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 and equivalent foreign laws.

We may be subject to HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (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 HIPAA (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 well 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 & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.

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

The U.S. Foreign Corrupt Practices Act (FCPA) prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Similar laws exist in other countries, such as the United Kingdom (UK) or in EU member states, which restrict improper payments to public and private parties. Many countries have laws prohibiting these types of payments within the respective country. In addition to these anti-corruption laws, we are subject to import and export control laws, tariffs, trade barriers, economic sanctions, and regulatory limitations on our ability to operate in certain foreign markets.

In August 2025, we received a civil investigative demand from the U.S. Department of Justice (DOJ) requesting certain documents and information related to our sales and marketing of INGREZZA. We are cooperating with the DOJ's request. No assurance can be given as to the timing or outcome of the DOJ's investigation. 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 and equivalent foreign 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 application (IND) and to equivalent foreign authorities before clinical trials can begin in humans. Typically, clinical evaluation involves a time consuming and costly multi-phase process.

Phase 1: 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 or in patients with the target disease.

Phase 2: 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 3: 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, the European Medicines Agency (EMA) and European Commission, or equivalent foreign authorities, 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 3 trials are completed, drug developers submit the results of preclinical studies and clinical trials to the FDA in the form of a new drug application (NDA) for approval to commence commercial sales. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act (PDUFA), the FDA has a goal of 10 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 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 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, 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 cGMP requirements and adequate to ensure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with Good Clinical Practice (GCP) requirements.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the 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 4 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., except for a certain limited number of drugs sold to certain Medicare beneficiaries beginning in 2023. The resulting prices may not be sufficient to generate an acceptable return to us or our corporate collaborators.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the U.S. will be sufficient to offset the costs of developing and making the drug available in the U.S. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 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 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. 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 indication(s) 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 pre-approval promotion of investigational drugs, as well as the promotion of off-label uses of approved drugs, and a company 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.

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 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 U.S., 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 obtained in the first instance or applied consistently.

Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of drug products and medical services, in addition to questioning their safety, efficacy and clinical appropriateness. 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 and CRENESSITY, 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 ensure 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.

Most recently, in August 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law, which, among other things, (1) directs the Secretary of the U.S. Department of Health and Human Services (HHS) to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, (2) redesigns the Medicare Part D prescription drug benefit to lower patient out-of-pocket costs and increase manufacturer liability and (3) requires drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. AUSTEDO and AUSTEDO XR, marketed by Teva Pharmaceuticals Industries, were selected for the Medicare drug negotiation program in 2025 (for initial price applicability year 2027) and CMS has announced a negotiated maximum fair price (MFP) for these products that is lower than their pre-negotiation prices. Lower negotiated prices for AUSTEDO and AUSTEDO XR may increase competitive pressures on INGREZZA, including heightened pricing pressure and potential adverse effects on formulary coverage.

While the Medicare drug negotiation program targets high-expenditure drugs/biologics that have been on the market for several years without generic or biosimilar competition, we were notified in January 2025 that INGREZZA qualifies for the small biotech exception, which provides an exemption from selection for price negotiation until 2027 (for initial price applicability year 2029, pursuant to which negotiated pricing would go into effect, if selected).

Additionally, on January 1, 2025, CMS implemented those provisions of the IRA establishing a new Medicare Part D manufacturer discount program. Under this discount program and subject to certain exceptions, manufacturers must give a 10 percent discount on Part D program drugs in the initial coverage phase, and a 20 percent discount on Part D drugs when the beneficiary enters the catastrophic coverage phase (the phase after the patient incurs costs above the initial phase out-of-pocket threshold, which is $2,000). However, the IRA allows the 10 and 20 percent discounts to be phased in over a multi-year period for "specified manufacturers" and "specified small manufacturers". During this phase-in period, such manufacturers would pay a lower percentage discount on Medicare Part D program drugs. In April 2024, we were notified by CMS that it qualified as a "specified small manufacturer" and will receive the discount phase-in discussed above for INGREZZA. INGREZZA is reimbursed under Medicare Part D, and increased discounts could impact INGREZZA revenues, while also having an industry-wide impact on the cost of other Part D program drugs such as AUSTEDO and AUSTEDO XR. The overall impact on INGREZZA revenues is inherently uncertain and difficult to predict and we are still evaluating the potential impact of this discount program and our designation as a "specified small manufacturer."

Our designation as a "specified small manufacturer" under the new Medicare Part D manufacturer discount program and INGREZZA's qualification for the small biotech exception for purposes of the Medicare drug price negotiation program are subject to various requirements and there is no assurance that we will continue to qualify for these exemptions in the future. The loss or potential loss of these exemptions, including as a result of a third party acquiring us, could have an adverse impact on our business.

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 Measures

The U.S. and some foreign jurisdictions 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. In the U.S., the pharmaceutical industry and the cost of prescription drugs has been a continuous focus of these efforts and has been significantly affected by major legislative initiatives.

The most significant prior revisions to federal law governing the pharmaceutical industry and prescription drug pricing were enacted through the March 2010 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA). This law was intended to broaden access to health insurance by reducing the number of uninsured persons, reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding transparency requirements for the healthcare and health insurance industries, imposing taxes and fees on the health industry and imposing additional health policy reforms. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expiring ACA subsidies. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in the ACA marketplaces through plan year 2025 and eliminated the "donut hole" under the Medicare Part D program in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost to $2,000 through a newly established manufacturer discount program. Additionally, on July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was signed into law, which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. The OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance.

We expect that these health reform measures may result in more rigorous coverage criteria and lower reimbursement for prescription drugs, as well as result in additional downward pressure on any 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 payors.

Other significant legislative changes impacting the pharmaceutical industry and prescription drug pricing have been 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, due to subsequent legislative amendments, including the Investment and Jobs Act, will remain in effect through 2032.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directives to reduce agency workforces and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again (MAHA) Commission’s recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers’ global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court’s Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to examine and/or 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. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. Further, certain states through legislation have created a state prescription drug affordability board (PDAB) to help control costs of drugs for that state. The functions of the PDABs vary by state, and may include among others, negotiating the price the state pays for certain drugs, recommending or setting upper limits on drug prices, performing drug affordability reviews, and advising state lawmakers on additional ways to reduce the state's drug spending. It is possible that the actions taken by the PDABs may result in lower prices for certain drug products sold in their states.

Proposed Healthcare Reform Measures

The U.S. and some foreign jurisdictions are considering 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 may be significantly affected by major legislative initiatives.

We are currently unable to predict what other additional legislation or regulation, if any, relating to the healthcare 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, particularly in light of the recent U.S. Presidential and Congressional elections.

Regulation and Procedures Governing Approval of Medicinal Products in the EU

To market any product outside of the U.S., a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally aligns with the requirements in the U.S. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement may vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

Clinical Trials in the EU

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 (CTR) which entered into application on January 31, 2022, repealing and replacing the former Clinical Trials Directive 2001/20 (CTD). The CTR became effective for all clinical trials on January 31, 2025. The regulation introduces a streamlined application procedure via a single entry point, the Clinical Trials Information System (CTIS); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts.

Marketing Authorizations

In the EU, medicinal products can only be commercialized after a related marketing authorization (MA) has been granted. To obtain an MA for a product in the EU, an applicant must submit a marketing authorization application (MAA) either under a centralized procedure administered by the EMA or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the European Economic Area (which is comprised of the 27 EU Member States plus Norway, Iceland and Liechtenstein). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products (ATMPs), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Accelerated assessment may be granted by the EMA's Committee for Medicinal Products for Human Use (CHMP) in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Orphan Designation and related Exclusivity in the EU

In the EU, Regulation (EC) No. 141/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than five in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan (PIP). The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination.

Post-Authorization Obligations in the EU

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the U.S., both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports (PSURs).

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another.

Regulatory Framework in the UK

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK's standalone regulator for medicinal products and medical devices.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On April 28, 2026, the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024 will enter into application to modernize the UK clinical trials framework and introduce significant changes.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. This legislation includes procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedures (IRP) which entered into application on January 1, 2024. There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU but have been tailored for the market.

Human Capital Management

Employee Profile

Since 2017, the number of our full-time employees (which are primarily based in the U.S.) has grown from approximately 200 to approximately 2,000 as of December 31, 2025. We also rely on a number of highly skilled consultants and contingent workers who support our commercialization and research and development efforts. In October 2025, we announced the planned expansion of the INGREZZA and CRENESSITY sales teams to maximize our commercial momentum. The expansion is expected to be completed by the end of the first quarter of 2026. In addition, we expect to continue making substantial investments in our research and development personnel to support our expansion into the development of biologics, including peptides, proteins, antibodies, conjugates, and gene therapies.

Culture and Engagement

Our core values of Passion, Integrity, Collaboration, Innovation, and Tenacity are the foundation on which we have deliberately cultivated a mission-driven culture centered on a simple purpose: to relieve suffering for people with great needs. To ensure we foster a culture where every individual feels respected, valued, and able to contribute as their authentic self, we listen to our employees and act on their feedback. We conduct a confidential employee engagement survey annually to assess employee engagement and identify the key drivers of attrition and retention, thereby enabling us to develop targeted, data-driven action plans that protect our talent assets and support a high-performance culture. Senior management and our Board of Directors review the results of our engagement initiatives at least annually, underscoring that human capital is a strategic priority at Neurocrine Biosciences.

We are proud that our efforts have earned Neurocrine Biosciences recognition as an employer of choice – we ranked among the Fortune "Best Workplaces in Biopharma" Top 10 for the third consecutive year (2023-2025) and continue to strive for workplace excellence.

Talent Development and Growth

Developing the skills and careers of our employees is critical to our long-term success. We provide a range of opportunities and resources to help employees learn, grow, and lead. All new hires undergo a structured onboarding program that immerses them in our culture and core values. In addition, we offer continuous learning through professional development courses ranging from technical training, competency-based workshops, and leadership development programs facilitated by external partners who are experts in their respective fields. By investing in our people's growth, we not only increase engagement but also ensure that Neurocrine Biosciences has the skills and leadership needed to sustain our innovation and growth.

Compensation and Benefits

Our compensation philosophy is to attract, motivate, and retain top talent in a competitive industry by offering market-driven, performance-oriented pay and comprehensive benefits. We provide competitive base salaries and annual performance bonuses tied to both company and individual performance. All regular employees are eligible for our annual cash bonus program, which is funded based on corporate goal attainment and allocated in line with individual contributions. We also believe in employees sharing in our long-term success: equity grants (such as stock options or restricted stock units) are a key component of compensation for the majority of our employees, not just executives. We make refresh equity grants on a periodic basis and new-hire grants for eligible employees, aligning their interests with shareholders. Beyond pay, our benefits package is designed to support the well-being of our employees and their families: we offer comprehensive health insurance (medical, dental, and vision plans), company-paid life and disability insurance, a 401(k) retirement plan with company matching contributions (dollar-for-dollar up to 6% of salary), and a generous paid time off policy (including vacation, sick leave, holidays, and floating days for personal or cultural observances). Additional benefits include an enhanced family leave policy providing 12 weeks of paid parental leave for all new parents (maternal, paternal, and adoptive), flexible spending accounts, an Employee Stock Purchase Plan (ESPP) enabling employees to buy shares of our common stock at a discount, and free employee assistance programs offering confidential counseling and work-life support services. Overall, our goal is to reward employees fairly for their contributions and provide benefits that promote their health, safety, and work-life balance.

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 6027 Edgewood Bend Court, 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 those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website at *www.neurocrine.com*, as soon as reasonably practicable after such reports are available on the Securities and Exchange Commission (SEC) website at *www.sec.gov*. Additionally, copies of our Annual Report to Security Holders 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 continue to successfully commercialize INGREZZA or any of our product candidates if they are approved in the future.
- We may not be able to successfully launch and commercialize CRENESSITY.
- If physicians and patients do not continue to accept INGREZZA or do not accept CRENESSITY, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.
- We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced.
- Government and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products or impose policies and/or make decisions regarding the status of our products that could limit our product revenues and delay sustained profitability.
- 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 trials may be delayed for safety or other reasons, or fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.
- Enacted healthcare reform, drug pricing measures and other recent legislative initiatives, including the Inflation Reduction Act of 2022 (IRA), could adversely affect our business.
- We have increased the size of our organization and will need to continue to increase the size of our organization. Such increases may not be sufficient and we may encounter difficulties with managing our growth, which could adversely affect our results of operations.
- We are transforming our research and development strategies to include the development of biologics, which requires substantial investment, including in personnel and facilities. We may encounter difficulties as we expand and may fail to successfully develop or commercialize our biologic product candidates, which could adversely affect our results of operations.
- If we are unable to retain and recruit qualified scientists and other employees 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, CRENESSITY, or any product candidate approved by the FDA in the future.
- Use of our approved products or those of our collaborators could be associated with side effects or adverse events.
- 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, CRENESSITY, or our product candidates, could materially and adversely affect our ability to successfully develop or commercialize INGREZZA, CRENESSITY, or any 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 currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA, CRENESSITY, or any of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our ability to commercialize existing products, conduct clinical trials and develop new products could be impaired and our costs may rise.
- We license some of our core technologies, drug leads, products, and product 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, drug leads, products, and product candidates, or be required to pay damages.
- 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 customers are concentrated and therefore the loss of a significant customer may harm our business.
- We may need additional capital in the future. If we cannot raise additional funding, we may be unable to fund our business plan and our future research, development, commercial and manufacturing efforts.
- We expect to increase our expenses for the foreseeable future, and we may not be able to sustain growth and profitability.

Risks Related to Our Company

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

We launched INGREZZA in the U.S. as the first FDA-approved drug for the treatment of TD in May 2017 and for the treatment of chorea associated with Huntington's disease in August 2023. Our ability to produce INGREZZA revenues consistent with expectations ultimately depends on our ability to continue to successfully commercialize INGREZZA and secure and maintain 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, including the recent expansion of our sales teams for INGREZZA which we anticipate to be completed by the end of the first quarter of 2026. 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 any product candidate approved by the FDA, or equivalent foreign authorities, in the future.

We may not be able to successfully launch and commercialize CRENESSITY.

In December 2024, we announced FDA approval and launched CRENESSITY capsules and oral solution as an adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients four years of age and older with classic CAH. We have also established our commercial team and hired our U.S. sales force for CRENESSITY. The successful commercial launch of CRENESSITY depends on the extent to which patients and physicians accept and adopt CRENESSITY as a treatment for CAH, and we do not know whether our expectations or estimates in this regard, or those of investors or securities analysts, will be accurate. Physicians may not prescribe CRENESSITY and patients may be unwilling to use CRENESSITY. In addition, patients may be unwilling to use CRENESSITY if reimbursement is not provided or reimbursement is inadequate to cover a significant portion of the cost to the patient. CRENESSITY is a first-in-class therapy for children and adults with classic CAH and will therefore require us to expend substantial time and resources to educate physicians and other healthcare providers about the benefits of CRENESSITY. If we are unable to provide our sales force with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of CRENESSITY, our efforts to commercialize CRENESSITY may not be successful. Further, any negative publicity related to CRENESSITY, or negative development for CRENESSITY in our post-marketing commitments or in regulatory processes in other jurisdictions, may adversely impact the potential of CRENESSITY and our commercial results. If the commercialization of CRENESSITY and future sales are less successful than anticipated by us or our investors or securities analysts, our stock price could decline and our business may be harmed.

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

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

The market acceptance of INGREZZA and CRENESSITY could be affected by a number of factors, including:

- the timing of receipt of marketing approvals for additional indications;
- the safety and efficacy of the products;
- the pricing of these products;
- the availability of healthcare payor coverage and adequate reimbursement for the products;
- public perception regarding these products;

- 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, patients and payors do not continue to accept our products as being safe, effective, superior and/or cost effective, we may not generate sufficient 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 (including the development of generic equivalents) 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 TD, chorea associated with Huntington's disease, classic congenital adrenal hyperplasia, uterine fibroids, endometriosis, pain, Parkinson’s disease, schizophrenia, epilepsy, and other neurology, psychiatry, endocrinology, obesity and related metabolic diseases, and immunology-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 (including the development of generic equivalents), the market for our products may be reduced or eliminated.

- INGREZZA competes with AUSTEDO (deutetrabenazine), marketed by Teva Pharmaceuticals Industries, for the treatment of TD in adults and chorea associated with Huntington's disease. A once-daily dosing of AUSTEDO (AUSTEDO XR) was introduced in February 2023. Additionally, there are a number of commercially available medicines used to treat TD off-label, such as XENAZINE (tetrabenazine) and generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin. In addition, there are several programs in clinical development by other companies targeting Huntington's disease.
- CRENESSITY competes with high dose corticosteroid monotherapy which is the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive adrenocorticotropic hormone levels for patients with CAH. In the U.S. alone, there are more than two dozen companies manufacturing steroid-based products. In addition, there are several programs in clinical development by other companies targeting CAH.
- Our investigational treatments for potential use in schizophrenia and depression may in the future compete with several development-stage programs being pursued by other companies. In addition, there are a number of different anti-psychotic, including the muscarinic agonist COBENFY, and anti-depressant medications currently used in these patient populations.
- Our investigational treatments for potential use in neurology, psychiatry, endocrinology, obesity and related metabolic diseases, and immunology 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;
- sales and marketing experience;
- research and development capabilities and capacity, 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.

Government and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products or impose policies and/or make decisions regarding the status of our products that could limit our product revenues and delay sustained profitability.

Our ability to continue to commercialize INGREZZA and successfully launch and commercialize CRENESSITY 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 healthcare and the price of prescription drugs through various means may impact our 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 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 out-of-pocket 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. Coverage decisions by payors for our competitors' products may also impact coverage for our products.

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, media outlets, and others regarding healthcare 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 or indications, 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, manufacturing, sale and distribution. In addition, we could also be subject to amendments in our rebate agreements with pharmaceutical benefit managers that require us to pay larger rebate amounts or modify our formulary position, which could have a material adverse effect on our business. 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. For example, government authorities could make a decision that adversely impacts the status of one of our products, which could impact the eligibility and/or the amount of government reimbursement for that product.

As a pharmaceutical manufacturer, we are subject to various federal statutes and regulations requiring the reporting of price data and the subsequent provision of concessions to certain purchasers/payors, including state Medicaid programs. Federal agencies issue guidance to manufacturers related to the interpretation of laws and regulations, and this guidance has changed and may change or be updated over time. In interpreting these laws, regulations and guidance, manufacturers may make reasonable assumptions to fill gaps, and these reasonable assumptions may need to be updated upon issuance of additional agency guidance.

If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may be unable to successfully commercialize INGREZZA, CRENESSITY, or any of our product candidates for which we obtain marketing approval in the future. 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. Further, a majority of our current revenue is derived from federal healthcare program payors, including Medicare and Medicaid. Thus, changes in government reimbursement policies, government negotiation of the price of any of products, reductions in payments and/or our suspension or exclusion from participation in federal healthcare programs could have a material adverse effect on our business.

Further, the use of clinician telehealth services remains elevated, fueled by expansion of coverage and reimbursement for telehealth services across public and private insurers. The limitations that telehealth places on the ability to conduct a thorough physical examination may impact the ability of providers to screen for TD or chorea associated with Huntington's disease, leading to fewer patients being diagnosed and/or treated.

Outside the U.S., reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. The EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

To obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. The Health Technology Assessment (HTA) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. Since January 12, 2025, the clinical elements of the HTA must be assessed via Joint Clinical Assessment at the EU level - initially, all new oncology medicines and ATMPs, expanded to orphan medicines in 2028, and covering all remaining centrally authorized medicines from 2030. If we are unable to obtain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

Legislators, policymakers, and payors may continue to propose and implement cost-containing measures to keep healthcare costs down. For example, in April 2025, the President issued an executive order that, among other things, directed specified agency heads to develop a Center for Medicare and Medicaid Innovation (CMMI) model that enables the Medicare program to obtain better value for high-cost prescription drugs and biological products. In May 2025, the President issued another executive order directing the administration to take immediate steps to end global freeloading and take additional aggressive action should drug manufacturers fail to offer American consumers the Most-Favored Nation (MFN) price. In December 2025, CMS issued proposed regulations that, if finalized, would create CMMI demonstrations that would institute MFN-level pricing in the Medicare Part D and Part B markets. At present, given that the demonstrations are proposed rules that may or may not be finalized or implemented, there is uncertainty as to how these and other potential legal and regulatory changes may impact our business. However, if implemented, these policies could reduce or limit the prices we are able to charge for our products and product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for our products from governmental authorities or third-party payors. Further, in January 2026, the President released The Great Healthcare Plan, a proposal which calls on Congress to codify the administration's 16 MFN drug-pricing agreements with manufacturers and potentially extend MFN pricing to additional manufacturers. In addition, the OBBBA is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding and limiting provider taxes used to fund the program. The OBBBA also narrows access to the Patient Protection and Affordable Care Act (ACA) marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, which expired at the end of 2025. These changes, along with other provisions of the OBBBA, are anticipated to reduce the number of Americans with health insurance. Further, an increasing number of countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of

the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere, including in the U.S.

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, which could adversely affect our business, results of operations and future growth prospects, and could cause the market price of our common stock to decline.

Only a small number of research and development programs ultimately result in commercially successful drugs.

Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals on a timely basis or at all;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical to commercialize or fail to achieve market acceptance.

If any of our product candidates encounters any of these potential problems, we may never successfully market that product candidate. Because we believe our continued growth and success depend in part on our ability to identify (by internal development, in-license or acquisition), develop and ultimately commercialize a steady number of additional product candidates, our failure or perceived failure to achieve that plan could adversely affect our business, results of operations and future growth prospects, and could cause the market price of our common stock to decline.

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

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

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

- the FDA or similar foreign regulatory authority may not allow an IND or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA or similar foreign regulatory authorities may require additional preclinical studies as a condition of the initiation of Phase 1 clinical studies, or additional clinical studies for progression from Phase 1 to Phase 2, or Phase 2 to Phase 3, 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 or similar foreign regulatory authorities;
- clinical trial results may not replicate or improve upon the results of previous trials;
- we or the FDA or similar foreign regulatory authorities may suspend or vary the trials;
- the results may not be statistically significant;
- clinical site initiation or patient recruitment and enrollment may be slower or more difficult than expected;
- the FDA or similar foreign regulatory authorities may not accept the data from any trial or trial site outside of the U.S.;
- a study is compromised due to patients dropping out and not completing the trials;
- unforeseen disruptions or delays may occur, caused by geopolitical and macroeconomic developments, man-made or natural disasters, public health pandemics or epidemics, armed conflicts, trade restrictions, tariffs, the recent shutdown of the U.S. federal government and the resulting effects on its regulatory agencies, or other business interruptions; 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. Geopolitical tensions could also affect our ability to obtain supplies of our investigational products, which could cause delays or otherwise disrupt our clinical trials and research and development efforts. Some of our suppliers and research and development collaborators are located in China, exposing us to the possibility of supply disruption in the event of changes to the laws, rules, regulations, and policies of the governments of the U.S. or China. Any such changes to laws or the adoption of tariffs or other restrictions could impact our ability to contract with certain Chinese biotechnology companies, cause delays, or have other adverse effects on the development of certain of our research programs.

