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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

or

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

For the transition period from _____ to _____

Commission File Number: 0-22705

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

6027 Edgewood Bend Court
San Diego, CA
(Address of principal executive office)

33-0525145
(IRS Employer
Identification No.)

92130
(Zip Code)

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

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

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

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

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

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 100,637,227 as of April 25, 2024.

NEUROCRINE BIOSCIENCES, INC.

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Part I. Financial Information

Item 1. Financial Statements

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

(in millions, except share data)	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 396.3	$ 251.1
Debt securities available-for-sale	814.3	780.5
Accounts receivable	450.7	439.3
Inventory	37.2	38.3
Other current assets	100.5	97.8
Total current assets	1,799.0	1,607.0
Deferred tax assets	378.2	362.6
Debt securities available-for-sale	700.4	687.5
Right-of-use assets	270.8	276.5
Equity security investments	163.5	161.9
Property and equipment, net	75.3	70.8
Intangible assets, net	34.3	35.5
Other noncurrent assets	50.9	49.6
Total assets	$ 3,472.4	$ 3,251.4
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 417.2	$ 448.8
Convertible senior notes, at carrying value ($170.4 face value as of March 31, 2024 and December 31, 2023)	122.8	170.1
Convertible senior notes embedded derivative liability	136.2	—
Other current liabilities	36.7	35.9
Total current liabilities	712.9	654.8
Noncurrent operating lease liabilities	252.9	258.3
Other noncurrent liabilities	120.5	106.3
Total liabilities	1,086.3	1,019.4
Stockholders’ equity:		
Preferred stock, $0.001 par value; 5.0 million shares authorized; no shares issued and outstanding	—	—
Common stock, $0.001 par value; 220.0 shares authorized; 100.6 and 98.7 shares issued and outstanding, respectively	0.1	0.1
Additional paid-in capital	2,496.4	2,382.0
Accumulated other comprehensive income	3.3	7.0
Accumulated deficit	(113.7)	(157.1)
Total stockholders’ equity	2,386.1	2,232.0
Total liabilities and stockholders’ equity	$ 3,472.4	$ 3,251.4

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

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

(in millions, except per share data)	Three Months Ended March 31, 2024	2023
Revenues:		
Net product sales	$ 509.0	$ 415.3
Collaboration revenues	6.3	5.1
Total revenues	515.3	420.4
Operating expenses:		
Cost of revenues	7.5	8.5
Research and development	159.4	139.5
Acquired in-process research and development	6.0	143.9
Selling, general and administrative	243.1	242.7
Total operating expenses	416.0	534.6
Operating income (loss)	99.3	(114.2)
Other (expense) income:		
Interest expense	(1.1)	(1.1)
Unrealized gain on equity security investments	1.6	2.2
Charges associated with convertible senior notes	(88.7)	—
Investment income and other, net	23.4	9.8
Total other (expense) income, net	(64.8)	10.9
Income (loss) before benefit from income taxes	34.5	(103.3)
Benefit from income taxes	(8.9)	(26.7)
Net income (loss)	43.4	(76.6)
Foreign currency translation adjustments, net of tax	(0.5)	1.2
Unrealized (loss) gain on debt securities available-for-sale, net of tax	(3.2)	4.0
Comprehensive income (loss)	$ 39.7	$ (71.4)
Earnings (loss) per share:		
Basic	$ 0.43	$ (0.79)
Diluted	$ 0.42	$ (0.79)
Weighted-average shares outstanding:		
Basic	99.8	97.1
Diluted	103.6	97.1

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)

(in millions)	Common Stock Shares	Common Stock $	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance at December 31, 2023	98.7	$ 0.1	$ 2,382.0	$ 