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 conduct, completion and 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 similar foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. The FDA and similar foreign regulatory authorities have substantial discretion in the approval process and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. To the extent that the FDA or similar foreign regulatory authorities do not accept our application for review or approve our application, 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. Depending on the extent of these additional trials or any other studies that might be required, approval of any applications that we submit may be significantly delayed. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA or similar foreign regulatory authorities and we may be forced to delay or abandon our applications for approval.

We have increased the size of our organization and will need to continue to increase the size of our organization. Such increases may not be sufficient and we may encounter difficulties with managing our growth, which could adversely affect our results of operations.

Since 2017, the number of our full-time employees has grown from approximately 200 to over 2,000. Although we have substantially increased the size of our organization, we may need to add additional qualified personnel and resources, especially with the recent increase in the size of our 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 our organization, including the need to identify, recruit, maintain and integrate additional employees and implement and expand managerial, operational, and financial systems and may be costly and take time away from running other aspects of our business, including development and commercialization of our product candidates. For example, we implemented a company-wide enterprise resource planning (ERP) system in 2024 to streamline certain existing business, operational, and financial processes. This project has required and may continue to require investment of capital and human resources, the re-engineering of processes of our business, and the attention of many employees who would otherwise be focused on other aspects of our business, including post-implementation optimization and upgrades. Any deficiencies in the design, implementation, or subsequent upgrades of the ERP system could adversely affect the effectiveness of our internal control over financial reporting or our ability to accurately maintain our books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Any of these consequences could have an adverse effect on our results of operations and financial condition.

Our future financial performance and our ability to commercialize INGREZZA, CRENESSITY, or any of our product candidates that receive regulatory approval in the future, will partially depend on our ability to manage any future growth effectively. In particular, as we commercialize INGREZZA and CRENESSITY, 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;
- compensate our employees on adequate terms in an increasingly competitive, inflationary market;
- attract and retain personnel; 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 are transforming our research and development strategies to include the development of biologics, which requires substantial investment, including in personnel and facilities. We may encounter difficulties as we expand and may fail to successfully develop or commercialize our biologic product candidates, which could adversely affect our results of operations.

We are transforming our research and development strategies to include the development of biologics, including peptides, proteins, antibodies, conjugates, and gene therapies. As a company, we do not have experience successfully developing and commercializing biologics and our current infrastructure may be inadequate to support the expected growth and transformation of processes, personnel, and technologies required for these new programs. We have hired employees with expertise in these modalities, but we will need to hire additional qualified personnel and expand our management, administrative, and technical staff to support the research and development organization. If we are unable to identify, recruit and integrate additional employees with the requisite skills, or effectively manage our transformation activities, the development of our biologic product candidates may not be successful, or be delayed or paused indefinitely. Gene therapies, in particular, may entail additional safety and development risks because they often require specialized administration (including intravenous administration) and may cause serious adverse events, including immune or inflammatory reactions, which could delay, suspend or terminate clinical development. Pre-existing immunity or immunity that develops after dosing may limit eligible patients and may prevent repeat dosing, which could reduce effectiveness and limit commercial adoption. Additionally, the manufacture of biologics and cognate devices are more complex than the manufacture of small molecule therapies. We currently have no manufacturing capabilities for biologic product candidates and devices and rely on third-party manufacturers. We may encounter delays in production and delivery of our biologic product candidates and devices by our third-party manufacturers or other vendors, which would result in corresponding delays to our development and commercialization of such biologic candidates. In addition, the regulatory requirements in the U.S. and in other countries governing biologics are evolving and the FDA or comparable foreign regulatory authorities may change the requirements, or identify different regulatory pathways, for approval for any of our biologic candidates. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our biologic candidates. We have made, and expect to continue making, substantial investments in our research and development personnel and facilities, as well in external innovation to support our expansion into the development of our biologics. If any of these risks occur and we fail to successfully develop or commercialize our biologic product candidates, we may not realize a return on our investments which could have an adverse effect on our results of operations and financial condition.

If we are unable to retain and recruit qualified scientists and other employees 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, CRENESSITY, or any product candidate approved by the FDA in the future.

We are highly dependent on the principal members of our management, commercial, and scientific staff. The loss of any of these people could impede the achievement of our objectives, including the successful commercialization of INGREZZA, the launch of CRENESSITY, or the commercialization of any product candidate approved by the FDA in the future. 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 healthcare companies, and 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.

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.

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, CRENESSITY, or our product candidates, could materially and adversely affect our ability to successfully develop or commercialize INGREZZA, CRENESSITY, or any of our product candidates.

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 (API), the finished drug product and packaging 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 and validation, 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 or delays caused by geopolitical and macroeconomic developments, man-made or natural disasters, public health pandemics or epidemics, armed conflicts, trade restrictions, tariffs, the recent shutdown of the U.S. federal government and the resulting effects on its regulatory agencies, or other business interruptions. We depend on a limited number of suppliers for the production (including API) of INGREZZA, CRENESSITY, and our product candidates and for the packaging of INGREZZA and CRENESSITY. If our third-party suppliers for INGREZZA, CRENESSITY, or any of our product candidates encounter these or any other manufacturing, quality, or compliance difficulties, our ability to successfully develop or commercialize INGREZZA, CRENESSITY, or any of our product candidates could be materially and adversely affected.

In addition, if our suppliers fail or refuse to supply us with INGREZZA, CRENESSITY, or any of our product candidates, or their APIs for any reason, or terminate our supply agreements or do not perform as agreed, it would take a significant amount of time and expense to qualify a new supplier. The FDA and similar foreign regulatory authorities 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 if a new supplier is unable to meet FDA or a similar foreign regulatory authority's requirements for approval, there could be a shortage of INGREZZA, CRENESSITY, or any of our product candidates, which could materially and adversely affect our ability to successfully develop or commercialize INGREZZA, CRENESSITY, or any 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 depend on AbbVie for the manufacture and commercialization of ORILISSA and ORIAHNN and for the continued development of elagolix. We collaborate with TPC for the commercialization of DYSVAL in Japan and for the continued development and commercialization of valbenazine for movement disorders in other select Asian markets. Some of our other collaborators include Nxera Pharma UK Limited (formerly Sosei Heptares), Takeda Pharmaceutical Company Limited, Voyager Therapeutics, Inc., and Xenon Pharmaceuticals Inc. Additionally, we depend on collaborators for the development of some of our biologics leads and candidates.

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

- strategic collaborators may sell, transfer or divest assets or programs related to our partnered product or product candidates;
- 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;

- we or strategic collaborators could terminate the arrangement (in whole or in part) or allow it to expire, which would delay the development and commercialization, result in disagreements or disputes or may increase the cost of developing and commercializing our products or product candidates;
- strategic collaborators could develop, either alone or with others, products or product candidates that may compete with ours; and
- our strategic collaborator's decisions regarding the development and commercialization of a partnered product or product candidate within their territory(ies) could negatively impact us in the territories where we have development and commercialization rights for such product or product candidate.

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 currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA, CRENESSITY, or any of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our ability to commercialize existing products, conduct clinical trials and develop new products could be impaired 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 CRENESSITY. 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 CRENESSITY.

The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA and equivalent foreign regulations, including current good manufacturing practice (cGMP) regulations. Our third-party manufacturers might not comply with FDA or equivalent foreign regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. Our reliance on contract manufacturers also exposes us to the following risks:

- contract manufacturers may encounter difficulties in achieving volume production, quality control or quality assurance, and also may experience shortages in qualified personnel or materials and ingredients necessary to conduct their operations. 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 or product candidates; and
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration, equivalent foreign regulatory authorities, and other agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. Any delay, interruption, or other issue that arises in the manufacture of our products or product candidates as a result of a failure of a third-party manufacturer to pass regulatory inspections or maintain cGMP compliance could significantly impair our ability to develop our product candidates or to obtain approval for or successfully commercialize our products.

Further, changes in federal policy could affect the geopolitical landscape and could give rise to circumstances that negatively affect our business. The third parties that manufacture our products have manufacturing facilities located in Europe. The U.S. has implemented, and has proposed to further implement, tariffs that may increase the costs of our third-party manufacturers and the expense to us to produce the drug compounds we use in our clinical trials and for the commercialization of our products. If such actions were to materially affect us or our third-party manufacturers, we may not be able to successfully develop our product candidates or commercialize our products.

Our current dependence upon third parties for the manufacture of our products may reduce our profit margin, if any, on the sale of INGREZZA, CRENESSITY, or our future products and our ability to develop and deliver products on a timely and competitive basis.

We license some of our core technologies, drug leads, products, and product 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, drug leads, products, and product candidates or be required 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. 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 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 distributors. In addition, CRENESSITY is distributed by one specialty pharmacy provider. In the aggregate, four of these customers across our INGREZZA and CRENESSITY distribution arrangements represent over 90% of our total gross product sales. If any of our significant customers becomes subject to bankruptcy, is unable to pay us for our products or wants to terminate their 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. Also, we may need to enter into agreements with additional distributors or specialty pharmacy providers, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. 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.

We may need additional capital in the future. If we cannot raise additional funding, we may be unable to fund our business plan and our future research, development, commercial and manufacturing efforts.

Our future funding requirements will depend on many factors and we may need to raise additional capital to fund our business plan and our future research, development, commercial and manufacturing efforts.

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

- the commercial success of INGREZZA and CRENESSITY;
- the cost of commercialization activities and arrangements, including advertising campaigns;
- continued scientific progress in our research and development 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 cost involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- costs associated with securing adequate coverage and reimbursement for our products;
- competing technological and market developments;
- developments related to any future litigation;
- the cost of manufacturing our product candidates;
- the impact of pandemics or epidemics on our business; and
- the cost of any strategic alliances, collaborations, product in-licensing, or acquisitions.

We may seek additional funding through public or private sales of our securities, including equity securities. In addition, we have previously financed capital purchases and may continue to pursue opportunities to obtain debt financing in the future. Additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any debt financings may involve operating covenants that restrict our business.

We expect to increase our expenses for the foreseeable future, and we may not be able to sustain growth and profitability.

We received FDA approval for INGREZZA for TD in April 2017 and for chorea associated with Huntington's disease in August 2023. We received FDA approval for CRENESSITY capsules and oral solution as an adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients four years of age and older with classic CAH in December 2024. Our partner AbbVie received FDA approval for ORILISSA for endometriosis in July 2018 and for ORIAHNN for uterine fibroids in May 2020. Additionally, our partner TPC received Japanese Ministry of Health, Labour, and Welfare approval for DYSVAL for the treatment of TD in March 2022. However, we have not yet obtained regulatory approvals for any other product candidates. Even if we continue to succeed in commercializing INGREZZA, or are successful in commercializing CRENESSITY or any of our product candidates, we may not be able to sustain profitability. We also expect to continue to incur significant operating and capital expenditures as we:

- commercialize INGREZZA for TD and chorea associated with Huntington's disease;
- commercially launch CRENESSITY as an adjunctive treatment to glucocorticoid replacement to control androgens in adult and pediatric patients four years of age and older with classic CAH;
- seek regulatory approvals for our product candidates or for additional indications for our current products;
- 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, marketing and administrative personnel.

We expect to increase our expenses and other investments in the coming years as we fund our operations and capital expenditures. Thus, 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. In addition, there is no guarantee that our prioritization determinations regarding our research and development and clinical development programs, including the acceleration or discontinuation of certain programs and product candidates, will generate their expected benefits and/or meet investor expectations. Our prioritization decisions may also adversely affect other internal programs and initiatives as well as our ability to recruit and retain skilled and motivated personnel. Our failure to maintain or increase profitability on a sustained basis could negatively impact the market price of our common stock.

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

We depend on independent clinical investigators and 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 (GCPs), it may delay or prevent the approval of our regulatory applications and our introduction of new treatments. 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 product candidates. 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 are subject to ongoing obligations and continued regulatory review for INGREZZA and CRENESSITY. Additionally, our 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 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. For INGREZZA, CRENESSITY, 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 is 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 GCPs for any clinical trials that we conduct post-approval. In addition, advertising and promotional materials for approved products must comply with FDA regulations and those of foreign regulatory authorities and may be subject to other potentially applicable federal and state laws. As part of the Make America Healthy Again (MAHA) Commission's recent Strategy Report, the current administration has prioritized stricter oversight of direct-to-consumer advertising, including increasing the amount of information manufacturers provide regarding risks associated with the use of prescription drugs and ensuring that advertisements are not false, misleading or lacking in fair balance through coordination across government agencies. In September 2025, the FDA Office of Prescription Drug Promotion issued numerous untitled letters and warning letters to drug manufacturers regarding advertising and promotion, including one untitled letter addressed to us which alleges that certain claims made in promotional material for INGREZZA are misleading. Although we believe that our advertisement complies with applicable laws and regulations, resolving the concerns stated in the letter or future letters we may receive could negatively impact the effectiveness of our advertising campaigns, increase compliance and media costs, and reduce demand for our products.

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, misbranding allegations, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA or similar foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- adverse inspection findings, enforcement actions, or other activities that temporarily delay manufacture and distribution of our products;
- 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.

The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

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

Certain of the diseases that INGREZZA, CRENESSITY, and our product candidates are being developed to address are in underserved and underdiagnosed populations, and, in the case of CRENESSITY, patients may also be incorrectly coded or misclassified in medical and reimbursement records. Accordingly, 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. As we expand the number of product candidates we are developing, it will become increasingly important that we accurately assess the market opportunities for those candidates. If our estimates of the prevalence or number of patients potentially on therapy prove to be inaccurate, the market opportunities for INGREZZA, CRENESSITY, and our product candidates may be smaller than we believe they are, our prospects for generating expected revenue may be adversely affected and our business may suffer.

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

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to seasonality and timing of customer purchases and commercial sales of INGREZZA and CRENESSITY, royalties from out-licensed products, the impact of Medicare Part D coverage, including redesign of the Part D benefit enacted as part of the IRA, 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, disruptions caused by geopolitical and macroeconomic developments, man-made or natural disasters, public health pandemics or epidemics, armed conflicts, trade restrictions, tariffs, the recent shutdown of the U.S. federal government and the resulting effects on its regulatory agencies, or other business interruptions. Because a majority of our costs are predetermined on an annual basis, due in part to our significant research and development costs, small declines in revenue could disproportionately affect financial results in a quarter. Thus, 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 of 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 tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified, or applied in a manner that is adverse to us or our customers, which could adversely affect our business and financial condition. Federal laws such as the One Big Beautiful Bill Act (OBBBA), enacted in 2025, the IRA enacted in 2022, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017, made significant changes to the U.S. tax laws. For example, the Tax Cuts and Jobs Act required taxpayers to capitalize and amortize U.S.-based and non-U.S. based research and experimental (R&E) expenditures over five and fifteen years, respectively. The OBBBA restored the deductibility of domestic R&E expenditures in the year incurred for tax years beginning after December 31, 2024, but retained the capitalization and amortization requirement for foreign R&E expenditures. Future guidance from the Internal Revenue Service and other tax authorities with respect to any laws may affect us, and certain aspects of such laws could be repealed or modified or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal tax laws.

Furthermore, our tax obligations (including the cost of compliance) and effective tax rate in the jurisdictions in which we conduct business could increase as a result of international tax developments, including the implementation of the Organization for Economic Co-operation and Development's (OECD) Base Erosion and Profit Shifting "Two-Pillar" framework, which involves, among other measures, the imposition of a minimum effective corporate tax rate (referred to as Pillar Two). Certain countries in which we conduct business have enacted, or are in the process of enacting, core provisions of the Pillar Two rules (with further provisions expected to be enacted in the future). Based on our current understanding of the minimum revenue thresholds contained in the Pillar Two proposal, we currently expect to fall within the scope of its rules. The OECD has issued (and is expected to

continue to issue further) administrative guidance providing transition and safe harbor rules in relation to the implementation of the Pillar Two proposal. For example, on January 5, 2026, the OECD published details of a proposed "side-by-side" arrangement providing for, among other things, additional safe harbors for multinational groups headquartered in certain qualifying jurisdictions. We continue to evaluate and assess the potential impact of these new rules, including on our effective tax rate, and our eligibility to qualify for any transition relief or safe harbor (including under the proposed "side-by-side" arrangement). Any changes in tax laws, including any new tax laws or initiatives, could not only significantly increase our tax provision, cash tax liabilities, and effective tax rate, but could also have a material impact on the value of our deferred tax assets, result in significant one-time charges and ongoing compliance costs, and increase our future tax expense.

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

We have a multinational tax structure and are subject to income tax in the U.S. and various foreign jurisdictions, including the United Kingdom and Switzerland. Our effective tax rate is influenced by many factors including changes in our operating structure, changes in the mix of our earnings among countries, our allocation of profits and losses among our subsidiaries, our intercompany transfer pricing agreements and rules relating to transfer pricing, our inability to secure or sustain acceptable agreements with tax authorities, the impact of stock-based compensation, the availability of U.S. research and development tax credits, the results of examinations and audits of our tax filings, changes in accounting for income taxes, and future changes in tax laws and regulations in the U.S. and foreign countries. Significant judgment is required in determining our tax liabilities including management's judgment for uncertain tax positions. The Internal Revenue Service, other U.S. taxing authorities, or non-U.S. taxing authorities may disagree with our interpretation of tax laws as applied to our operations. Our reported effective tax rate and after-tax cash flows may be materially and adversely affected by tax assessments in excess of amounts accrued for our financial statements. This could cause us to experience an effective tax rate significantly different from previous periods or our current expectations.

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. For example, the applicability of the Medicare drug price negotiation provisions in the IRA negatively affected investor sentiment and 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 12 months, the price of our common stock has ranged from approximately $84 per share to approximately $160 per share.

The market price of our common stock may fluctuate in response to many factors, including:

- sales of INGREZZA and CRENESSITY;
- failure of CRENESSITY to achieve commercial success;
- the results of our clinical trials;
- reports of safety issues related to INGREZZA or CRENESSITY;
- any delay in filing an IND, NDA, marketing authorization application (MAA), or other regulatory submission for any of our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory agency's review of that IND, NDA, MAA, or other regulatory submission, including but not limited to the imposition of a temporary or permanent clinical hold by a regulatory agency;
- the perceived success of our plan to develop a steady cadence of innovative medicines for years to come;
- developments concerning new and existing collaboration agreements;
- announcements of technological innovations or new therapeutic products by us or others, including our competitors;

- 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, the Centers for Medicare & Medicaid Services (CMS) and foreign regulatory agencies;
- government regulation, including the IRA;
- future sales of our common stock by us or our stockholders;
- any trading activity pursuant to a share repurchase program;
- comments by securities analysts;
- additions or departures of key personnel;
- fluctuations in our operating results;
- potential litigation matters;
- government and third-party payor coverage and reimbursement;
- failure of any of our product candidates to achieve commercial success even if approved;
- disruptions caused by geopolitical and macroeconomic developments, man-made or natural disasters, public health pandemics or epidemics, armed conflicts, trade restrictions, tariffs, including protectionist or retaliatory measures taken by the U.S. or other countries, the recent shutdown of the U.S. federal government and the resulting effects on its regulatory agencies, or other business interruptions; and
- public concern as to the safety of our drugs.

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

There can be no assurance that any share repurchases will enhance long-term stockholder value.

In October 2024, our Board of Directors authorized a share repurchase program to repurchase up to $300 million of our common stock and we subsequently entered into an accelerated share repurchase (ASR) transaction to repurchase the entirety of this authorized amount. The purchase period for this ASR transaction ended in February 2025 and an aggregate of 2.3 million shares were delivered to us at an average repurchase price of $131.83 per share. Additionally, in February 2025, our Board of Directors authorized a share repurchase program under which we may repurchase up to $500 million of our common stock (of which $332.3 million remained available for additional repurchases as of December 31, 2025). This subsequent share repurchase authorization was in addition to the $300 million accelerated share repurchase program that was announced in October 2024 and completed in early February 2025. Our share repurchases may change from time to time, and we can provide no assurance that we will repurchase shares of our common stock at favorable prices, in particular amounts, or at all, and any repurchases may not enhance long-term stockholder value or prove to be the best use of our cash. If our Board of Directors authorizes any additional share repurchase programs, it could affect the trading price of our stock and increase volatility.

Compliance with changing laws, regulations and standards relating to various aspects of our business, including corporate governance, workforce initiatives and public disclosure, may result in additional expenses and failure to comply with such laws, regulations and standards could adversely affect our business.

Changing laws, regulations and standards relating to various aspects of our business, including corporate governance, workforce initiatives and public disclosure, including as a result of the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and Nasdaq rules and executive orders, 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, policies and governance

practices. We are committed to maintaining high standards of corporate governance, workforce initiatives 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, or are perceived to fail, to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to litigation, sanctions, investigations or other regulatory proceedings 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.

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.

Risks Related to Our Industry

Enacted healthcare reform, drug pricing measures and other recent legislative initiatives, including the IRA, could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of government and third-party payors to contain or reduce the costs of healthcare and to lower drug prices. In the U.S., comprehensive drug pricing legislation enacted by the Federal government implements, for the first time, government control over the pricing of certain prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is also subject to government control. Additionally, other federal and state laws impose obligations on manufacturers of pharmaceutical products, among others, related to disclosure of new drug products introduced to the market and increases in drug prices above a specified threshold.

For example, the IRA provides for, among other things: (1) the Secretary of the HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare; (2) the redesign of the Medicare Part D prescription drug benefit to lower patient out-of-pocket costs and increase manufacturer liability; and (3) drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. AUSTEDO and AUSTEDO XR, marketed by Teva Pharmaceuticals Industries, were selected for the Medicare Drug Negotiation Program in 2025 (for initial price applicability year 2027) and CMS has announced a negotiated maximum fair price (MFP) for these products that is lower than their pre-negotiation prices. Lower negotiated prices for AUSTEDO and AUSTEDO XR may increase competitive pressures on INGREZZA, including heightened pricing pressure and potential adverse effects on formulary coverage.

We were notified in January 2025 that INGREZZA qualifies for the small biotech exception, which provides an exemption from selection until 2027 (for initial price applicability year 2029, pursuant to which negotiated pricing would go into effect, if selected). If negotiated for initial price applicability year 2029, we expect that the negotiated price for INGREZZA would be constrained by the "short monopoly" price ceiling and temporary price floor for small biotech drugs.

Additionally, on January 1, 2025, CMS implemented those provisions of the IRA establishing a new Medicare Part D manufacturer discount program. Under this discount program and subject to certain exceptions, manufacturers must give a 10 percent discount on Part D program drugs in the initial coverage phase, and a 20 percent discount on Part D drugs when the beneficiary enters the catastrophic coverage phase (the phase after the patient incurs costs above the initial phase out-of-pocket threshold, which is $2,000 in 2025, indexed to inflation thereafter annually). However, the IRA allows the 10 and 20 percent discounts to be phased in over a multi-year period for "specified manufacturers" and "specified small manufacturers". During this phase-in period, such manufacturers would pay a lower percentage discount on Medicare Part D program drugs. In April 2024, we were notified by CMS that it qualified as a "specified small manufacturer" and will receive the discount phase-in discussed above for INGREZZA. INGREZZA is reimbursed under Medicare Part D, and increased discounts could impact INGREZZA revenues, while also having an industry-wide impact on the cost of other Part D program drugs such as AUSTEDO and AUSTEDO XR. The overall impact on INGREZZA revenues is inherently uncertain and difficult to predict, and we are still evaluating the potential impact of this discount program and our designation as a "specified small manufacturer."

Our designation as a "specified small manufacturer" under the new Medicare Part D manufacturer discount program and INGREZZA's qualification for the small biotech exception for purposes of the Medicare drug price negotiation program are subject to various requirements and there is no assurance that we will continue to qualify for these exemptions in the future. The loss or potential loss of these exemptions, including as a result of a third party acquiring us, could have an adverse impact on our business.

The most significant prior revisions to federal law governing the pharmaceutical industry and prescription drug pricing occurred in March 2010, when the ACA was signed into law. This law was intended to broaden access to health insurance by reducing the number of uninsured persons, reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding transparency requirements for the healthcare and health insurance industries, imposing taxes and fees on the health industry and imposing additional health policy reforms. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expiring ACA subsidies. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in the ACA marketplaces through plan year 2025 and eliminated the "donut hole" under the Medicare Part D program in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost to $2,000 through a newly established manufacturer discount program.

We expect that these health reform measures may result in more rigorous coverage criteria and lower reimbursement for prescription drugs, as well as result in additional downward pressure on any 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 payors.

Other significant legislative changes impacting the pharmaceutical industry and prescription drug pricing have been 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, due to subsequent legislative amendments, including the Investment and Jobs Act, will remain in effect through 2032.

We participate in the Public Health Service's 340B Drug Pricing Program (which is administered by the Health Resources and Services Administration), the Medicaid Drug Rebate program, and other federal and state government pricing programs. Participation in some of these programs is required in order to obtain reimbursement of our drug products under Medicaid or Medicare Part B. These programs generally require that we provide discounts or pay rebates to certain payers when our products are dispensed to beneficiaries of these programs. Pricing and rebate calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Furthermore, regulatory and legislative changes, and judicial rulings relating to these programs and policies could introduce additional uncertainty for our business and impact our product prices and rebate liability. These could include expansion of the 340B Drug Pricing Program

and growth of entities claiming entitlement under this program, changes to the calculation of rebates under the programs, or other regulatory changes impacting reimbursement. Continued expansion of the 340B Drug Pricing Program and growth of entities claiming entitlement to 340B pricing, including in ways that may be inconsistent with the statutory scheme, could impact our revenue.

The current administration is pursuing policies to reduce regulations and expenditures across the government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues.

Other recent actions, for example, include (1) directives to reduce agency workforces and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing MFN pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the MAHA Commission's recent Strategy Report, working across government agencies to increase enforcement of direct-to-consumer pharmaceutical advertising, each of which creates uncertainty for us and could negatively impact our business.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, 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. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. Further, certain states through legislation have created a state prescription drug affordability board (PDAB) to help control costs of drugs for that state. The functions of the PDABs vary by state, and may include among other things, recommending or setting upper limits on the price the state pays for certain drugs, performing drug affordability reviews, and advising state lawmakers on additional ways to reduce the state's drug spending. It is possible that the actions taken by the PDABs may result in lower prices for certain drug products sold in their states. The implementation of these cost containment measures may prevent us from being able to generate revenue, attain sustained profitability or commercialize our drugs, particularly since the majority of our current revenue is derived from federal healthcare programs, including Medicare and Medicaid.

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;
- obtain, maintain, and enforce trademark, trade name, and service mark protection;
- 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. Additionally, if our employees, commercial collaborators or consultants use generative artificial intelligence (AI) technologies to develop our proprietary technology and compounds, it may impact our ability to obtain or successfully defend certain intellectual property rights.

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. In addition, potential competitors have in the past and may in the future file an abbreviated new drug application (ANDA) with the FDA seeking approval to market a generic version of our products, or our competitors' products, before the expiration of the patents covering our products or our competitors' products, as applicable.

To prevent infringement or unauthorized use, we have in the past and may in the future 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 or a patent of a competitor 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. Derivation 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) or a patent of a competitor. Litigation or derivation proceedings may fail and, even if successful, may result in substantial costs and be a distraction to management. Litigation or derivation proceedings, including proceedings of a competitor, may also result in a competitor entering the marketplace faster than expected. 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.

Changes in the FDA, the U.S. Patent and Trademark Office, other government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, delay the development and commercialization of new products or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products, and the ability of the U.S. Patent and Trademark Office and other government agencies to perform their normal business functions, can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and manage user fee programs, and statutory, regulatory, and policy changes (such as reductions in force). FDA review performance has fluctuated in recent years as a result. In addition, government funding of other government agencies or comparable foreign regulatory authorities on which our operations may rely, including the U.S. Patent and Trademark Office, the Patent Trial and Appeal Board and those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, other government agencies or comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities to the extent they are not funded by existing available user fees. A prolonged government shutdown could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, government shutdowns could impact our ability to access the public markets and obtain additional capital in the future.

Proposed healthcare reform, drug pricing measures and other prospective legislative initiatives could adversely affect our business.

We expect that there will continue to be a number of federal and state proposals to implement additional government controls over the pricing of prescription pharmaceuticals. Increasing emphasis on reducing the cost of healthcare in the U.S. will continue to put pressure on the pricing and reimbursement of prescription pharmaceuticals.

In addition, certain jurisdictions outside of the U.S., including the EU, have instituted price ceilings on specific products and therapies, as described further in the risk factor titled "Government and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products or impose policies and/or make decisions regarding the status of our products that could limit our product revenues and delay sustained profitability."

We are currently unable to predict what other additional legislation or regulation, if any, relating to the healthcare industry may be enacted in the future or what effect recently enacted federal or equivalent foreign legislation or any such additional legislation or regulation would have on our business, particularly in light of recent U.S. presidential and congressional elections. 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 HITECH 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), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members; and
- analogous state, local and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state laws that require disclosure of price increases above certain identified thresholds as well as of new commercial launches in the state; state laws that create Prescription Drug Price Affordability Boards to review or attempt to cap drug spending; 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 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, business practices of our vendors or consultants, or a rogue employee's activities, may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws. For example, we maintain a patient assistance program to help eligible patients afford our products. These and other types of programs have become the subject of governmental scrutiny, and numerous organizations, including pharmaceutical manufacturers, have been subject to litigation, enforcement actions and settlements related to their patient assistance programs. In August 2025, we received a civil investigative demand from the U.S. Department of Justice (DOJ) requesting certain documents and information related to our sales and marketing of INGREZZA. We are cooperating with the DOJ's request. No assurance can be given as to the timing or outcome of the DOJ's investigation. If our operations or activities or those of our vendors are found to be in violation of any of the laws described above or any other applicable governmental regulations, 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.

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. Additionally, because of our U.S. and international operations, we are also subject to anti-corruption laws and regulations, in the U.S. and internationally, including but not limited the U.S. Foreign Corrupt Practices (FCPA), the U.K. Bribery Act 2010, and other applicable anti-bribery and corruption laws. Anti-corruption laws are interpreted broadly and prohibit corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Recent years have seen substantial increase in the global enforcement of anti-corruption laws. Our operations outside the U.S. could increase the risk of such violations. Our business is also heavily regulated and involves significant interaction with foreign

officials. In many countries outside the U.S., independent clinical investigators conducting our clinical trials and prescribers of our products are employed by government entities, and purchasers themselves can be government entities. As such, our interactions with such investigators, prescribers and purchasers may be subject to regulation under the FCPA, as well as other similar under anti-corruption laws and/or regulations enacted by other countries. 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 and equivalent foreign 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.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, and our business depends on a global supply chain for the development, manufacturing, and distribution of our products, and for the advancement of our development programs. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations.

We source and procure APIs, precursor chemicals, and specialized equipment from international suppliers, with substantial reliance on foreign contract manufacturers in Europe. Tariff policies, particularly those affecting pharmaceutical products, could increase our costs and reduce our profitability. Additionally, recent policy discussions have included potential targeted tariffs or other trade measures specifically aimed at pharmaceutical products and ingredients as part of broader healthcare cost control or national security initiatives. In April 2025, the U.S. Department of Commerce initiated an investigation on imports of pharmaceuticals and pharmaceutical ingredients, which may result in the current U.S. presidential administration taking actions to impose tariffs on the pharmaceutical industry. The U.S. presidential administration also indicated that it may impose a 100% tariff on any branded or patented pharmaceutical product, unless a company is building a pharmaceutical manufacturing plant in the U.S. The specific impact of the investigation and announcements to enact substantial tariffs on patented pharmaceutical products remain uncertain at this time but could negatively impact our business and operations. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Should tariffs be imposed specifically targeting pharmaceutical imports, our production costs could rise, and it would be difficult and costly to qualify alternative sources within another country with a lower tariff rate or within the U.S., as developing and qualifying alternative sources typically requires substantial time, investment, and regulatory approvals.

Unlike many industries, our ability to pass increased costs to customers is limited by the structure of pharmaceutical pricing and reimbursement systems. As a result, cost increases due to tariffs may be difficult or impossible to pass through to customers.

Current or future tariffs will also result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence and negatively impact our business, results of operations, financial condition and growth prospects.

Trade disputes, tariffs, restrictions and other political tensions between the U.S. and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this report.

We could face liability if a regulatory authority determines that we are promoting INGREZZA, CRENESSITY, 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.

If the FDA or any other governmental agency, including equivalent foreign authorities, 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 our information technology systems, those third parties upon which we rely, or our data is or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited to, interruptions to our operations such as our clinical trials, claims that we breached our data protection obligations, harm to our reputation, regulatory investigations or actions, litigation, fines and penalties, and a loss of customers or sales.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies and technology systems and infrastructure of third parties upon whom we rely, including CROs and other vendors, to operate our business. In the ordinary course of our business, we and the third parties upon which we rely, collect, receive, store, process, generate, disclose, make accessible, protect, dispose of, transmit, use, safeguard, share and transfer, or collectively, process, confidential and sensitive electronic information on our networks and in our data centers. This information includes, among other things, de-identified or pseudonymous sensitive personal data (including health data), our intellectual property and proprietary information, the confidential information of our collaborators and licensees, and the personal data 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 a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code, malware (such as malicious code, adware, and command and control (C2)), denial-of-service attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, attacks enhanced or facilitated by AI, telecommunications failures, and other similar threats. In addition, AI has and will continue to make existing threats more sophisticated and difficult to detect, increase the volume of threats, and generate new threats.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors (also referred to as APTs). Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, which could materially disrupt our systems and operations, as well as our ability to conduct clinical trials.

Ransomware attacks are also becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations (including our ability to conduct clinical trials), loss of sensitive data (including related to our clinical trials) and income, reputational harm, and diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties in our supply chain have not been compromised or that they do not contain exploitable defects, vulnerabilities, or bugs that could result in a breach of or disruption to our information technology systems and infrastructure or the information technology systems and infrastructure of third parties that support our operations.

Remote work has increased risks to our information technology systems and data, as certain of our employees work from home, utilizing network connections, computers and devices outside our premises, including at home, while in transit or in public locations.

Additionally, natural disasters, public health pandemics or epidemics, terrorism, war and geopolitical conflicts, 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 data.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

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 or modify our business activities (including our clinical trial activities) to try to protect against security incidents.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information security systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks. Any of the previously identified or similar threats may in the future cause a security incident or other interruption that may result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon who we rely.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business, including clinical trial sites and investigators, contractors, manufacturers, suppliers and consultants. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers or CROs experience a security incident or other interruption, we could experience adverse consequences. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or otherwise subject to a security incident. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

Although to our knowledge we, or the third parties upon who we rely, have not experienced a security incident or disruption to date that is material to us, we and our vendors have been, either directly or indirectly, the target of cybersecurity incidents and expect them to continue. While we have implemented security measures designed to protect our data security and information technology systems, such measures may not prevent such events. Furthermore, while we have implemented certain redundancies designed to avoid interruptions to our operations, not all potential events can be anticipated and interruptions to our operations could lead to decreased productivity.

If we (or a third party upon whom we rely) experience a security incident, ransomware attack or are perceived to have experienced a security incident, we may experience material adverse consequences. Such material consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm (including but not limited to damage to our patient, partner, or employee relationships); monetary fund diversions; diversion of management's attention; interruptions in our operations (including availability of data, loss of connectivity to our network or internet); financial loss (including decreased productivity resulting from interruptions in our operations); and other similar harms. 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. In addition, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Applicable data privacy and security obligations may also require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

Our contracts, with for example third parties or CROs, may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We also cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' potential use of generative AI technologies.

Unfavorable geopolitical and macroeconomic developments could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by conditions in the U.S. and global economies, the U.S. and global financial markets and adverse geopolitical and macroeconomic developments, including potential future disruptions in access to bank deposits due to bank failures, tariffs and trade barriers, the recent shutdown of the U.S. federal government and the resulting effects on its regulatory agencies, geopolitical tensions, and military conflicts. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, inflation and interest rates, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and suppliers, and our collaborators operate. A weak or declining global economy due to geopolitical tensions or tariffs and trade barriers could also strain our suppliers and manufacturers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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.

In addition to any patent protection, we rely on forms of regulatory exclusivity to protect our products such as orphan drug designation. 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. for seven years and EU for 10 years 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 product 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.

If we do not have adequate patent protection for our products, then the relative importance of obtaining regulatory exclusivity is even greater. We may not be successful in obtaining orphan drug designations for any indications and, even if we succeed, such product candidates with such orphan drug designations may fail to achieve FDA approval. Even if a product candidate with orphan drug designation may receive marketing approval from the FDA, it 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 business operations may subject us to disputes, claims and lawsuits, which may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.

From time to time, we may become involved in disputes, claims and lawsuits relating to our business operations. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. Any dispute, claim or lawsuit may divert management's attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results.

Litigation related to these disputes may be costly and time-consuming and could materially and adversely impact our financial position and results of operations if resolved against us. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

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 CRENESSITY, may expose us to liability claims. These claims might be made directly by consumers, healthcare providers, pharmaceutical companies or others selling our products. We have product liability insurance coverage for both our clinical trials as well as related to the sale of INGREZZA and CRENESSITY in amounts consistent with customary industry practices. 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 CRENESSITY, 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.

We are subject to stringent and changing obligations related to data privacy and information security. Our actual or perceived failure to comply with such obligations could have a material adverse effect on our reputation, business, financial condition or results of operations.

In the ordinary course of our business, we process confidential and sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about clinical trial participants in connection with clinical trials, and sensitive third-party data, on our networks and in our data centers. We are subject to numerous federal, state, local and foreign laws, orders, codes, regulations and regulatory guidance regarding privacy, data protection, information security and the processing of personal information (including clinical trial data), the number and scope of which are expanding, changing, subject to differing applications and interpretations, and may be inconsistent among jurisdictions. Our data processing activities may also subject us to other data privacy and security obligations, such as industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of data by us and by third parties on our behalf.

Laws regarding privacy, data protection, information security and the processing of personal data are becoming increasingly common in the U.S. at both the federal and state level. Additionally, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act of 2020 (collectively, CCPA), requires businesses to provide specific disclosures in privacy notices, and honor requests of California residents to exercise certain privacy rights. The CCPA allows for fines for noncompliance. Although some U.S. comprehensive privacy laws and the CCPA exempt some data processed in the context of clinical trials, these laws may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. Other states have also enacted data privacy laws and we expect more jurisdictions to pass similar laws in the future. These developments may further complicate compliance efforts, and may increase legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information.

Laws in Europe regarding privacy, data protection, information security and the processing of personal data have also been significantly reformed and continue to undergo reform. For example, the EU's General Data Protection Regulation (EU GDPR) and the UK's GDPR (UK GDPR) (collectively, GDPR) impose strict requirements for processing the personal data of individuals located, respectively, within the European Economic Area (EEA) and the UK, and the Swiss Federal Act on Data Protection similarly applies to the collection and processing of personal data, including health-related information, in Switzerland. The GDPR provides for enhanced 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; and implementing safeguards to protect the security and confidentiality of personal data. The GDPR imposes substantial fines for breaches of data protection requirements. For example, under the GDPR, such fines can be up to four percent of global revenue or 20 million euros under the EU GDPR / 17.5 million pounds sterling under the UK GDPR, whichever is greater in either case, and also allow for private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. 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.

We may be subject to additional foreign data laws. For example, in Canada, the Personal Information Protection and Electronic Documents Act (PIPEDA) and various related provincial laws, as well as Canada's Anti-Spam Legislation (CASL), may apply to our operations. As another example, the General Data Protection Law, Lei Geral de Proteção de Dados Pessoais (LGPD) (Law No. 13,709/2018), may apply to our operations. The LGPD broadly regulates processing personal data of individuals in Brazil and imposes compliance obligations and penalties comparable to those of the EU GDPR. We also target customers in Asia and may be subject to new and emerging data privacy regimes in Asia, including Japan's Act on the Protection of Personal Information and Singapore's Personal Data Protection Act.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the U.S. or other countries. Certain jurisdictions have enacted data localization laws and cross-border personal data transfers laws. For example, countries in the EEA and the UK have significantly restricted the transfer of personal data to the U.S. and other countries, whose privacy laws it generally believes are inadequate. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U.S. in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for to relevant

U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S. If we cannot implement a valid compliance mechanism for cross-border personal data transfers or if the requirements for a legally-compliant transfer are too onerous, we may face increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal data from Europe or elsewhere. The inability to import personal data to the U.S. may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties subject to European and other data protection laws or requiring us to increase our personal data processing capabilities in Europe and/or elsewhere at significant expense. Other jurisdictions may adopt or have already adopted similarly stringent interpretations of their data localization and cross-border data transfer laws. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the DOJ issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in certain transactions or agreements.

Our employees and personnel are permitted to use generative AI technologies to perform some of their work, and the disclosure and use of personal information data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. Furthermore, it is possible that use of generative AI to develop our proprietary technology and compounds may also impact our ability to obtain or successfully defend certain intellectual property rights. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we may contractually be subject to industry standards adopted by industry groups and, we are, or may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements regarding data privacy and security. Regulators in the U.S. are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing in an increasingly stringent fashion and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent among jurisdictions or in conflict. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems and practices and those of any third parties that process personal data on our behalf. In addition, these obligations may even require us to change our business model.

Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third-parties upon whom we rely may fail to comply such obligations that impacts our compliance posture. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions, litigation (including class claims), additional reporting requirements and/or oversight, bans on processing personal data, imprisonment of company officials, and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly

more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, financial condition or results of operations.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We rely on information technology and data to operate our business and develop, market, and deliver our therapies to our customers. We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to critical computer networks, third-party hosted services, communications systems, hardware, lab equipment, software, and our critical data, including confidential, personal, proprietary, and sensitive data (collectively, Information Assets). Accordingly, we maintain certain risk assessment processes intended to identify cybersecurity threats, determine their likelihood of occurring, and assess potential material impact to our business. Based on our assessment, we implement and maintain risk management processes designed to protect the confidentiality, integrity, and availability of our Information Assets and mitigate harm to our business. Our cybersecurity program is informed in part by the National Institute of Standards and Technology (NIST) Cybersecurity Framework, and identified cybersecurity risks are documented and tracked within a formal cybersecurity risk register.

Our general risk management program is designed to manage identified material risks, which include material cybersecurity risks.

We engage in processes designed to identify such threats by, among other things, monitoring the threat environment using manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, conducting scans of the threat environment, evaluating our and our industry's risk profile, evaluating threats reported to us, coordinating with law enforcement concerning threats, conducting threat assessments for internal and external threats, and conducting vulnerability assessments to identify vulnerabilities. We also conduct annual third-party penetration testing, maintain external cybersecurity incident response partners who can assist in the event of an incident, and conduct annual incident-response tabletop exercises to evaluate and improve our readiness.

We rely on a multidisciplinary team (including personnel from management, and third-party service providers, as described further below) to assess how identified cybersecurity threats could impact our business. These assessments may leverage, among other processes, industry tools and metrics designed to assist in the assessment of risks from such cybersecurity threats.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures designed to manage and mitigate material risks from cybersecurity threats to our Information Assets. The cybersecurity risk management and mitigation measures we implement for certain of our Information Assets include:

- policies and procedures designed to address cybersecurity threats, including an incident response plan, vulnerability management policy, and disaster recovery/business continuity plans, which are evaluated periodically;
- incident detection and response tools;
- internal and/or external audits to assess our exposure to cybersecurity threats, environment, compliance with risk mitigation procedures, and effectiveness of relevant controls;
- documented risk assessments;
- implementation of security standards/certifications;
- encryption of data;
- network security controls;

- threat modeling;
- data segregation;
- physical and electronic access controls;
- physical security;
- asset management, tracking, and disposal;
- systems monitoring;
- vendor risk management program;
- employee security training, including mandatory annual cybersecurity training for all employees and additional role-based training where appropriate, with contractors who have access to our systems also required to complete cybersecurity training, as well as regular phishing simulations;
- penetration testing, including annual third-party penetration testing;
- red/blue team exercises;
- cyber insurance; and
- dedicated cybersecurity staff and officers.

We work with third parties from time to time that assist us in identifying, assessing, and managing cybersecurity risks, including professional services firms, threat intelligence service providers, cybersecurity consultants, cybersecurity software providers, managed cybersecurity service providers, and penetration testing firms.

To operate our business, we utilize certain third-party service providers to perform a variety of functions, such as outsourced business-critical functions, clinical research, professional services, Software as a Service (SaaS) platforms, managed services, property management, cloud-based infrastructure, data-center facilities, content delivery, encryption and authentication technology, corporate productivity services, and other functions. We have certain vendor management processes designed to help manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity and quantity of information processed, and the identity of the service provider, our vendor management process may include reviewing the cybersecurity practices of such provider, contractually imposing obligations on the provider related to the services provided and/or the information processed (including requirements that service providers notify us of certain cybersecurity incidents), conducting security assessments, conducting on-site inspections, requiring completion of written questionnaires regarding the service provider's services and data-handling practices, and conducting periodic re-assessments of critical or high-risk providers during their engagement.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see Part I, Item 1A. Risk Factors for additional information about cybersecurity-related risks.

Governance

Our cybersecurity risk assessment and management processes are implemented and maintained by certain of our management, including our Chief Information Officer (CIO), who reports to the Chief Financial Officer (CFO), and our Head of Cyber Security, who reports to the CIO and is responsible for day-to-day cybersecurity operations. Our CIO has 24 years of experience in global information technology leadership focused on digital transformation and artificial intelligence (AI) automation, including establishing responsible AI councils and leading AI governance. Our Head of Cyber Security has 25 years of experience in cybersecurity, including security operations, incident response, vulnerability management, penetration testing, identity and access management, security architecture, AI security and governance, and third-party risk management, and holds a Master of Science in Cyber Security and a Bachelor of Science in Information Systems, maintains industry certifications including Certified Information Systems Security Professional (CISSP), and is a Digital Directors Network Boardroom Qualified Technology Expert (QTE).

Management is also responsible for hiring appropriate personnel, integrating cybersecurity considerations into our overall risk management strategy, communicating key priorities to employees, approving budgets, preparing for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports. Our cybersecurity incident response and vulnerability management processes involve management who participates in our disclosure controls and procedures.

Our cybersecurity incident response and vulnerability management processes are designed to escalate certain cybersecurity incidents and vulnerabilities to members of management depending on the circumstances, and significant cybersecurity incidents are immediately escalated to executive management. Our incident response team is cross-functional and includes representatives from the CIO's organization, the Head of Cyber Security, Legal, Finance, Compliance/Privacy, and Communications. This team works together to help mitigate and remediate cybersecurity incidents. In addition, ours incident response processes include reporting to the Audit Committee for certain cybersecurity incidents.

Management is involved with our efforts to prevent, detect, and mitigate cybersecurity incidents by overseeing preparation of cybersecurity policies and procedures, testing of incident response plans (including annual tabletop exercises), and engagement of vendors to conduct penetration tests. Management participates in cybersecurity incident response efforts by being part of the incident response team and helping direct our response to cybersecurity incidents.

Our Board of Directors addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats. The Head of Cyber Security briefs the Audit Committee on cybersecurity matters quarterly, and the Audit Committee also has access to various reports, summaries, and/or presentations related to cybersecurity threats, risks, and mitigation.

Item 2. Properties

The following table presents information on our leased facilities.

Location	Use	Square Feet	Expiration Date
San Diego, California	Corporate Headquarters, Office and Laboratory	535,000	October 31, 2036
San Diego, California	Office and Laboratory	229,000 (1)	July 31, 2031
San Diego, California	Office	45,000 (2)	April 30, 2029
Washington, DC	Office	5,300	August 31, 2027

(1) This property is associated with our former corporate headquarters. Approximately 73,000 square feet are subleased by multiple third parties for general office space through the remaining term of the lease.

(2) This property is associated with our former corporate headquarters. We are actively marketing this property for sublease. Approximately 22,500 square feet are subleased by a third party for general office space through the remaining term of the lease with approximately 22,500 square feet of available space remaining.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative facilities will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

For a description of our legal proceedings, see Note 15 to the consolidated financial statements, which is incorporated herein by reference.

From time to time, we may become subject to other legal proceedings or claims arising in the ordinary course of our business. We currently believe that none of the claims or actions pending against us is likely to have, individually or in the aggregate, a material adverse effect on our business, financial condition, or results of operations. Given the unpredictability inherent in litigation, however, we cannot predict the outcome of these matters.

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".

As of February 4, 2026, there were 35 stockholders of record of our common stock. The actual number of stockholders is greater than this number because certain stockholders who are beneficial owners hold our common stock in "street" name with brokers and other nominees.

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

See Part III, Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters for information about our equity compensation plans which is incorporated by reference herein.

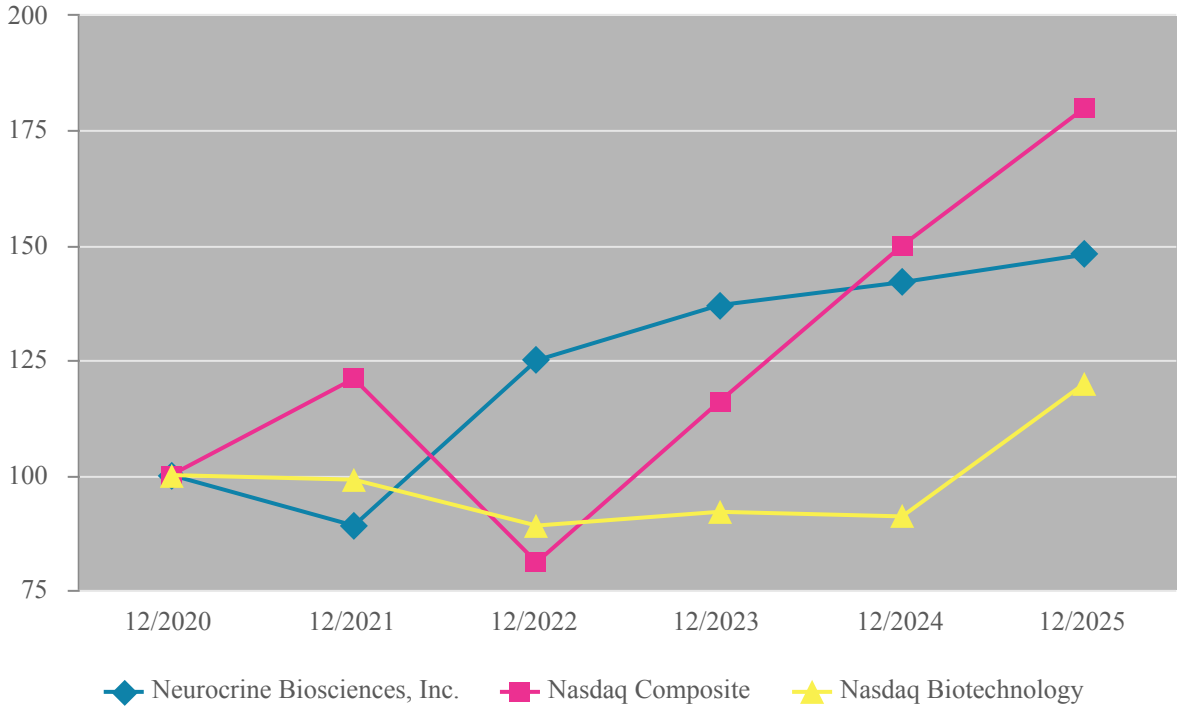
We did not repurchase any of our equity securities during the three months ended December 31, 2025.

Recent Sales of Unregistered Securities

During the year ended December 31, 2025, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

STOCK PERFORMANCE GRAPH AND CUMULATIVE TOTAL RETURN*

The following graph presents the cumulative total stockholder return assuming the investment of $100 on December 31, 2020 (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 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 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 progress, timing, results or implications of clinical trials and other development activities, our plans and timing with respect to seeking regulatory approvals, 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

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs. We are dedicated to discovering, developing, and commercializing life-changing treatments for patients with under-addressed neurological, psychiatric, endocrine, and immunological disorders.

Our portfolio of products includes U.S. Food and Drug Administration (FDA) approved treatments for tardive dyskinesia (TD), chorea associated with Huntington's disease, classic congenital adrenal hyperplasia due to 21-hydroxylase deficiency (CAH), and endometriosis and uterine fibroids in collaboration with AbbVie Inc. (AbbVie). In addition, we have a diversified portfolio of multiple compounds in mid- to late-phase development across our core therapeutic areas and an expanding early-phase pipeline that includes a range of modalities including small molecules, peptides, proteins, antibodies, conjugates, and gene therapies.

We launched INGREZZA® (valbenazine) in the U.S. as the first FDA-approved drug for the treatment of TD in May 2017 and for the treatment of chorea associated with Huntington's disease in August 2023 and launched CRENESSITY® (crinecerfont) in the U.S. as a first-in-class FDA-approved treatment of CAH in December 2024.

We estimate that TD affects approximately 800,000 people in the U.S., that approximately 90% of the 40,000 people in the U.S. affected by Huntington's disease will develop chorea, and that CAH affects at least 20,000 people in the U.S. Key elements of our commercial strategy include maximizing the opportunities in INGREZZA and CRENESSITY through consistent and effective commercial execution, continued development of valbenazine as the best-in-class treatment for new patient populations, and to lead the evolving understanding of vesicular monoamine transporter 2 (VMAT2) biology and its role in disease. Net product sales of INGREZZA were $2.51 billion for 2025, $2.31 billion for 2024, and $1.84 billion for 2023 and accounted for a significant portion of our total net product sales during each of these years. Net product sales of CRENESSITY were $301.2 million for 2025 during its first full-year of launch.

2025 Business Highlights

- Total net product sales for 2025 increased $503.3 million, or 21.6%, to $2.83 billion, reflecting increased net product sales of CRENESSITY, which was launched in the U.S. as a first-in-class FDA-approved treatment of CAH in December 2024, and INGREZZA, driven by record total prescriptions on strong patient demand, partially offset by a lower net price due to new market access investments to support long-term growth.
- In October 2025, we announced the planned expansion of the INGREZZA and CRENESSITY sales teams to maximize our commercial momentum. The expansion is expected to be completed by the end of the first quarter of 2026.
- Appointed Sanjay Keswani, M.D., as Chief Medical Officer (CMO) and member of our executive management team, effective June 2, 2025.
- In February 2025, our Board of Directors authorized a new share repurchase program (the 2025 Repurchase Program) under which we may repurchase up to $500.0 million of our common stock, subject to market conditions. The 2025 Repurchase Program is in addition to the $300.0 million accelerated repurchase program (the 2024 Repurchase Program) that was announced in October 2024 and completed in February 2025. During 2025, we repurchased 1.5 million shares on the open market under the 2025 Repurchase Program and received an additional 0.3 million shares upon settlement of the 2024 Repurchase Program in February 2025.

- In January 2025, we received Centers for Medicare and Medicaid Services (CMS) notification that INGREZZA qualifies for the small biotech exception under the Medicare Drug Price Negotiation Program, which provides exemption from selection until 2027 for initial price applicability in 2029. In addition, we expanded formulary access for INGREZZA, significantly improving coverage to include approximately 70% of TD and Huntington's disease Medicare beneficiaries to support long-term growth.

2025 Pipeline Highlights

- Announced the initiation of a Phase 2 clinical study of investigational compound NBI-1065890 in adults with TD. NBI-1065890 is a next-generation, selective inhibitor of VMAT2.
- Initiated a comprehensive Phase 3 clinical program for direclidine (NBI-1117568) in schizophrenia, including studies evaluating efficacy in acutely psychotic hospitalized patients and long-term safety. In addition, we initiated a Phase 2 study evaluating direclidine in bipolar mania in the fourth quarter of 2025.
- Initiated a comprehensive Phase 3 clinical program for osavampator (NBI-1065845) in major depressive disorder (MDD), including three acute randomized, double-blind, placebo-controlled studies, a randomized-withdrawal maintenance-of-effect study, and a long-term open-label safety extension.
- Initiated a Phase 1 clinical study for NBIP-01435, an investigational, long-acting corticotropin-releasing factor type 1 (CRF-1) receptor antagonist administered as a subcutaneous injection for the potential treatment of CAH.
- Initiated a Phase 1 clinical study for NBI-921355, an investigational, selective inhibitor of voltage-gated sodium channels $Na_v1.2$ and $Na_v1.6$ in development for the potential treatment of certain types of epilepsy.
- Initiated a Phase 1 clinical study for NBI-1140675, an investigational, oral, selective second-generation small molecule VMAT2 inhibitor in development for the potential treatment of certain neurological and neuropsychiatric conditions.
- Announced top-line data from a Phase 4 study, KINECT-PRO™, demonstrating clinically meaningful and sustained effects of INGREZZA capsules on the physical, social, and emotional impacts experienced by patients living with TD, irrespective of TD severity or underlying psychiatric condition.
- Presented new data from a post-hoc analysis of the Phase 4 KINECT-PRO open-label study confirming that robust rates of symptomatic remission of TD were achieved with once-daily INGREZZA capsules. The analysis also showed sustained improvements in patient-reported outcomes among participants who achieved symptomatic remission.
- Presented new data from the Phase 2 SAVITRI™ study, which showed statistically significant and clinically meaningful improvement in depression severity at Day 28 and Day 56 with once-daily oral administration of 1 mg osavampator.
- Announced the Phase 3 studies of valbenazine in schizophrenia and dyskinesia due to cerebral palsy (DCP) and Phase 2 study of NBI-1070770 in major depressive disorder (MDD) did not meet their primary endpoints.

Results of Operations

	Year Ended December 31,		
(in millions, except per share data)	2025	2024	2023
Revenues	$ 2,860.5	$ 2,355.3	$ 1,887.1
Operating expenses	2,241.4	1,784.8	1,636.2
Operating income	619.1	570.5	250.9
Other income (expense)	86.3	(84.5)	81.2
Provision for income taxes	226.8	144.7	82.4
Net income	$ 478.6	$ 341.3	$ 249.7
Earnings per share, diluted	$ 4.67	$ 3.29	$ 2.47
Weighted average common shares outstanding, diluted	102.5	103.7	101.0

Revenues

(in millions)	Year Ended December 31, 2025	2024	2023
INGREZZA	$ 2,513.7	$ 2,313.5	$ 1,836.0
CRENESSITY	301.2	1.7	—
Other	19.0	15.4	24.6
Total net product sales	2,833.9	2,330.6	1,860.6
Collaboration revenues	26.6	24.7	26.5
Total revenues	$ 2,860.5	$ 2,355.3	$ 1,887.1

Net Product Sales

For 2025 compared to 2024, the increase primarily reflected increased net product sales of CRENESSITY, which was launched in the U.S. as a first-in-class FDA-approved treatment of CAH in December 2024, and INGREZZA, driven by record total prescriptions on strong patient demand, partially offset by a lower net price due to new market access investments to support long-term growth.

For 2024 compared to 2023, the increase primarily reflected increased net product sales of INGREZZA driven by strong underlying patient demand and improved gross-to-net dynamics.

Collaboration Revenues

Collaboration revenues for all periods presented primarily reflected royalties earned on AbbVie net sales of elagolix and Tanabe Pharma Corporation (formerly Mitsubishi Tanabe Pharma Corporation) net sales of valbenazine.

Operating Expenses

Cost of Revenues

(dollars in millions)	Year Ended December 31, 2025	2024	2023
Cost of revenues	$ 52.1	$ 34.0	$ 39.7
as a % of total revenues	1.8 %	1.4 %	2.1 %

For 2025 compared to 2024, the increase primarily reflected increased net product sales of INGREZZA and increased royalties payable on net product sales of CRENESSITY. In addition, cost of revenues for 2025 excluded costs that were charged to R&D expense prior to FDA approval of CRENESSITY. As a result, this lower-cost drug product reduced our cost of revenues and improved related product gross margins for 2025. In future periods, we expect to incur a higher cost of revenues that includes the cost of CRENESSITY active pharmaceutical ingredients produced following FDA approval.

For 2024 compared to 2023, the decrease primarily reflected decreased net product sales of ONGENTYS® (opicapone) and decreased ONGENTYS inventory reserves in connection with the termination of our license agreement with BIAL, which became effective in December 2023, partially offset by increased net product sales of INGREZZA.

Research and Development

We support our drug discovery and development efforts through the commitment of significant resources to discovery, research and development 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 research and development activities are part of our collaborative arrangements.

(dollars in millions)	Year Ended December 31, 2025	2024	2023
Late stage	$ 190.7	$ 101.8	$ 106.1
Early stage	72.4	96.1	107.4
Research and discovery	244.2	145.6	96.5
Milestones	65.4	71.7	0.8
Payroll and benefits	306.4	236.7	206.7
Facilities and other	136.6	79.2	47.5
Total research and development	$ 1,015.7	$ 731.1	$ 565.0
as a % of total revenues	35.5 %	31.0 %	29.9 %

Late Stage. Late stage consists of costs incurred for product candidates in Phase 2 registrational studies and all subsequent activities.

For 2025 compared to 2024, the increase primarily reflected increased investments in the Phase 3 programs for osavampator in MDD and direclidine in schizophrenia, partially offset by lower spend on crinecerfont in CAH.

For 2024 compared to 2023, the decrease primarily reflected the successful completions of the Phase 3 programs for crinecerfont in CAH, partially offset by increased investments in the Phase 3 programs for osavampator in MDD and direclidine in schizophrenia.

*Early Stage***.** Early stage consists of costs incurred for product candidates after the approval of an investigational new drug application by the applicable regulatory agency through Phase 2 non-registrational studies.

For 2025 compared to 2024, the decrease primarily reflected the progression of the Phase 2 program for direclidine in schizophrenia to late-stage in the fourth quarter of 2024 and lower spend on certain early-stage psychiatry programs, partially offset by increased investment in our early-stage muscarinic portfolio and the advancements of NBI-921355, NBI-1140675, and NBIP-01435 into Phase 1 development.

For 2024 compared to 2023, the decrease primarily reflected lower spend on certain early-stage epilepsy and psychiatry programs, including the successful completions of the Phase 2 programs for osavampator in MDD and direclidine in schizophrenia, partially offset by increased investments in certain early-stage psychiatry programs and our early-stage muscarinic portfolio.

*Research and Discovery***.** Research and discovery consists of costs incurred prior to the approval of an investigational new drug application by the applicable regulatory agency, including discovery research and preclinical development activities (such as lead optimization, nonclinical studies, preclinical manufacturing, and toxicology).

For 2025 compared to 2024, the increase primarily reflected increased investments to expand our discovery and preclinical programs across therapeutic areas and modalities, including endocrinology and metabolic disease (including obesity) and immunology, and expanding our capabilities in biologics (including peptides and antibodies) and gene therapy.

For 2024 compared to 2023, the increase primarily reflected increased investments in gene therapy and other preclinical development programs.

Milestones. Milestones consist of costs incurred in connection with the achievement of development milestones under collaborative arrangements. The following table presents milestones expense by collaboration partner.

	Year Ended December 31,		
(in millions)	**2025**	**2024**	**2023**
Nxera Pharma UK Limited	$ 15.0	$ 50.0	$ —
Takeda Pharmaceutical Company Limited	37.5	7.5	—
Xenon Pharmaceuticals Inc.	7.5	—	—
Voyager Therapeutics, Inc.	3.0	11.0	—
Other	2.4	3.2	0.8
Total milestones	$ 65.4	$ 71.7	$ 0.8

See Note 11 to the consolidated financial statements for more information on our significant collaboration and license agreements.

Payroll and Benefits. Payroll and benefits consist of costs incurred for salaries and wages, payroll taxes, benefits, and stock-based compensation associated with employees involved in research and development activities. Stock-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 stock-based grants are issued.

For 2025 compared to 2024, the increase primarily reflected higher headcount (including an increase of $22.2 million in non-cash stock-based compensation expense) to support our expanded discovery and preclinical programs across therapeutic areas and modalities, including endocrinology and metabolic disease (including obesity) and immunology, and expanding our capabilities in biologics (including peptides and antibodies) and gene therapy.

For 2024 compared to 2023, the increase primarily reflected higher headcount.

Facilities and Other. Facilities and other consists of indirect costs incurred for the benefit of multiple programs, including facility-based expenses (such as rent expense) and other overhead allocations.

For 2025 compared to 2024 and 2024 compared to 2023, the increases primarily reflected increased facility-based expenses related to our new campus facility.

Acquired In-Process Research and Development (IPR&D)

	Year Ended December 31,		
(dollars in millions)	**2025**	**2024**	**2023**
Acquired in-process research and development	$ 17.4	$ 12.5	$ 143.9
as a % of total revenues	0.6 %	0.5 %	7.6 %

For 2025 compared to 2024, the increase primarily reflected higher upfront payments under licensing agreements for early-stage development candidates.

For 2024 compared to 2023, the decrease primarily reflected the payment of a $143.9 million upfront fee in 2023 pursuant to the expansion of our collaboration with Voyager.

Selling, General, and Administrative (SG&A)

	Year Ended December 31,		
(dollars in millions)	**2025**	**2024**	**2023**
Selling, general, and administrative	$ 1,156.2	$ 1,007.2	$ 887.6
as a % of total revenues	40.4 %	42.8 %	47.0 %

For 2025 compared to 2024, the increase primarily reflected continued investment in our commercial organization (including the expansion of our psychiatry and long-term care sales teams completed in September 2024 and CRENESSITY-related headcount and commercial launch activities), partially offset by decreased impairment charges associated with our vacated legacy campus facilities.

For 2024 compared to 2023, the increase primarily reflected continued investment in our commercial organization (including the expansion of our psychiatry and long-term care sales teams completed in September 2024 and CRENESSITY-related pre-launch activities), increased facility-based expenses related to our new campus facility, and impairment charges of $14.0 million associated with our vacated legacy campus facilities.

Other Income (Expense)

	Year Ended December 31,		
(in millions)	**2025**	**2024**	**2023**
Unrealized (loss) gain on equity investments	$ (4.0)	$ (37.1)	$ 28.4
Charges associated with convertible senior notes	—	(138.4)	—
Investment income and other, net	90.3	91.0	52.8
Total other income (expense), net	$ 86.3	$ (84.5)	$ 81.2

For 2025 compared to 2024, the change primarily reflected prior year charges associated with the convertible senior notes that matured in May 2024 and periodic fluctuations in the fair values of our equity investments.

For 2024 compared to 2023, the change primarily reflected $138.4 million of expense associated with the convertible senior notes that matured in May 2024, periodic fluctuations in the fair values of our equity investments, and increased interest income on our debt security investments.

Provision for Income Taxes

	Year Ended December 31,		
(dollars in millions)	**2025**	**2024**	**2023**
Provision for income taxes	$ 226.8	$ 144.7	$ 82.4
Effective tax rate	32.2 %	29.8 %	24.8 %

For 2025, the effective tax rate differed from the federal and state statutory rates primarily due to foreign tax effects, including the impact of global intangible low-taxed income (GILTI), credits generated for research activities, excess tax benefits related to stock-based compensation, certain nondeductible expenses, and state income tax effects including fluctuations in state effective tax rates.

For 2024 and 2023, the effective tax rate varied from the federal and state statutory rates primarily due to credits generated for research activities, certain nondeductible expenses, excess tax benefits related to stock-based compensation, and losses incurred in foreign jurisdictions for which no tax benefit was recorded as management cannot conclude that it is more likely than not that the tax benefit of such losses will be realized in the future. Additionally, in 2024, we incurred a loss on the extinguishment of debt that was nondeductible for tax purposes.

Liquidity and Capital Resources

Sources of Liquidity

We believe that our existing capital resources, funds generated by anticipated INGREZZA and CRENESSITY net product sales, and investment income will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, we cannot guarantee that our existing capital resources and anticipated revenues will be sufficient to conduct and complete all of our research and development programs or commercialization activities as planned. We may seek to access the public or private equity markets whenever conditions are favorable or pursue opportunities to obtain debt financing in the future. We may also seek additional funding through strategic alliances or other financing mechanisms. However, we cannot provide assurance that adequate funding will be available on terms acceptable to us, if at all.

Information Regarding Our Financial Condition

(in millions)	December 31, 2025	2024
Total cash, cash equivalents and marketable securities	$ 2,543.4	$ 1,815.6
Working Capital:		
Total current assets	$ 2,522.7	$ 1,724.7
Less total current liabilities	743.4	507.7
Total working capital	$ 1,779.3	$ 1,217.0

Information Regarding Our Cash Flows

(in millions)	Year Ended December 31, 2025	2024	2023
Cash flows from operating activities	$ 782.7	$ 595.4	$ 389.9
Cash flows from investing activities	(264.4)	(126.8)	(467.1)
Cash flows from financing activities	(38.3)	(486.7)	65.3
Effect of exchange rate changes on cash and cash equivalents	—	—	0.3
Change in cash, cash equivalents and restricted cash	$ 480.0	$ (18.1)	$ (11.6)

Cash Flows from Operating Activities

For 2025 compared to 2024, the increase primarily reflected increased total net product sales, partially offset by continued investments in our commercial organization (including the expansion of our psychiatry and long-term care sales teams completed in September 2024 and CRENESSITY-related headcount and commercial launch activities) and expanded pre-clinical and clinical portfolio. The increase in accounts receivable was driven by higher total gross product sales. The increase in accounts payable and accrued liabilities was driven primarily by higher revenue-related reserves for discounts and allowances attributed to higher gross product sales combined with expanded formulary access for INGREZZA. In addition, the change in income tax assets and liabilities primarily related to timing of foreign tax expense recognition, partially offset by the federal tax benefit on current income taxes payable from the enactment of the OBBBA.

For 2024 compared to 2023, the increase primarily reflected increased total net product sales and decreased total payments for upfront fees and development milestones achieved in connection with our collaborations, partially offset by increased payments for income taxes and continued investments in our commercial organization (including CRENESSITY-related pre-launch activities) and expanded pre-clinical and clinical portfolio.

Cash Flows from Investing Activities

For 2025 compared to 2024 and 2024 compared to 2023, the changes primarily reflected timing differences related to the purchases, sales, and maturities of debt security investments and changes in our portfolio-mix.

For 2024 compared to 2023, the change also reflected a $31.3 million equity investment in Voyager in 2023.

Cash Flows from Financing Activities

For 2025 compared to 2024, the change primarily reflected decreased share repurchases under the 2025 Repurchase Program compared to the 2024 Repurchase Program and decreased cash payments associated with the convertible senior notes that matured in May 2024.

For 2024 compared to 2023, the change reflected $300.0 million of share repurchases under the 2024 Repurchase Program, $308.8 million in cash payments to settle the convertible senior notes that matured in May 2024, and increased proceeds from issuances of our common stock.

Material Cash Requirements

In the pharmaceutical industry, it can take a significant amount of time and capital resources to successfully complete all stages of research and development and commercialize a product candidate, which ultimate length of time and spend required cannot be accurately estimated as it varies substantially according to the type, complexity, novelty and intended use of a product candidate.

The funding necessary to execute our business strategies is subject to numerous uncertainties and we may be required to make substantial expenditures if unforeseen difficulties arise in certain areas of our business. In particular, our future capital requirements will depend on many factors, including:

- the commercial success of INGREZZA and CRENESSITY;
- continued scientific progress in our research 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;
- costs associated with securing adequate coverage and reimbursement for our products;
- competing technological and market developments;
- developments related to any future litigation;
- the cost of commercialization activities and arrangements, including our advertising campaigns; and
- the cost of manufacturing our product candidates.

In addition to the foregoing factors, we have significant future capital requirements, including:

External Business Developments

In addition to our independent efforts to develop and market products, we may enter into collaboration and license agreements or acquire businesses from time-to-time to enhance our drug development and commercial capabilities. With respect to our existing collaboration and license agreements, we may be required to make potential future payments of up to $14.87 billion upon the achievement of certain milestones.

See Note 11 to the consolidated financial statements for more information on our significant collaboration and license agreements.

Share Repurchase Program

In addition to the foregoing future capital requirements, in February 2025, our Board of Directors authorized the 2025 Repurchase Program under which we may repurchase up to $500.0 million of our common stock, subject to market conditions. The 2025 Repurchase Program is in addition to the $300.0 million 2024 Repurchase Program that was announced in October 2024 and completed in February 2025. Under the 2025 Repurchase Program, we repurchased 1.5 million shares on the open market for a cost of $167.7 million during 2025. As of December 31, 2025, we had $332.3 million remaining available for additional repurchases under the 2025 Repurchase Program.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to revenue recognition. 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:

Reserves for Government Rebates

We recognize revenues from product sales of INGREZZA net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, payors, and other third parties. Such reserves include estimates for government rebates that we are obligated to pay for discounts including 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 require us to project the magnitude of our sales that will be subject to such rebates and 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. There is a significant time-lag in our receiving rebate notices from each state (generally, several months or longer after a sale is recognized). To date, actual government rebates have not differed materially from our estimates.

Income Taxes

Our income tax provision is computed under the asset and liability method. Significant estimates are required in determining our income tax 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 reassess 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.

We recognize a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the relevant taxing authority, based on the technical merits of the position. The tax benefit recognized in our consolidated financial statements for a particular tax position is measured as the largest amount of benefit that is more likely than not to be realized upon settlement with the relevant taxing authority. We reevaluate uncertain tax positions and related unrecognized tax benefits as appropriate for changes in facts and circumstances, including significant changes in tax law, regulations or interpretations, new information obtained during a tax examination, the resolution of tax examinations and appeals, and the expiration of statutes of limitations. We recognize accrued interest and penalties, when appropriate, related to uncertain tax positions in income tax expense. An adverse resolution of one or more uncertain tax positions, or changes in our assessment of the recognition or measurement of such positions, could have a material impact on our results of operations in the period in which the change occurs.

See Note 10 to the consolidated financial statements for information on our income taxes.

Additional Information

See 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We maintain a diversified investment portfolio consisting of low-risk, investment-grade debt securities with maturities of up to three years, including investments in commercial paper, securities of government-sponsored entities and corporate bonds that are subject to interest rate risk. The primary objective of our investment activities is to preserve principal and maintain liquidity. If a 1% unfavorable change in interest rates were to have occurred on December 31, 2025, it would not have had a material effect on the fair value of our investment portfolio as of that date.

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 Stockholders 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, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, 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, 2025, 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 11, 2026 expressed an unqualified opinion thereon.

Basis for Opinion

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

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

Critical Audit Matter

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 Medicaid rebates related to product sales

Description of the Matter

The Company sells product 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 product sales to its customers after deducting management's estimates of reserves for rebates it will provide under Medicaid rebate programs ("Medicaid rebates"). Estimated Medicaid rebates are presented within accounts payable and accrued liabilities on the consolidated balance sheet.

Auditing the estimates of Medicaid 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 the portion of product that is expected to be subject to a Medicaid rebate and the applicable contractual rebate percentage underlying the revenue and the applicable rebate amount.

How We Addressed the Matter in Our Audit

We tested the Company's internal controls over management's process for estimating the rebate amounts and the portion of product that is expected to be subject to a Medicaid rebate for product that remains in the distribution channel at December 31, 2025. This included controls over management's review of significant assumptions and other inputs into the estimation of Medicaid rebates including the completeness and accuracy of data used in the calculation.

To test management's estimate of Medicaid 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, 2025. 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 11, 2026

NEUROCRINE BIOSCIENCES, INC.

CONSOLIDATED BALANCE SHEETS

(in millions, except per share data)	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 713.0	$ 233.0
Available-for-sale debt securities	767.4	843.1
Accounts receivable	686.8	479.1
Inventory	69.0	57.4
Prepaid expenses	170.7	48.5
Other current assets	115.8	63.6
Total current assets	2,522.7	1,724.7
Deferred tax assets	320.3	485.7
Available-for-sale debt securities	1,063.0	739.5
Right-of-use assets	455.4	509.4
Equity investments	120.8	124.8
Property and equipment, net	89.8	82.6
Other noncurrent assets	59.5	52.0
Total assets	$ 4,631.5	$ 3,718.7
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 674.3	$ 461.6
Other current liabilities	69.1	46.1
Total current liabilities	743.4	507.7
Noncurrent operating lease liabilities	415.3	455.1
Other noncurrent liabilities	219.7	166.2
Total liabilities	1,378.4	1,129.0
Stockholders' equity:		
Preferred stock, $0.001 par value; 5.0 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 220.0 shares authorized; 100.1 and 99.4 shares issued and outstanding, respectively	0.1	0.1
Additional paid-in capital	2,792.2	2,554.6
Accumulated other comprehensive income	13.1	5.8
Retained earnings	447.7	29.2
Total stockholders' equity	3,253.1	2,589.7
Total liabilities and stockholders' equity	$ 4,631.5	$ 3,718.7

See accompanying notes to consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME

(in millions, except per share data)	Year Ended December 31, 2025	2024	2023
Revenues:			
Net product sales	$ 2,833.9	$ 2,330.6	$ 1,860.6
Collaboration revenues	26.6	24.7	26.5
Total revenues	2,860.5	2,355.3	1,887.1
Operating expenses:			
Cost of revenues	52.1	34.0	39.7
Research and development	1,015.7	731.1	565.0
Acquired in-process research and development	17.4	12.5	143.9
Selling, general, and administrative	1,156.2	1,007.2	887.6
Total operating expenses	2,241.4	1,784.8	1,636.2
Operating income	619.1	570.5	250.9
Other income (expense):			
Unrealized (loss) gain on equity investments	(4.0)	(37.1)	28.4
Charges associated with convertible senior notes	—	(138.4)	—
Investment income and other, net	90.3	91.0	52.8
Total other income (expense), net	86.3	(84.5)	81.2
Income before provision for income taxes	705.4	486.0	332.1
Provision for income taxes	226.8	144.7	82.4
Net income	478.6	341.3	249.7
Foreign currency translation adjustments, net of tax	3.8	(1.1)	2.4
Unrealized gain (loss) on available-for-sale debt securities, net of tax	3.5	(0.1)	12.5
Comprehensive income	$ 485.9	$ 340.1	$ 264.6
Earnings per share, basic	$ 4.81	$ 3.40	$ 2.56
Earnings per share, diluted	$ 4.67	$ 3.29	$ 2.47
Weighted average common shares outstanding, basic	99.5	100.4	97.7
Weighted average common shares outstanding, diluted	102.5	103.7	101.0

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)	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
Balances at December 31, 2022	96.5	$ 0.1	$ 2,122.4	$ (7.9)	$ (406.8)	$ 1,707.8
Net income	—	—	—	—	249.7	249.7
Other comprehensive income, net of tax	—	—	—	14.9	—	14.9
Stock-based compensation expense	—	—	194.3	—	—	194.3
Issuances of common stock under benefit plans	2.2	—	65.3	—	—	65.3
Balances at December 31, 2023	98.7	$ 0.1	$ 2,382.0	$ 7.0	$ (157.1)	$ 2,232.0
Net income	—	—	—	—	341.3	341.3
Other comprehensive loss, net of tax	—	—	—	(1.2)	—	(1.2)
Stock-based compensation expense	—	—	195.5	—	—	195.5
Issuances of common stock under benefit plans	2.7	—	122.1	—	—	122.1
Repurchases of common stock	(2.0)	—	(145.0)	—	(155.0)	(300.0)
Balances at December 31, 2024	99.4	$ 0.1	$ 2,554.6	$ 5.8	$ 29.2	$ 2,589.7
Net income	—	—	—	—	478.6	478.6
Other comprehensive income, net of tax	—	—	—	7.3	—	7.3
Stock-based compensation expense	—	—	217.9	—	—	217.9
Issuances of common stock under benefit plans	2.5	—	127.3	—	—	127.3
Repurchases of common stock	(1.8)	—	(107.6)	—	(60.1)	(167.7)
Balances at December 31, 2025	100.1	$ 0.1	$ 2,792.2	$ 13.1	$ 447.7	$ 3,253.1

See accompanying notes to consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)	Year Ended December 31, 2025	2024	2023
Cash flows from operating activities:			
Net income	$ 478.6	$ 341.3	$ 249.7
Adjustments to reconcile net income to net cash from operating activities:			
Stock-based compensation	217.9	195.5	194.3
Charges associated with convertible senior notes	—	138.4	—
Impairment charges associated with leased properties	0.7	14.0	—
Depreciation	26.0	23.5	17.8
Accretion of discount on available-for-sale debt securities, net	(12.7)	(26.2)	(18.3)
Amortization of acquired intangible assets	4.1	3.6	3.5
Changes in fair values of equity investments	4.0	37.1	(28.4)
Deferred tax assets	165.4	(123.1)	(56.7)
Non-cash lease expense	26.8	10.4	(0.9)
Other	0.7	0.1	0.7
Changes in operating assets and liabilities:			
Accounts receivable	(210.5)	(39.8)	(89.3)
Inventory	(15.3)	(19.1)	5.4
Accounts payable and accrued liabilities	160.2	43.4	49.0
Income tax assets and liabilities	(18.8)	50.3	91.6
Other assets and liabilities, net	(44.4)	(54.0)	(28.5)
Cash flows from operating activities	782.7	595.4	389.9
Cash flows from investing activities:			
Purchases of available-for-sale debt securities	(1,319.8)	(1,056.1)	(1,379.9)
Sales and maturities of available-for-sale debt securities	1,089.4	967.5	972.4
Purchases of equity investments	—	—	(31.3)
Capital expenditures	(34.0)	(38.2)	(28.3)
Cash flows from investing activities	(264.4)	(126.8)	(467.1)
Cash flows from financing activities:			
Issuances of common stock under benefit plans	129.4	122.1	65.3
Repurchases of common stock	(167.7)	(300.0)	—
Payments to settle convertible senior notes	—	(308.8)	—
Cash flows from financing activities	(38.3)	(486.7)	65.3
Effect of exchange rate changes on cash and cash equivalents	—	—	0.3
Change in cash and cash equivalents and restricted cash	480.0	(18.1)	(11.6)
Cash, cash equivalents and restricted cash at beginning of period	241.0	259.1	270.7
Cash, cash equivalents and restricted cash at end of period	$ 721.0	$ 241.0	$ 259.1
Supplemental Disclosure:			
Accrued capital expenditures	$ 2.2	$ 2.2	$ 2.5
Right-of-use assets acquired through operating leases	$ —	$ 271.6	$ 200.8
Cash paid for interest	$ —	$ 1.6	$ 3.8
Cash paid for income taxes	$ 81.4	$ 217.5	$ 51.5

See accompanying notes to consolidated financial statements.

1. Business Overview and Summary of Significant Accounting Policies

Nature of Operations

Neurocrine Biosciences, Inc. and its subsidiaries (Neurocrine Biosciences, the Company, we, our, or us) is a neuroscience-focused global biopharmaceutical company focused on discovering, developing, and commercializing life-changing treatments for patients with under-addressed neurological, psychiatric, endocrine, and immunological disorders.

Use of Estimates

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP), which requires us to make estimates and assumptions that affect the amounts reported in the consolidated financial statements. Actual results could differ from those estimates.

Basis of Consolidation

The consolidated financial statements include the accounts of Neurocrine Biosciences as well as our wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation. Certain reclassifications have been made to previously reported amounts to conform to the current period presentation.

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 such goods or services. Revenue is recognized using a five-step model: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation.

Product Revenue

We sell INGREZZA® (valbenazine) exclusively in the U.S. through a limited specialty network. Our customers include select specialty pharmacy providers, wholesale distributors, and specialty distributors. In addition, we sell CRENESSITY® (crinecerfont) in the U.S. through a single specialty pharmacy provider. Net product sales of INGREZZA were $2.51 billion for 2025, $2.31 billion for 2024, and $1.84 billion for 2023 and accounted for a significant portion of our total net product sales during each of these years. Net product sales of CRENESSITY were $301.2 million for 2025.

Product revenue is recorded net of reserves for variable consideration, including discounts and allowances offered within contracts with our customers, payors, and other third parties. These reserves, classified as reductions of accounts receivable or liabilities, are based on estimates and include the following categories:

- *Product discounts* represent estimated obligations for trade term discounts and other incentives offered to our customers. We accrue for product discounts based on actual historical discounts, including the timing of customer payments.
- *Distributor and other fees* represent fees for inventory management, data, and distribution services and are generally recorded as a reduction of revenue or expensed as selling, general, and administrative to the extent we can demonstrate a separable benefit and fair value for these services.
- *Government rebates* represent estimated obligations to government agencies under the Medicaid Drug Rebate Program and Medicare Part D and are recorded as a reduction of revenue in the period the related revenue is recognized. We accrue for government rebates based on estimated claims for the current quarter, estimated claims for prior quarters for which an invoice has not been received, and claims for prior quarters for which an invoice has been received but not paid.
- *Chargebacks* represent estimated obligations to our customers for differences between list and contract prices. We accrue for chargebacks as a reduction of revenue based on estimated contractual discounts on product inventory levels on-hand in our distribution channel.

- *Payor and pharmacy rebates* represent estimated obligations to payors and pharmacies for contract discounts on product sales and are recorded as a reduction of revenue in the period the related revenue is recognized. We accrue for payor and pharmacy rebates based on actual historical rebates, contractual rebate percentages, sales made through the payor channel, and purchases made by pharmacies.
- *Copay assistance* represents financial assistance to qualified patients with prescription drug copay requirements. We accrue for copay assistance as a reduction of revenue based on estimated claims and the cost per claim we expect to receive in connection with inventory that exists in the distribution channel at period end.
- *Product returns* represent estimated obligations for return rights offered to our customers due to shipment errors and damaged product and are recorded as a reduction of revenue in the period the related revenue is recognized. We accrue for product returns based on actual historical returns, benchmarking data, and industry experience.

Collaboration Revenues

We have entered into collaboration and license agreements under which we out-license certain rights to our product candidates to third parties. For arrangements that include sales-based royalties, and under which 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.

Cash Equivalents

We consider all highly liquid investments that are readily convertible into cash without penalty 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 credit losses. Our estimate for the allowance for credit losses, which has not been significant to date, is determined based on existing contractual payment terms, actual payment patterns of our customers, and individual customer circumstances.

Our exposure to credit losses may increase if our customers are adversely affected by changes in healthcare laws, coverage and reimbursement, economic pressures or uncertainty associated with local or global economic recessions, or other customer-specific factors.

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. Available-for-sale debt securities 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 (accretion) of purchase premiums (discounts). Premiums (discounts) on debt securities are amortized (accreted) 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 available-for-sale debt securities 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 available-for-sale debt securities 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 available-for-sale debt securities were $20.5 million and $14.4 million, respectively, as of December 31, 2025 and 2024. 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 2025, 2024, or 2023.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk include cash and cash equivalents, investments in available-for-sale debt securities, and accounts receivable.

To minimize the risks related to cash and cash equivalents and investments in available-for-sale debt securities, we have established guidelines related to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. Our investment portfolio is maintained in accordance with our investment policy, which defines allowable investments, specifies credit quality standards, and limits the credit exposure of any single issuer.

To minimize the risks related to accounts receivable, which are typically unsecured, we monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profiles.

The following table presents the percent of total gross product sales and total accounts receivable for each of our customers who individually accounted for 10% or more of total gross product sales and/or 10% or more of total accounts receivable.

	Percent of Total Gross Product Revenues			Percent of Accounts Receivable	
	Year Ended December 31,			December 31,	
	2025	2024	2023	2025	2024
Customer A	39 %	43 %	36 %	41 %	41 %
Customer B	28 %	28 %	28 %	31 %	37 %
Customer C	19 %	13 %	15 %	16 %	< 10 %
Customer D	< 10 %	< 10 %	12 %	10 %	11 %

Equity Investments

We account for certain equity investments subject to the equity method of accounting, or through which we have the ability to exercise significant influence (but not control) over the operating and financial policies of an investee, under the fair value option. In assessing whether we exercise significant influence, we consider the nature and magnitude of such an investment, the voting and protective rights we hold, any participation in the governance of the investee and other relevant factors, such as the presence of a collaborative or other business relationship. Such investments in publicly traded companies are currently classified within Level 1 of the fair value hierarchy and carried at fair value, with any changes in the fair value of such investments recognized in earnings.

Fair Value of Financial Instruments

We record cash equivalents, debt securities available-for-sale, and equity security investments 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.

We deem transfers between levels of the fair value hierarchy to have occurred at the end of the reporting period during which the event or change in circumstances that caused the transfer occurred.

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 perform an assessment of the recoverability of our inventory on a quarterly basis and write down any excess and obsolete inventory to its net realizable value in the period in which the impairment is first identified. 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.

Prior to U.S. Food and Drug Administration (FDA) approval of CRENESSITY in December 2024, all costs related to its manufacturing were expensed as research and development (R&D) in the period incurred. As a result, our physical inventory as of December 31, 2025 and 2024 included active pharmaceutical product with no cost basis. Costs related to the manufacturing of bulk drug product, finished bottling, and other labeling activities that occurred post-FDA approval are included in the inventory value as of December 31, 2025 and 2024.

Leases

We determine if an arrangement is a lease at contract inception. Right-of-use (ROU) assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. ROU assets and operating lease liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. When determining the lease term, we include options to extend or terminate the lease when it is reasonably certain that such options will be exercised.

As none of our operating leases provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Our incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease.

The lease payments used to determine our ROU assets may include prepaid or accrued lease payments and any lease incentives received and are recognized in ROU assets on our consolidated balance sheets.

Our lease agreements may include both lease and non-lease components, which we account for as a single lease component when the payments are fixed. Variable payments included in lease agreements are expensed as incurred.

Our operating leases are reflected in ROU assets, noncurrent operating lease liabilities, and other current liabilities on our consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

Impairment of ROU Assets

ROU assets are reviewed for impairment when indicators of impairment are present. ROU assets are tested for impairment individually or as part of an asset group if the cash flows related to the ROU asset are not independent from the cash flows of other assets and liabilities. An asset group is the unit of accounting for long-lived assets to be held and used, which represents the lowest level for which identifiable cash flows are largely independent of the cash flows of other groups of assets and liabilities.

Corporate ROU assets that are actively being marketed for sublease in connection with excess leased capacity are tested for impairment individually when the cash flows related to the ROU asset are determined to be independent from the cash flows of other assets and liabilities. Corporate ROU assets are otherwise tested for impairment on a consolidated level with consideration given to all cash flows of the company as corporate functions do not generate cash flows and are funded by revenue-producing activities at lower levels of the entity.

Property and Equipment

Property and equipment are stated at cost and depreciated over the estimated useful lives of the assets using the straight-line method. Equipment is depreciated over an average estimated useful life of 3 to 7 years. Leasehold improvements are depreciated over the shorter of their estimated useful lives or the remaining lease term. Depreciation expense was $26.0 million for 2025, $23.5 million for 2024, and $17.8 million for 2023.

Share Repurchases

Shares repurchased pursuant to our share repurchase program are immediately retired upon purchase. Repurchased common stock is reflected as a reduction of stockholders' equity by reducing our common stock for the par value of the shares repurchased and reducing our capital surplus for the excess of the repurchase price over the par value. The excess over the par value of the shares repurchased is recorded as a reduction to retained earnings to the extent available, with any remainder recorded as a reduction to additional paid-in capital.

Cost of Revenues

Cost of revenues primarily consists of third-party manufacturing, transportation, freight, and indirect overhead costs for the manufacture and distribution of INGREZZA and CRENESSITY drug product sold, royalties on net product sales of CRENESSITY, amortization of intangible assets, manufacturing costs in connection with our supply of valbenazine drug product under our collaboration with Tanabe Pharma Corporation (TPC) (formerly Mitsubishi Tanabe Pharma Corporation), and adjustments for excess and obsolete inventory to the extent management determines that the cost cannot be recovered based on estimates about future demand.

A portion of the costs associated with the manufacture of CRENESSITY sold to date was expensed as R&D prior to the FDA’s approval of CRENESSITY and is therefore excluded from cost of sales during this period.

Research and Development

R&D expenses primarily consist of preclinical and clinical trial costs, payroll and benefits costs, including stock-based compensation associated with employees involved in R&D activities, certain costs associated with our collaborative arrangements, and certain facility-based expenses (such as rent expense) and other overhead allocations. All such costs are expensed as R&D when incurred.

Collaborations and Other Arrangements

We enter into collaborative agreements with third parties to develop and commercialize drug candidates. Collaborative activities may include joint R&D and commercialization of new products. We generally receive certain licensing rights under these arrangements. These collaborations often require upfront payments and may include additional milestone, R&D cost sharing, royalty, or profit share payments, contingent upon the occurrence of certain future events linked to the success of the assets in development and commercialization. Upfront payments associated with collaborative arrangements are generally expensed as in-process research and development (IPR&D) when incurred. Milestone payments that are contingent upon the achievement of specified development, regulatory, or commercial events are recognized when the applicable contingency is resolved and the consideration is paid or becomes payable. Milestone payments that are paid or payable prior to regulatory approval are expensed as R&D, and milestone payments that are paid or payable subsequent to regulatory approval are capitalized as intangible assets and amortized to cost of revenues over the estimated useful life of the related asset. Royalties are expensed as cost of revenues when incurred.

Asset Acquisitions

We account for acquisitions of assets (or groups 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 (or group of assets) acquired on the basis of their relative fair value(s) on the measurement date. No goodwill is recognized in an asset acquisition. Intangible assets acquired in an asset acquisition for use in R&D activities which have no alternative future use are expensed as IPR&D on the acquisition date. Amounts paid to acquire such assets are classified as operating cash outflows on the consolidated statements of cash flows. Future costs to develop these assets are expensed as R&D when incurred.

Advertising

Costs associated with advertising are expensed as incurred and are included in selling, general, and administrative on the consolidated statements of income. Advertising expenses were $226.8 million for 2025, $191.0 million for 2024, and $159.9 million for 2023.

Stock-Based Compensation

We grant stock options to purchase our common stock to eligible employees and directors and also grant certain employees restricted stock units (RSUs) and performance-based restricted stock units (PRSUs). Additionally, we allow employees to participate in an employee stock purchase plan (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. RSUs 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 is 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 is recognized and amortized on a straight-line basis over the purchase period, which is generally six months. PRSUs vest upon the achievement of certain predefined company-specific performance-based criteria. Expense related to 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 provision is computed under the asset and liability method. Significant estimates are required in determining our income tax 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 reassess 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.

Our income tax provision is also affected by intercompany transfer pricing arrangements, including the allocation of income related to intellectual property held by foreign affiliates. These arrangements are intended to reflect arm's-length pricing and require management judgment in their application.

We have elected to account for Global Intangible Low-Taxed Income (GILTI) as a current period tax expense in the period incurred in accordance with its accounting policy under ASC 740.

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.

Earnings Per Share

Basic earnings per share are computed using the weighted average number of common shares outstanding during the period. Diluted earnings per share are computed using the treasury stock and if-converted methods and reflect the weighted average number of common and potentially dilutive shares outstanding during the period, excluding those whose effect would be anti-dilutive. PRSUs for which the performance condition has not been achieved are excluded from the calculation of diluted earnings per share.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for annual reporting periods beginning after December 15, 2024, and should be applied on a prospective basis. We adopted ASU 2023-09 on January 1, 2025. Our adoption of ASU 2023-09 did not have a material impact on our consolidated financial statements (since the requirements of this ASU are disclosure-specific) and will not affect our quarterly income tax disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which requires public entities to disclose specified information about certain costs and expenses on an interim and annual basis. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. We are currently evaluating the impact that adoption of ASU 2024-03 will have on our financial statement disclosures.

2. Available-for-Sale Debt Securities

The following table presents a summary of available-for-sale debt securities, aggregated by major security type and contractual maturity.

		December 31, 2025				December 31, 2024			
(dollars in millions)	Contractual Maturity	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Commercial paper	0 to 1 years	$ 22.6	$ —	$ —	$ 22.6	$ 37.1	$ —	$ —	$ 37.1
Corporate debt securities	0 to 1 years	622.6	1.7	—	624.3	527.0	0.6	(0.1)	527.5
Securities of government-sponsored entities	0 to 1 years	120.2	0.3	—	120.5	278.2	0.3	—	278.5
		$ 765.4	$ 2.0	$ —	$ 767.4	$ 842.3	$ 0.9	$ (0.1)	$ 843.1
Corporate debt securities	1 to 3 years	$ 945.0	$ 4.5	$ (0.5)	$ 949.0	$ 584.4	$ 2.0	$ (1.0)	$ 585.4
Securities of government-sponsored entities	1 to 3 years	113.8	0.3	(0.1)	114.0	154.4	0.3	(0.6)	154.1
		$ 1,058.8	$ 4.8	$ (0.6)	$ 1,063.0	$ 738.8	$ 2.3	$ (1.6)	$ 739.5

Unrealized losses on available-for-sale debt securities were primarily due to changes in interest rates. Our investments in available-for-sale debt securities are of high credit quality, and 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 their maturity. No allowance for credit losses was recognized as of December 31, 2025 or 2024.

The following table presents available-for-sale debt securities that were in an unrealized loss position as of December 31, 2025, aggregated by major security type and length of time in a continuous 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	$ 298.2	$ (0.5)	$ —	$ —	$ 298.2	$ (0.5)

The following table presents available-for-sale debt securities that were in an unrealized loss position as of December 31, 2024, aggregated by major security type and length of time in a continuous 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	$ 334.9	$ (1.1)	$ —	$ —	$ 334.9	$ (1.1)
Securities of government-sponsored entities	$ 123.8	$ (0.6)	$ —	$ —	$ 123.8	$ (0.6)

3. Fair Value Measurements

The following table presents a summary of certain financial assets, which were measured at fair value on a recurring basis.

	December 31, 2025			December 31, 2024		
		Leveling			Leveling	
(in millions)	Fair Value	Level 1	Level 2	Fair Value	Level 1	Level 2
Cash and cash equivalents	$ 713.0	$ 713.0	$ —	$ 233.0	$ 233.0	$ —
Available-for-sale debt securities	1,830.4	—	1,830.4	1,582.6	—	1,582.6
Equity investments	120.8	120.8	—	124.8	124.8	—
	$ 2,664.2	$ 833.8	$ 1,830.4	$ 1,940.4	$ 357.8	$ 1,582.6

4. Leases

Our operating leases have terms that expire beginning 2027 through 2036 and consist of office space and research and development laboratories, including our corporate headquarters. Certain of these lease agreements contain clauses for renewal at our option. As we were not reasonably certain to exercise any of these renewal options at commencement of the associated leases, no such options were recognized as part of our ROU assets or operating lease liabilities.

The following table presents supplemental operating lease information for operating leases that have commenced.

	Year Ended December 31,		
(dollars in millions)	2025	2024	2023
Operating lease cost	$ 64.6	$ 43.6	$ 17.1
Sublease income	(3.5)	(2.0)	(0.7)
Net operating lease cost	$ 61.1	$ 41.6	$ 16.4
Cash paid for amounts included in the measurement of operating lease liabilities	$ 37.8	$ 33.1	$ 17.9

	December 31,	
	2025	2024
Weighted average remaining lease term	9.9 years	10.8 years
Weighted average discount rate	4.9 %	4.9 %
Restricted cash related to leases	$ 7.8	$ 7.8

The following table presents approximate future non-cancelable minimum lease payments under operating leases and sublease income as of December 31, 2025.

(in millions)	Operating Leases	Sublease Income
Year ending December 31, 2026	$ 56.7	$ (3.9)
Year ending December 31, 2027	59.1	(4.0)
Year ending December 31, 2028	59.7	(4.0)
Year ending December 31, 2029	59.8	(3.6)
Year ending December 31, 2030	60.7	(3.5)
Thereafter	306.9	(2.0)
Total operating lease payments (sublease income)	602.9	$ (21.0)
Less imputed interest	131.6	
Total operating lease liabilities	471.3	
Less current operating lease liabilities included in other current liabilities	56.0	
Noncurrent operating lease liabilities	$ 415.3	

Impairment of ROU Assets

During 2024, we reassessed the asset groupings for corporate ROU assets that are actively being marketed for sublease in connection with leased office space that was vacated to occupy our new campus facility. For asset groups where impairment was triggered, we used discounted cash flow models (an income approach) with Level 3 inputs to estimate the fair values of the asset groups and recognized corresponding impairment charges totaling $14.0 million in 2024, of which $11.3 million and $2.7 million, respectively, was related to the ROU assets and tenant improvements associated with the underlying leased properties. The significant assumptions used in the discounted cash flows models included projected sublease income over the remaining lease term, expected downtime prior to the commencement of executed or future subleases, and discount rates that reflected a market participant's assumptions in valuing the asset groups. Impairment charges were not significant for 2025 or 2023.

5. Convertible Senior Notes

In May 2017, we issued $517.5 million in aggregate principal amount of 2.25% fixed-rate convertible senior notes due May 15, 2024 (the 2024 Notes) and entered into an indenture in May 2017 with U.S. Bank National Association, as trustee, with respect to the 2024 Notes. From 2020 through 2022, we repurchased $347.0 million in aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $465.9 million in cash.

In January 2024, we provided notice to the holders of the 2024 Notes electing to settle all conversions of the 2024 Notes which occur on or after January 15, 2024 in cash. Consequently, the embedded conversion option of the 2024 Notes (the conversion feature) required bifurcation and separate accounting from the 2024 Notes as it no longer qualified for the equity scope exception under ASC 815, Derivatives and Hedging. Upon bifurcation of the conversion feature, we recorded a derivative liability at a fair value of $126.6 million (Level 3) and a corresponding debt discount that was accreted over the remaining term of the 2024 Notes using the straight-line method. Subsequent changes in the fair value of the derivative liability and accretion of the associated debt discount were recorded in other income (expense), net on the consolidated statements of income and comprehensive income.

During 2024, holders of the 2024 Notes converted $169.8 million in aggregate principal amount of the 2024 Notes for $308.2 million in cash, reflecting a conversion premium of $138.4 million. The 2024 Notes were settled in full upon maturity on May 15, 2024.

The following table presents a summary of charges recognized in connection with the bifurcation of the conversion feature of the 2024 Notes and conversions of the 2024 Notes by holders during 2024.

(in millions)	Amount
Accretion of debt discount associated with derivative liability	$ 126.6
Change in fair value of derivative liability	9.6
Loss on extinguishment of convertible senior notes	2.2
Total charges associated with convertible senior notes	$ 138.4

6. Supplemental Financial Information

Prepaid expenses consisted of the following:

	December 31,	
(in millions)	2025	2024
Prepaid income taxes	$ 94.0	$ —
Prepaid development costs	55.6	32.1
Other prepaid expenses	21.1	16.4
Total prepaid expenses	$ 170.7	$ 48.5

Inventory consisted of the following:

	December 31,	
(in millions)	2025	2024
Raw materials	$ 35.7	$ 33.7
Work in process	19.2	10.9
Finished goods	14.3	12.8
	69.2	57.4
Less inventory reserves	(0.2)	—
Total inventory	$ 69.0	$ 57.4

Property and equipment, net, consisted of the following:

	December 31,	
(in millions)	2025	2024
Scientific equipment	$ 123.3	$ 95.7
Computer equipment	28.9	38.9
Tenant improvements	35.6	35.9
Furniture and fixtures	20.3	18.6
	208.1	189.1
Less accumulated depreciation	(118.3)	(106.5)
Total property and equipment, net	$ 89.8	$ 82.6

Accounts payable and accrued liabilities consisted of the following:

	December 31,	
(in millions)	2025	2024
Sales rebates and reserves	$ 226.0	$ 144.2
Accrued employee related costs	128.8	107.5
Accrued development costs	101.3	50.8
Current income taxes payable	68.0	10.0
Current branded prescription drug fee	45.3	49.2
Accounts payable and other accrued liabilities	104.9	99.9
Total accounts payable and accrued liabilities	$ 674.3	$ 461.6

Other noncurrent liabilities consisted of the following:

	December 31,	
(in millions)	2025	2024
Noncurrent income taxes payable	$ 214.5	$ 160.7
Other noncurrent liabilities	5.2	5.5
Total other noncurrent liabilities	$ 219.7	$ 166.2

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

	December 31,	
(in millions)	2025	2024
Cash and cash equivalents	$ 713.0	$ 233.0
Restricted cash included in other noncurrent assets	8.0	8.0
Total cash, cash equivalents, and restricted cash	$ 721.0	$ 241.0

7. Stockholders' Equity

Share Repurchases

In February 2025, our Board of Directors authorized a new share repurchase program (the 2025 Repurchase Program) under which we may repurchase up to $500.0 million of our common stock, subject to market conditions. Under the 2025 Repurchase Program, we repurchased 1.5 million shares on the open market for a cost of $167.7 million during 2025. As of December 31, 2025, we had $332.3 million remaining available for additional repurchases under the 2025 Repurchase Program.

Under the 2025 Repurchase Program, share repurchases may be made from time to time at management's discretion through a variety of methods, such as open-market transactions including pre-set trading plans, privately negotiated transactions, accelerated share repurchases, and other transactions in accordance with applicable securities laws. Shares repurchased under the 2025 Repurchase Program are retired immediately, resulting in an immediate reduction of the outstanding shares used to calculate the weighted-average common shares for both basic and diluted earnings per share, and included in the category of authorized but unissued shares. The excess of the purchase price over the par value of the common shares was recorded as reductions to retained earnings and additional paid-in capital.

In November 2024, we entered into an accelerated share repurchase transaction (the 2024 Repurchase Program) with a third-party financial institution to repurchase an aggregate of $300.0 million of our common stock. Shares repurchased under the 2024 Repurchase Program were retired immediately upon receipt, resulting in an immediate reduction of the outstanding shares used to calculate the weighted-average common shares for both basic and diluted earnings per share in the period received, and included in the category of authorized but unissued shares. At inception, we paid the financial institution $300.0 million using cash on hand and took initial delivery of 2.0 million shares in November 2024. The fair market value of the 2.0 million initial shares received was $240.5 million, with the excess of the fair market value over the par value of the initial shares received recorded as reductions to retained earnings and additional paid-in capital. The remaining $59.5 million of the repurchase price was recorded as a reduction to additional paid-in capital. The 2024 Repurchase Program was completed in February 2025, at which time we received an additional 0.3 million shares upon settlement, with the excess of the fair market value over the par value of the settlement shares received recorded as an increase to additional paid-in capital and a reduction to retained earnings. In total, we repurchased 2.3 million shares under the 2024 Repurchase Program at an average price of $131.83 per share, which represents the daily volume-weighted average price of our common stock over the term of the transaction, less a negotiated discount.

8. Earnings Per Share

Earnings per share were calculated as follows:

	Year Ended December 31,		
(in millions, except per share data)	2025	2024	2023
Net income - basic and diluted	$ 478.6	$ 341.3	$ 249.7
Weighted-average common shares outstanding:			
Basic	99.5	100.4	97.7
Effect of dilutive securities	3.0	3.3	3.3
Diluted	102.5	103.7	101.0
Earnings per share:			
Basic	$ 4.81	$ 3.40	$ 2.56
Diluted	$ 4.67	$ 3.29	$ 2.47
Shares excluded from diluted per share amounts because their effect would have been anti-dilutive	4.0	2.4	4.7

9. Stock-Based Compensation

2025 Equity Incentive Plan

In May 2025, our stockholders approved the 2025 Equity Incentive Plan (the 2025 Plan). The 2025 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, and other awards. As of December 31, 2025, 7.4 million shares of common stock remain available for future grant under the 2025 Plan.

Under the terms of the 2025 Plan, the number of shares of common stock available for issuance will be: (i) reduced by (a) one share for each share issued pursuant to an appreciation award (as defined in the 2025 Plan) and (b) 2.43 shares for each share issued pursuant to a full value award (as defined in the 2025 Plan); and (ii) increased by (a) one share for each share subject to an appreciation award that becomes available again for issuance under the terms of the 2025 Plan and (b) 2.43 shares for each share subject to a full value award that becomes available again for issuance under the terms of the 2025 Plan.

2020 Equity Incentive Plan

In May 2020, we adopted the 2020 Equity Incentive Plan (as amended, the Amended 2020 Plan). The Amended 2020 Plan was a stockholder-approved plan pursuant to which no additional awards will be granted following the effective date of the 2025 Plan. Outstanding awards under the Amended 2020 Plan will continue to be governed by its terms.

2011 Equity Incentive Plan

In May 2011, we adopted the 2011 Equity Incentive Plan (the 2011 Plan). The 2011 Plan was a stockholder-approved plan pursuant to which outstanding awards have been made, but from which no further awards can or will be made.

2018 Employee Stock Purchase Plan

In May 2022 and 2025, our stockholders approved amendments and restatements of the 2018 Employee Stock Purchase Plan (as so amended and restated, the Amended 2018 ESPP). As of December 31, 2025, 1.0 million shares of common stock remain available for future issuance under the Amended 2018 ESPP.

Stock-Based Compensation Expense

The effect of stock-based compensation expense on the consolidated statements of income and comprehensive income by line-item follows:

	Year Ended December 31,		
(in millions)	2025	2024	2023
Selling, general, and administrative	$ 126.9	$ 126.7	$ 126.3
Research and development	91.0	68.8	68.0
Total stock-based compensation expense	$ 217.9	$ 195.5	$ 194.3

Stock-based compensation expense by award-type follows:

	Year Ended December 31,		
(in millions)	2025	2024	2023
Stock options	$ 83.8	$ 80.7	$ 91.6
RSUs	107.6	97.7	93.4
PRSUs	19.0	11.5	4.6
ESPP	7.5	5.6	4.7
Total stock-based compensation expense	$ 217.9	$ 195.5	$ 194.3

As of December 31, 2025, unrecognized stock-based compensation expense by award-type and the weighted-average period over which such expense is expected to be recognized, as applicable, was as follows:

(dollars in millions)	Unrecognized Expense	Weighted-Average Recognition Period
Stock options	$ 95.3	2.4 years
RSUs	$ 213.8	2.3 years
PRSUs	$ 22.7	

Stock Options

Typically, stock options have a 10-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 $49.66 for 2025, $55.74 for 2024, and $45.19 for 2023.

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,		
	2025	2024	2023
Risk-free interest rate	4.4 %	4.3 %	3.9 %
Expected volatility of common stock	37.6 %	37.2 %	40.8 %
Dividend yield	0.0 %	0.0 %	0.0 %
Expected option term	5.4 years	5.5 years	5.5 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.

The following table presents summary of activity related to stock options.

(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, 2024	9.6	$ 95.48		
Granted	1.9	$ 118.85		
Exercised	(1.5)	$ 76.54		
Canceled	(0.2)	$ 117.03		
Outstanding at December 31, 2025	9.8	$ 102.54	6.0 years	$ 384.9
Exercisable at December 31, 2025	7.0	$ 95.65	5.1 years	$ 324.8

The total intrinsic value of stock options exercised was $96.2 million for 2025, $122.5 million for 2024, and $39.9 million for 2023. Cash received from stock option exercises was $115.5 million for 2025, $110.8 million for 2024, and $55.5 million for 2023.

Restricted Stock Units

RSUs typically vest over a four-year period and may be subject to a deferred delivery arrangement at the election of eligible employees. The fair value of RSUs is based on the closing sale price of our common stock on the date of issuance. The total fair value of RSUs that vested was $116.1 million for 2025, $116.7 million for 2024, and $101.0 million for 2023.

The following table presents a summary of activity related to RSUs.

(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, 2024	2.4	$ 111.90		
Granted	1.3	$ 119.14		
Released	(0.9)	$ 107.48		
Canceled	(0.2)	$ 115.53		
Unvested at December 31, 2025	2.6	$ 116.79	1.2 years	$ 373.4

Performance-Based Restricted Stock Units

PRSUs vest based on the achievement of certain predefined Company-specific performance criteria. Any unvested PRSUs will expire if it is determined the related performance criteria has not been met during the applicable three to four-year performance period. The fair value of PRSUs is estimated based on the closing sale price of our common stock on the date of grant. The fair value of PRSUs that vested was $34.4 million during 2023. No PRSUs vested during 2025 or 2024.

The following table presents a summary of activity related to PRSUs.

(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, 2024	0.4	$ 105.11		
Granted	0.1	$ 118.24		
Canceled	(0.1)	$ 81.19		
Unvested at December 31, 2025	0.4	$ 114.70	1.5 years	$ 61.2

Employee Stock Purchase Plan

Under the Amended 2018 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.

10. Income Taxes

The following table presents income from continuing operations before provision for income taxes for domestic and international operations.

	Year Ended December 31,		
(in millions)	2025	2024	2023
Domestic	$ 845.2	$ 597.5	$ 409.2
Foreign	(139.8)	(111.5)	(77.1)
Income before provision for income taxes	$ 705.4	$ 486.0	$ 332.1

The following table presents the components of income tax expense for continuing operations.

	Year Ended December 31,		
(in millions)	2025	2024	2023
Current:			
Federal	$ 55.5	$ 215.2	$ 115.0
State	50.9	52.5	28.1
Foreign	(43.8)	—	—
Current income taxes	62.6	267.7	143.1
Deferred:			
Federal	142.5	(104.9)	(45.2)
State	1.9	(18.1)	(15.5)
Foreign	19.8	—	—
Deferred income taxes	164.2	(123.0)	(60.7)
Provision for income taxes	$ 226.8	$ 144.7	$ 82.4

As discussed in Note 1, we adopted ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, on January 1, 2025 on a prospective basis. As a result, our rate reconciliation for 2025 is presented in accordance with the new disclosure requirements, while the reconciliations for 2024 and 2023 continue to be presented under disclosure requirements in effect for those periods.

The provision for income taxes on earnings subject to income taxes differed from the statutory federal rate due to the following (after the adoption of ASU 2023-09):

	Year Ended December 31, 2025	
(dollars in millions)	Amount	%
Federal income taxes at 21%	$ 148.1	21.0 %
State and local income taxes, net of federal benefit [1]	3.1	0.4 %
Foreign tax effects		
Switzerland		
Statutory tax rate difference between Switzerland and U.S.	16.4	2.3 %
Changes in valuation allowances	(18.8)	(2.7)%
Undistributed earnings	19.8	2.8 %
Other	(11.2)	(1.6)%
Other foreign jurisdictions	3.7	0.5 %
Effect of cross-border tax laws		
Global intangible low-taxed income, net	52.9	7.5 %
Foreign tax credits	(7.9)	(1.1)%
Other effects of cross-border tax laws total - below 1.05%	(0.5)	(0.1)%
Tax credits		
Research and development tax credits	(35.6)	(5.0)%
Changes in valuation allowance	7.7	1.1 %
Nontaxable or nondeductible items		
Officer compensation	13.6	1.9 %
Branded prescription drug fee	7.5	1.1 %
Other non-deductible and non-taxable total - below 1.05%	8.3	1.2 %
Other		
Stock-based compensation expense (windfall/shortfall)	(13.7)	(1.9)%
Basis difference in subsidiary held for sale	(15.7)	(2.2)%
Changes in unrecognized tax benefits	49.1	7.0 %
Provision for income taxes	$ 226.8	32.2 %

(1) 50% or more of our state tax provision relates to the Tennessee and Kentucky state jurisdictions.

The provision for income taxes on earnings subject to income taxes differed from the statutory federal rate due to the following (prior to the adoption of ASU 2023-09):

	Year Ended December 31,	
(dollars in millions)	2024	2023
Federal income taxes at 21%	$ 102.1	$ 69.7
State income tax, net of federal benefit	34.6	17.5
Branded prescription drug fee	7.5	8.7
Loss on extinguishment of convertible senior notes	29.1	—
Stock-based compensation expense	(20.4)	(3.9)
Officer compensation	3.3	9.6
Foreign rate differential	7.2	3.4
Change in tax rate	(0.6)	(5.5)
Research credits	(49.2)	(42.2)
Change in valuation allowance	23.9	22.0
Other	7.2	3.1
Provision for income taxes	$ 144.7	$ 82.4

The following table presents income taxes paid for 2025:

(in millions)	Amount
U.S. Federal	$ 72.7
Aggregated state and local jurisdictions [1]	8.7
Total income taxes paid, net	$ 81.4

(1) The amount of income taxes paid during 2025 did not meet the 5% disaggregation threshold.

The following table presents the significant components of our deferred tax assets:

	December 31,	
(in millions)	2025	2024
Deferred tax assets:		
Net operating losses	$ 8.4	$ 50.5
Research and development credits	74.6	62.8
Capitalized research and development	85.7	255.7
Stock-based compensation expense	59.7	61.4
Operating lease assets	111.8	122.7
Intangible assets	117.0	121.4
Accrued payroll	27.2	24.1
Other	55.0	27.6
Total deferred tax assets	539.4	726.2
Deferred tax liabilities:		
Operating lease liabilities	(96.9)	(112.8)
Other	(24.9)	(15.5)
Total deferred tax liabilities	(121.8)	(128.3)
Net of deferred tax assets and liabilities	417.6	597.9
Valuation allowance	(97.3)	(112.2)
Net deferred tax assets	$ 320.3	$ 485.7

As of December 31, 2025 and 2024, we recorded a valuation allowance of $97.3 million and $112.2 million, respectively, against our gross deferred tax asset balance.

As of 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. As of December 31, 2025, management determined there was sufficient positive evidence to conclude that it is more likely than not deferred tax assets of $320.3 million are realizable. The recorded valuation allowance of $97.3 million consisted primarily of unrealized capital losses, state net operating losses, and state research credit carryforwards for which management cannot conclude it is more likely than not to be realized.

As of December 31, 2025, we had state income tax net operating loss carryforwards of $279.0 million. We had no federal or foreign income tax operating loss carryforwards as of December 31, 2025. California net operating losses and net operating losses related to other states will begin to expire in 2032 and 2041, respectively, unless previously utilized.

As of December 31, 2025, we had state R&D tax credit carryforwards of $114.7 million. California R&D tax credits carry forward indefinitely, while R&D tax credits related to other states will begin to expire in 2034 unless previously utilized.

Additionally, the future utilization of our state 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, 2025.

As of December 31, 2025, we have recorded a U.S. deferred income tax liability of $12.0 million on the unremitted earnings of certain foreign subsidiaries as we cannot assert these earnings are indefinitely reinvested in foreign operations.

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.

We recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2025 and 2024, we had accruals for interest related to income tax matters of $24.9 million and $10.9 million, respectively. In addition, we had accruals for penalties related to income tax matters of $3.8 million and $2.2 million, respectively, as of December 31, 2025 and 2024.

We are subject to taxation in the U.S. and various state and foreign jurisdictions. Our tax years for 2002 for federal, 2000 for California, 2015 for other significant state jurisdictions, and 2019 and forward for foreign jurisdictions are subject to examination by tax authorities due to the carryforward of net operating losses and R&D tax credits.

The IRS is currently examining the 2023 tax year. Management believes that an adequate provision has been made for any adjustments that may result from tax examinations. However, the outcome of tax audits cannot be predicted with certainty. If any issues addressed in the tax audits are resolved in a manner not consistent with management's expectations, we could be required to adjust the provision for income taxes in the period such resolution occurs.

The following table presents a summary of activity related to unrecognized tax benefits:

	Year Ended December 31,		
(in millions)	2025	2024	2023
Balance at January 1	$ 179.8	$ 121.0	$ 84.5
(Decrease) increase related to prior year tax positions	(11.2)	4.0	3.4
Increase related to current year tax positions	51.3	54.8	36.7
Decrease related to prior year tax positions	—	—	(3.6)
Balance at December 31	$ 219.9	$ 179.8	$ 121.0

As of December 31, 2025, we had $177.6 million of unrecognized tax benefits that, if recognized and realized, would affect the effective tax rate, subject to changes in the valuation allowance.

On July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law. The OBBBA includes significant changes to U.S. tax and related laws. Some of the provisions of the OBBBA affecting us include the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act (TCJA), changes to the treatment of research and development expenditures under Internal Revenue Code Section 174, modifications to the Global Intangible Low-Taxed Income (GILTI) and Foreign-Derived Intangible Income (FDII) international tax provisions, and reinstatement of 100% bonus depreciation deduction from the TCJA for eligible property acquired after January 19, 2025. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The OBBBA's financial reporting implications have been recognized in our income tax provision for 2025.

Swiss Cantonal Tax Relief

In August 2025, the Company received approval from Swiss tax authorities granting cantonal tax relief to its Swiss subsidiary, Neurocrine Switzerland GmbH. The tax relief applies for a period of 10 tax years beginning with the 2024 tax year through 2033.

The Swiss cantonal tax relief had a minimal impact on the Company's earnings per share for the year ended December 31, 2025.

11. Collaboration and License Agreements

Nxera Pharma UK Limited (Nxera)

In 2021, we entered into a collaboration and license agreement with Nxera (formerly Sosei Heptares) to develop and commercialize certain compounds containing sub-type selective muscarinic M1, M4, or dual M1/M4 receptor agonists, which we have the exclusive rights to develop, manufacture and commercialize worldwide, excluding in Japan, where Nxera retains the rights to develop, manufacture, and commercialize all compounds comprised of M1 receptor agonists, subject to certain exceptions. With respect to such rights retained by Nxera, we retain the rights to opt in to profit sharing arrangements, pursuant to which we and Nxera will equally share in the operating profits and losses for such compounds in Japan. Subject to specified conditions, we may elect to exercise such opt-in rights with respect to each such compound either before initiation of the first proof of concept Phase 2 clinical trial for such compound or following our receipt from Nxera of the top-line data from such clinical trial for such compound. We are responsible for all development, manufacturing, and commercialization costs of any collaboration product.

Direclidine (NBI-1117568) is a potential first-in-class, orally active, highly selective investigational M4 agonist in development as a potential treatment for schizophrenia. In connection with the initiation of a Phase 3 clinical study for direclidine in schizophrenia in 2025, we expensed a milestone payment of $15.0 million to Nxera as R&D in 2025. In connection with the successful completions of a long-term toxicity program for direclidine and Phase 2 clinical study for direclidine in schizophrenia in 2024, we expensed milestone payments totaling $50.0 million to Nxera as R&D in 2024.

Under the terms of the agreement, Nxera may be entitled to receive potential future payments of up to $2.50 billion upon the achievement of certain event-based milestones and is entitled to receive royalties on the future net sales of any collaboration product.

Unless earlier terminated, the agreement will continue on a licensed product-by-licensed product and country-by-country basis until the date on which the royalty term for such licensed product has expired in such country. On a licensed product-by-licensed product and country-by-country basis, royalty payments would commence on the first commercial sale of a licensed product and terminate on the later of (i) the expiration of the last patent covering such licensed product in such country, (ii) a number of years from the first commercial sale of such licensed product in such country and (iii) the expiration of regulatory exclusivity for such licensed product in such country.

Following the expiration of the research collaboration term, we may terminate the agreement in its entirety or with respect to one or more targets upon 90 days' written notice to Nxera. Following the expiration of the research collaboration term, Nxera may terminate the agreement on a target-by-target basis in the event that we do not conduct any material development activities outside of Japan with respect to a certain compound or licensed product within the applicable target class for a continuous period of not less than 365 days and do not commence any such activities within 120 days of receiving written notice. Either party may terminate the agreement, subject to specified conditions, (i) in the event of material breach by the other party, subject to a cure period, (ii) if the other party challenges the validity or enforceability of certain intellectual property rights, subject to a cure period, or (iii) if the other party becomes insolvent or takes certain actions related to insolvency.

Takeda Pharmaceutical Company Limited (Takeda)

In 2020, we entered into an exclusive license agreement with Takeda (the 2020 Takeda Agreement), pursuant to which we acquired the exclusive rights to develop and commercialize certain early to mid-stage psychiatry compounds, including luvadaxistat, NBI-1070770, osavampator (NBI-1065845), NBI-1065846, and three non-clinical stage compounds. Pursuant to the 2020 Takeda Agreement, osavampator was designated as a profit-share product, meaning we and Takeda would equally share in the operating profits and losses. Takeda also retained the right to opt-out of the profit-sharing arrangement, pursuant to which Takeda would be entitled to receive potential future payments upon the achievement of certain event-based milestones with respect to osavampator and receive royalties on the future net sales of osavampator (in lieu of equally sharing in the operating profits and losses).

In October 2024, we provided Takeda with written notice of termination of the license under the 2020 Takeda Agreement with respect to certain DAAO inhibitors, including the license to develop and commercialize luvadaxistat and NBI-1065846, which became effective in April 2025.

In January 2025, we and Takeda amended and restated the exclusive license agreement (the Restated Takeda Agreement) to, among other things, reflect the conversion from sharing operating profits and losses with respect to the development and commercialization of osavampator to a royalty-bearing license, the return of rights to osavampator in Japan to Takeda, and our previous termination of of the license to develop and commercialize certain DAAO inhibitors under the 2020 Takeda Agreement, including luvadaxistat, and GPR139 agonists, including NBI-1065846.

Under the Restated Takeda Agreement, we retain exclusive rights to develop and commercialize osavampator for all indications in all territories worldwide except Japan, where Takeda reacquired exclusive development and commercialization rights. In addition, each party is responsible for development costs for osavampator in its respective territory, and each party is eligible to receive royalty payments based on the other party's net sales of osavampator in the other party's territory. Pursuant to the Restated Takeda Agreement and upon the successful development and commercialization of osavampator, we will incur tiered based royalties payable to Takeda in the mid-to-upper teens in the U.S. and low double-digits outside of the U.S. on a blended basis as a percentage of net sales. Additionally, we are entitled to receive royalties from Takeda on the future net sales of osavampator in Japan.

Osavampator is a potential first-in-class alpha-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid (AMPA) positive allosteric modulator (PAM) in development for patients with inadequate response to treatment of major depressive disorder (MDD). In connection with the initiation of a Phase 3 clinical study for osavampator in MDD in 2025, we expensed a milestone payment of $37.5 million to Takeda as R&D in 2025.

NBI-1070770 is a novel, selective, and orally active, negative allosteric modulator (NAM) of the NR2B subunit-containing N-methyl-D-aspartate (NMDA NR2B) receptor in development as a potential treatment for MDD. In connection with the initiation of a Phase 2 clinical study for NBI-1070770 in MDD in 2024, we expensed a milestone payment of $7.5 million to Takeda as R&D in 2024. In November 2025, we announced that the Phase 2 study evaluating the efficacy, safety, and tolerability of NBI-1070770 in adults with MDD did not meet the primary endpoint.

Takeda may be entitled to receive potential future payments of up to $0.74 billion upon the achievement of certain event-based milestones and is entitled to receive royalties on the future net sales of any royalty-bearing product.

Unless earlier terminated, the Restated Takeda 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. On a licensed product-by-licensed product and country-by-country 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 such royalty-bearing product in such country.

We may terminate the Restated Takeda Agreement in its entirety or in one or more (but not all) of the U.S., Japan, the European Union and the United Kingdom, or, collectively, the major markets, upon six 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 Restated Takeda Agreement, prior to the first commercial sale of the first licensed product in such target class for which first commercial sale occurs. We may terminate the Restated Takeda Agreement in its entirety or in one or more (but not all) of the major markets upon 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 for which first commercial sale occurs. Takeda may terminate the Restated Takeda 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 Restated Takeda 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, or if either party challenges the validity or enforceability of certain intellectual property rights.

Xenon Pharmaceuticals Inc. (Xenon)

In 2019, we entered into a collaboration and license agreement with Xenon to identify, research, and develop sodium channel inhibitors, including NBI-921352 and three preclinical candidates, which compounds we have the exclusive rights to develop and commercialize. In connection with the agreement, we purchased 1.4 million shares (at $14.196 per share) of Xenon common stock in 2019, 0.3 million shares (at $19.9755 per share) of Xenon common stock in 2021, and 0.3 million shares (at $31.855 per share) of Xenon common stock in 2022. We are responsible for all development and manufacturing costs of any collaboration product, subject to certain exceptions.

NBI-921355 is an investigational, selective inhibitor of voltage-gated sodium channels $Na_v1.2$ and $Na_v1.6$ in development as a potential treatment of certain types of epilepsy. In connection with the initiation of a Phase 1 clinical study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of NBI-921355 in healthy adult participants in 2025, we expensed a milestone payment of $7.5 million to Xenon as R&D in 2025.

Under the terms of the agreement, Xenon may be entitled to receive potential future payments of up to $1.70 billion upon the achievement of certain event-based milestones and is entitled to receive royalties on the future net sales of any collaboration product. Xenon retains the right to elect to co-develop one product in a major indication, pursuant to which Xenon would receive a mid-single digit percentage increase in royalties earned on the future net sales of such product in the U.S. and we and Xenon would equally share in the development costs of such product in the applicable indication, except where such development costs relate solely to the regulatory approval of such product outside the U.S.

Unless earlier terminated, the agreement will continue on a licensed product-by-licensed 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 licensed product and country, the license obtained by us with respect to such product and country will become fully paid, royalty free, perpetual and irrevocable. We may terminate the agreement upon 90 days' written notice to Xenon, 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 Therapeutics, Inc. (Voyager)

2019 Voyager Agreement

In 2019, we entered into a collaboration and license agreement with Voyager (the 2019 Voyager Agreement), pursuant to which we obtained certain rights to develop and commercialize product candidates, including the rights to gene therapy product candidates for the treatment of Friedreich's ataxia (FA) and two undisclosed programs. In April 2025, we mutually agreed with Voyager to discontinue the two undisclosed programs and the rights to the targets selected under these programs returned to Voyager. We are responsible for all development and commercialization costs of any collaboration product under the 2019 Voyager Agreement, subject to certain co-development and co-commercialization rights retained by Voyager.

In connection with the 2019 Voyager Agreement, we purchased 4.2 million shares (at $11.9625 per share) of Voyager common stock (the 2019 Voyager Shares), which are subject to certain transfer, beneficial ownership, and voting restrictions until February 23, 2026, the third anniversary of the closing date of the share purchase transaction.

In connection with the selection of a development candidate under the FA program pursuant to our collaboration with Voyager, we expensed a milestone payment of $5.0 million to Voyager as R&D in 2024.

Under the terms of the 2019 Voyager Agreement, Voyager may be entitled to receive potential future payments of up to $0.47 billion upon the achievement of certain event-based milestones and is entitled to receive royalties on the future net sales of any collaboration product, subject to certain co-development and co-commercialization rights retained by Voyager.

Unless terminated earlier, the 2019 Voyager Agreement will continue in effect until the expiration of the last to expire royalty term with respect to any collaboration product under the agreement or the last expiration or termination of any exercised co-development and co-commercialization rights by Voyager as provided for in the 2019 Voyager Agreement. We may terminate the 2019 Voyager Agreement upon 180 days' written notice to Voyager prior to the first commercial sale of any collaboration product under the 2019 Voyager Agreement or upon one year after the date of notice if such notice is provided after the first commercial sale of any collaboration product under the 2019 Voyager Agreement.

2023 Voyager Agreement

In 2023, we entered into a collaboration and license agreement with Voyager, which we amended in April 2024 (as amended, the 2023 Voyager Agreement), pursuant to which we acquired the global rights to the gene therapy products directed to the gene that encodes glucosylceramidase beta 1 (GBA1) for the treatment of Parkinson's disease and other diseases associated with GBA1 (the GBA1 Program), and three gene therapy programs directed to rare central nervous system (CNS) targets, each enabled by Voyager's next-generation TRACER® capsids.

With respect to collaboration products subject to the GBA1 Program, we are responsible for all development and commercialization costs of any such products, including in the U.S., where Voyager retains certain co-development and co-commercialization rights. Voyager may elect to exercise such rights, pursuant to which we and Voyager would equally share in the operating profits and losses of such products in the U.S. (in lieu of Voyager being entitled to receive potential future payments of certain event-based milestones upon their achievement in the U.S. and receive royalties on the future net sales of such products in the U.S.), following Voyager's receipt of the top-line data from a first clinical trial in Parkinson's disease. However, if we and Voyager elect to focus on an indication other than Parkinson's disease prior to Voyager's receipt of top-line data from a first clinical trial for Parkinson's disease, then Voyager may elect to exercise such co-development and co-commercialization rights after the later of: (i) Voyager's receipt of top-line data from the first clinical trial of a product that is the subject of the GBA1 Program or (ii) the date we and Voyager decide not to pursue Parkinson's disease as an indication for development under the GBA1 Program. Irrespective of Voyager's election to exercise such rights, Voyager may be entitled to receive potential future payments upon the achievement of certain event-based milestones outside the U.S. and would be entitled to receive royalties on the future net sales of any such product outside the U.S.

With respect to collaboration products subject to the three gene therapy programs directed to rare CNS targets, we are responsible for all development and commercialization costs for any such products.

In connection with the 2023 Voyager Agreement, we paid Voyager $175.0 million upfront, including a purchase of 4.4 million shares (at $8.88 per share) of Voyager common stock (the 2023 Voyager Shares), which are subject to certain transfer, beneficial ownership, and voting restrictions until February 23, 2026, the third anniversary of the closing date of the share purchase transaction. We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. In addition, as part of the collaboration, Jude Onyia, Ph.D., Chief Scientific Officer of Neurocrine Biosciences, was appointed to Voyager's board of directors. Dr. Onyia (or another individual designated by us) will be nominated for election to Voyager's board of directors annually for a maximum duration of 10 years from the effective date of the 2023 Voyager Agreement. As a result, our equity investment in Voyager became subject to the equity method of accounting, and Voyager became a related party, following our purchase of the 2023 Voyager Shares, after which, together with the 2019 Voyager Shares, we owned approximately 19.9% of the voting stock of Voyager. We elected the fair value option to account for our equity investment in Voyager as we believe it creates greater transparency regarding the investment's fair value at future reporting dates. The 2023 Voyager Shares were recorded at a fair value of $31.3 million after considering Voyager's stock price on the measurement date. The remaining $143.9 million of the purchase price, which includes certain transaction-related costs, was expensed as in-process research and development in 2023 as the license had no foreseeable alternative future use.

In connection with the selection of development candidates under the GBA1 Program pursuant to our collaboration with Voyager, we expensed milestone payments totaling $3.0 million and $6.0 million, respectively, to Voyager as R&D in 2025 and 2024.

Under the terms of the 2023 Voyager Agreement, Voyager may be entitled to receive potential future payments of up to $6.10 billion upon the achievement of certain event-based milestones and is entitled to receive royalties on the future net sales of any collaboration product, subject to certain co-development and co-commercialization rights retained by Voyager.

Unless terminated earlier, the 2023 Voyager Agreement will continue in effect until the expiration of the last to expire royalty term with respect to any collaboration product under the 2023 Voyager Agreement or the last expiration or termination of any exercised co-development and co-commercialization rights by Voyager as provided for in the 2023 Voyager Agreement. We may terminate the 2023 Voyager Agreement upon 180 days' written notice to Voyager prior to the first commercial sale of any collaboration product under the 2023 Voyager Agreement or upon one year after the date of notice if such notice is provided after the first commercial sale of any collaboration product under the 2023 Voyager Agreement.

Sanofi S.A. (Sanofi)

In 2014, we entered into a license agreement with Sanofi, pursuant to which we acquired the global rights to develop and commercialize certain corticotropin-releasing factor type 1 (CRF-1) receptor antagonists, including crinecerfont. We launched CRENESSITY® (crinecerfont) in the U.S. as a first-in-class FDA-approved treatment of classic congenital adrenal hyperplasia due to 21-hydroxylase deficiency (CAH) in December 2024. We are responsible for all manufacturing, development, and commercialization costs of any licensed product.

In connection with FDA approval of CRENESSITY capsules and oral solution as an adjunctive treatment of CAH in December 2024, we paid a $5.0 million milestone to Sanofi in January 2025, which we accrued to other current liabilities and recorded within intangible assets, net on the consolidated balance sheet as of December 31, 2024.

Under the terms of our license agreement with Sanofi, Sanofi may be entitled to receive potential future payments of up to $10.0 million upon the achievement of certain event-based milestones and is entitled to receive royalties at tiered percentage rates ranging from 3.0% to 5.0% on our future net sales of CRENESSITY in the U.S. for the longer of 16 years or the life of the related patent rights.

12. Assets and Liabilities Held for Sale

On December 24, 2025, we committed to a plan to sell the Neurocrine Group Limited (formerly Diurnal Group plc) operating unit, which met the criteria for classification as held for sale under ASC 360. As a result, the assets and liabilities of the disposal group are presented separately as "Assets held for sale" and "Liabilities related to assets held for sale" below, and included in other current assets and other current liabilities, respectively, on the consolidated balance sheet as of December 31, 2025. In connection with the classification of the operating unit as held for sale on December 24, 2025, $29.8 million of intangible assets, net of amortization, have been included in the disposal group presented as "Assets held for sale" on the consolidated balance sheet as of December 31, 2025.

The disposal group was measured at the lower of the carrying amount or fair value less costs to sell. Based on an estimated fair value (net of selling costs) of $62.2 million and a carrying value of $34.6 million, no impairment loss was recognized in connection with the held-for-sale classification. In addition, depreciation and amortization associated with the disposal group ceased as of the held-for-sale classification date. The disposal group did not qualify as a discontinued operation under ASC 205, as it does not represent a strategic shift that will have a major effect on our operations or financial results. As required by ASC 360, any potential gain or loss will be recognized upon completion of the sale.

The major classes of assets and liabilities classified as held for sale as of December 31, 2025, were as follows:

(in millions)		**Amount**
Assets held for sale:		
Intangible assets, net	$	29.8
Other assets		13.0
Total assets held for sale included in other current assets	$	42.8
Liabilities related to assets held for sale:		
Accounts payable and accrued liabilities	$	6.8
Other liabilities		1.4
Total liabilities related to assets held for sale included in other current liabilities	$	8.2

As of December 31, 2025, the disposal group classified as held for sale excludes certain assets and obligations that will not be transferred to the buyer upon closing. Specifically, cash and cash equivalents of the disposal group are not expected to be conveyed to the buyer. Accordingly, such cash and the related liabilities expected to be settled prior to closing are excluded from the assets and liabilities presented as held for sale as of December 31, 2025.

Subsequent to December 31, 2025, on January 21, 2026, we completed the sale of Neurocrine Group Limited to Immedica Pharma AB for $65.0 million in cash, and we expect to recognize the related gain in the first quarter of 2026.

13. Retirement Plan

We have a 401(k) defined contribution savings plan 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 $19.7 million for 2025, $15.5 million for 2024, and $12.5 million for 2023.

14. Segment Reporting and Disaggregation of Relevant Expense Captions

Neurocrine Biosciences operates as a single global business segment dedicated to the research and development, commercialization, and sale of pharmaceuticals primarily in the U.S. for the treatment of under-addressed neurological, psychiatric, endocrine, and immunological disorders. The accounting policies of the segment are the same as those described in the summary of significant accounting policies.

The determination of a single business segment is consistent with the consolidated financial information regularly reviewed by the Chief Executive Officer as chief operating decision maker (CODM) in assessing segment performance and deciding how to allocate resources on a consolidated basis.

The CODM assesses performance for the segment and decides how to allocate resources based on net income that also is reported on the consolidated statements of income and comprehensive income as consolidated net income. The CODM uses net income to monitor budget and forecast versus actual results in assessing segment performance and to evaluate income generated from segment assets in deciding how to allocate resources. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets.

The following table presents information about reported segment revenues, segment profit, and significant segment expenses.

	Year Ended December 31,		
(in millions)	2025	2024	2023
Revenues:			
INGREZZA net product sales	$ 2,513.7	$ 2,313.5	$ 1,836.0
CRENESSITY net product sales	301.2	1.7	—
Other revenues [1]	45.6	40.1	51.1
Total revenues	2,860.5	2,355.3	1,887.1
Less:			
Cost of revenues	52.1	34.0	39.7
Research and development:			
External research and development	507.3	343.5	310.0
Payroll and benefits	306.4	236.7	206.7
Milestones	65.4	71.7	0.8
Other research and development [2]	136.6	79.2	47.5
Total research and development	1,015.7	731.1	565.0
Acquired in-process research and development	17.4	12.5	143.9
Selling, general, and administrative	1,156.2	1,007.2	887.6
Unrealized loss (gain) on equity investments	4.0	37.1	(28.4)
Charges associated with convertible senior notes	—	138.4	—
Interest income and other, net	(90.3)	(91.0)	(52.8)
Provision for income taxes	226.8	144.7	82.4
Net income	$ 478.6	$ 341.3	$ 249.7

(1) Other revenues primarily consist of net product sales of ALKINDI and EFMODY and royalties earned on AbbVie net sales of elagolix and TPC net sales of valbenazine.

(2) Other research and development consists of indirect costs incurred for the benefit of multiple research and development programs, including facility-based expenses (such as rent expense) and other overhead allocations.

15. Legal Matters

Legal Proceedings

In March 2025, we received a notice from Zydus Lifesciences Global FZE (Zydus FZE) that it had filed an abbreviated new drug application, or ANDA, with the FDA seeking approval of a generic version of INGREZZA SPRINKLE (valbenazine). The ANDA contained a Paragraph IV Patent Certification alleging that certain of our patents covering INGREZZA SPRINKLE are invalid and/or will not be infringed by Zydus FZE's importation, manufacture, use or sale of the medicine for which the ANDA was submitted. We filed suit in the U.S. District Court for the District of Delaware in April 2025 against Zydus Pharmaceuticals (USA) Inc. and its affiliates Zydus FZE, Zydus Worldwide DMCC (entity subsequently dismissed), Zydus Lifesciences Limited, and Zydus Healthcare (USA) LLC (entity subsequently dismissed) (collectively, Zydus). The complaint alleged that by filing their ANDAs, Zydus infringed certain of our patents covering INGREZZA SPRINKLE and sought to prevent Zydus from selling a generic version of INGREZZA SPRINKLE. We also filed suit in the U.S. District Court for the District of New Jersey in April 2025 against Zydus on a similar factual basis seeking to prevent Zydus from selling a generic version of INGREZZA SPRINKLE and this case was dismissed in favor of continued prosecution of the Delaware proceeding against the same entities.

From time to time, we may become subject to other legal proceedings or claims arising in the ordinary course of our business. We currently believe that none of the claims or actions pending against us is likely to have, individually or in the aggregate, a material adverse effect on our business, financial condition, or results of operations. Given the unpredictability inherent in litigation, however, we cannot predict the outcome of these matters.

U.S. Department of Justice Investigation

In August 2025, we received a civil investigative demand from the U.S. Department of Justice (DOJ) requesting certain documents and information related to our sales and marketing of INGREZZA. We are cooperating with the DOJ's request. No assurance can be given as to the timing or outcome of the DOJ's investigation.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods 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 Rule 13a-15(b) of the Exchange Act, 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 defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, 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 as of the end of the year covered by this report.

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, 2025. 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, 2025, 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 Stockholders 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, 2025, 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, 2025, 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, 2025 and 2024, 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, 2025, and the related notes and our report dated February 11, 2026 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 11, 2026

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

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 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2025. Such information is incorporated herein by reference.

We have adopted a code of business conduct and 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 business conduct and 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 business conduct and 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 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2025. Such information is incorporated herein by reference, except as to information disclosed therein pursuant to Item 402(v) of Regulation S-K relating to pay versus performance.

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 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2025. 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 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2025. Such information is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

Information required by this item will be contained in our Definitive Proxy Statement for our 2026 Annual Meeting of Stockholders, to be filed pursuant to Regulation 14A with the SEC within 120 days of December 31, 2025. Such information is incorporated herein by reference.

PART IV

Item 15. Exhibits and 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, 2025 and 2024

Consolidated Statements of Income and Comprehensive Income for the years ended December 31, 2025, 2024, and 2023

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2025, 2024, and 2023

Consolidated Statements of Cash Flows for the years ended December 31, 2025, 2024, and 2023

Notes to the Consolidated Financial Statements

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:	Certificate of Incorporation, as amended
	Reference:	Incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on November 5, 2018
3.2	Description:	Bylaws, as amended
	Reference:	Incorporated by reference to Exhibit 3.2 of the Company's Quarterly Report on Form 10-Q filed on October 30, 2024
4.1	Description:	Form of Common Stock Certificate
	Reference:	Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-03172)
4.2	Description:	Description of Common Stock of the Company
19.1	Description:	Neurocrine Biosciences, Inc. Insider Trading Policy
	Reference:	Incorporated by reference to Exhibit 19.1 of the Company's Annual Report on Form 10-K filed on February 10, 2025
21.1	Description:	Subsidiaries of the Company
23.1	Description:	Consent of Independent Registered Public Accounting Firm
24.1	Description:	Power of Attorney (included on signature page to this report)
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
97+	Description:	Neurocrine Biosciences, Inc. Clawback Policy
	Reference:	Incorporated by reference to Exhibit 97 of the Company's Annual Report on Form 10-K filed on February 9, 2024
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 10.1 of the Company's Quarterly Report on Form 10-Q filed on May 5, 2021
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 May 5, 2021
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 10.3 of the Company's Quarterly Report on Form 10-Q filed on May 5, 2021
10.4*	Description:	Collaboration and License Agreement dated January 28, 2019 between Voyager Therapeutics, Inc. and the Company
	Reference:	Incorporated by reference to Exhibit 10.4 of the Company's Annual Report on Form 10-K filed on February 10, 2025
10.5	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
10.6	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
10.7*	Description:	Collaboration and License Agreement dated November 22, 2021 between Heptares Therapeutics Limited and the Company
	Reference:	Incorporated by reference to Exhibit 10.10 of the Company's Annual Report on Form 10-K filed on February 11, 2022
10.8*	Description:	Collaboration and License Agreement dated January 8, 2023 between Voyager Therapeutics, Inc. and the Company
	Reference:	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on May 3, 2023
10.9*	Description:	First Amendment to the Collaboration and License Agreement, effective April 3, 2024, between the Company and Voyager Therapeutics, Inc.
	Reference:	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on August 1, 2024
10.10	Description:	Stock Purchase Agreement dated January 8, 2023 between Voyager Therapeutics, Inc. and the Company
	Reference:	Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on May 3, 2023
10.11	Description:	Amended and Restated Investor Agreement dated January 8, 2023 between Voyager Therapeutics, Inc. and the Company
	Reference:	Incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q filed on May 3, 2023
10.12*	Description:	Amended and Restated Exclusive License Agreement dated January 24, 2025 by and between Takeda Pharmaceutical Company Limited and the Company
	Reference:	Incorporated by reference to Exhibit 10.8 of the Company's Quarterly Report on Form 10-Q filed on May 5, 2025
10.13*	Description:	License Agreement dated December 19, 2014 by and between Sanofi S.A. and the Company

10.14*	Description:	Amendment 1 to the License Agreement dated December 19, 2016 by and between Sanofi S.A. and the Company
10.15*	Description:	Amendment 2 to the License Agreement dated October 21, 2019 by and between Sanofi S.A. and the Company

Equity Plans and Related Agreements:

10.16+	Description:	Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan, as amended
	Reference:	Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on October 30, 2024
10.17+	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
10.18+	Description:	Form of Stock Option Grant Notice and Option Agreement for use under the Neurocrine Biosciences, Inc. 2011 Equity Incentive Plan, as amended
	Reference:	Incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q filed on October 30, 2024
10.19+	Description:	Neurocrine Biosciences, Inc. 2020 Equity Incentive Plan, as amended and restated
	Reference:	Incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q filed on October 30, 2024
10.20+	Description:	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement for grants on or after February 13, 2024 made under the 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 May 1, 2024
10.21+	Description:	Form of Stock Option Grant Notice and Option Agreement for grants made to Kevin Gorman on or after February 13, 2024 made 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 May 1, 2024
10.22+	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 10.17 of the Company's Annual Report on Form 10-K filed on February 11, 2022
10.23+	Description:	Form of Stock Option Grant Notice and Option Agreement for grants made on or after January 30, 2025 made under the 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 May 5, 2025
10.24+	Description:	Neurocrine Biosciences, Inc. 2025 Equity Incentive Plan
	Reference:	Incorporated by reference to Exhibit 99.2 of the Company's Registration Statement on Form S-8 (Registration No. 333-287477)
10.25+	Description:	Form of Standard Stock Option Grant Notice and Option Agreement for use under the Neurocrine Biosciences, Inc. 2025 Equity Incentive Plan
	Reference:	Incorporated by reference to Exhibit 99.3 of the Company's Registration Statement on Form S-8 (Registration No. 333-287477)
10.26+	Description:	Form of Standard Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement for use under the Neurocrine Biosciences, Inc. 2025 Equity Incentive Plan
	Reference:	Incorporated by reference to Exhibit 99.4 of the Company's Registration Statement on Form S-8 (Registration No. 333-287477)
10.27+	Description:	Form of Director Stock Option Grant Notice and Option Agreement for use under the Neurocrine Biosciences, Inc. 2025 Equity Incentive Plan
	Reference:	Incorporated by reference to Exhibit 99.5 of the Company's Registration Statement on Form S-8 (Registration No. 333-287477)

10.28+	Description:	Form of Director Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement for use under the Neurocrine Biosciences, Inc. 2025 Equity Incentive Plan
	Reference:	Incorporated by reference to Exhibit 99.6 of the Company's Registration Statement on Form S-8 (Registration No. 333-287477)
10.29+	Description:	Form of Non-U.S. Stock Option Grant Notice and Option Agreement for use under the Neurocrine Biosciences, Inc. 2025 Equity Incentive Plan
	Reference:	Incorporated by reference to Exhibit 99.7 of the Company's Registration Statement on Form S-8 (Registration No. 333-287477)
10.30+	Description:	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement for use under the Neurocrine Biosciences, Inc. 2025 Equity Incentive Plan
	Reference:	Incorporated by reference to Exhibit 99.8 of the Company's Registration Statement on Form S-8 (Registration No. 333-287477)
10.31+	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
10.32+	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
10.33+	Description:	Neurocrine Biosciences, Inc. 2018 Employee Stock Purchase Plan, as amended and restated
	Reference:	Incorporated by reference to Exhibit 99.1 of the Company's Registration Statement on Form S-8 (Registration No. 333-287477)

Agreements with Officers and Directors:

10.34+	Description:	Neurocrine Biosciences, Inc. Executive Severance Plan effective February 7, 2025
	Reference:	Incorporated by reference to Exhibit 10.26 of the Company's Annual Report on Form 10-K filed on February 10, 2025
10.35+	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
10.36+	Description:	Amended and Restated Employment Agreement effective February 7, 2025 between the Company and Kyle W. Gano, Ph.D.
	Reference:	Incorporated by reference to Exhibit 10.31 of the Company's Annual Report on Form 10-K filed on February 10, 2025
10.37+	Description:	Amended and Restated Employment Agreement effective February 7, 2025 between the Company and Matthew C. Abernethy
	Reference:	Incorporated by reference to Exhibit 10.32 of the Company's Annual Report on Form 10-K filed on February 10, 2025
10.38+	Description:	Amended and Restated Employment Agreement effective February 7, 2025 between the Company and Eric Benevich
	Reference:	Incorporated by reference to Exhibit 10.33 of the Company's Annual Report on Form 10-K filed on February 10, 2025
10.39+	Description:	Employment Agreement effective April 2, 2025 between the Company and Sanjay Keswani
10.40+	Description:	Amended and Restated Employment Agreement effective February 7, 2025 between the Company and Jude Onyia
	Reference:	Incorporated by reference to Exhibit 10.34 of the Company's Annual Report on Form 10-K filed on February 10, 2025
10.41+	Description:	Amended and Restated Employment Agreement effective February 7, 2025 between the Company and Eiry W. Roberts
	Reference:	Incorporated by reference to Exhibit 10.35 of the Company's Annual Report on Form 10-K filed on February 10, 2025

10.42+	Description:	Amended and Restated Employment Agreement dated May 30, 2025 between the Company and Eiry W. Roberts, M.D.
	Reference:	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on May 30, 2025
10.43+	Description:	Amendment to Amended and Restated Employment Agreement dated November 21, 2025 between the Company and Eiry W. Roberts, M.D.
	Reference:	Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on November 24, 2025

Agreements Related to Real Property:

10.44	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
10.45	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
10.46	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
10.47	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
10.48	Description:	Commercial Lease dated February 8, 2022, by and between the Company and Gemdale Aperture Phase I, LLC
	Reference:	Incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed on May 4, 2022

+ Management contract or compensatory plan or arrangement.

* Certain information in this exhibit has been omitted pursuant to Item 601 of Regulation S-K.

** 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/ Kyle W. Gano
Kyle W. Gano
Chief Executive Officer

Date: February 11, 2026

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

Date: February 11, 2026

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kyle W. Gano 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 11, 2026:

Signature	Title
/s/ Kyle W. Gano Kyle W. Gano, 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/ Kevin C. Gorman Kevin C. Gorman, Ph.D.	Director
/s/ Gary A. Lyons Gary A. Lyons	Director
/s/ Johanna Mercier Johanna Mercier	Director
/s/ George J. Morrow George J. Morrow	Director
/s/ Leslie V. Norwalk Leslie V. Norwalk	Director
/s/ Christine A. Poon Christine A. Poon	Director
/s/ Richard F. Pops Richard F. Pops	Director
/s/ Shalini Sharp Shalini Sharp	Director
/s/ Stephen A. Sherwin Stephen A. Sherwin, M.D.	Director

Neurocrine Biosciences

Corporate Information

Neurocrine Biosciences is a leading biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs.

We are dedicated to discovering, developing and commercializing life-changing treatments for patients with under-addressed neurological, psychiatric, endocrine and immunological disorders.

The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, classic congenital adrenal hyperplasia, endometriosis* and uterine fibroids*, as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas.

For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders, because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, X and Facebook and YouTube.

CORPORATE MANAGEMENT

Kyle W. Gano, Ph.D.
Chief Executive Officer

Matthew C. Abernethy
Chief Financial Officer

Eric Benevich
Chief Commercial Officer

David W. Boyer
Chief Corporate Affairs Officer

Julie S. Cooke
Chief Human Resources Officer

Ingrid Delaet, Ph.D.
Chief Regulatory Officer

Darin M. Lippoldt, J.D.
Chief Legal Officer

Jude Onyia, Ph.D.
Chief Scientific Officer

Sanjay Keswani, M.D.
Chief Medical Officer

Andrew Ratz, Ph.D.
Chief Technical Operations Officer

BOARD OF DIRECTORS

Kyle W. Gano, Ph.D.
Chief Executive Officer

William H. Rastetter, Ph.D.
Chairman of the Board, Neurocrine Biosciences, Inc. and Fate Therapeutics

Kevin C. Gorman, Ph.D.
Former Chief Executive Officer, Neurocrine Biosciences, Inc.

Gary A. Lyons
Former President and Chief Executive Officer, Neurocrine Biosciences, Inc.

Johanna Mercier
Chief Commercial Officer, Gilead Sciences

George J. Morrow
Former Executive Vice President, Global Commercial Operations, Amgen Inc.

Leslie V. Norwalk
Former Acting Administrator for the Centers for Medicare & Medicaid Services

Christine A. Poon
Former Vice Chair and Worldwide Chair of Pharmaceuticals at Johnson & Johnson

Richard F. Pops
Chairman of the Board and Chief Executive Officer, Alkermes plc

Shalini Sharp
Former Chief Financial Officer and Executive Vice President of Ultragenyx

Stephen A. Sherwin, M.D.
Former Chairman of the Board and Chief Executive Officer, Cell Genesys, Inc.

STOCKHOLDER INFORMATION

Transfer Agent
Equiniti Trust Company

Corporate Counsel
Cooley LLP

Auditors
Ernst & Young LLP

*in collaboration with AbbVie

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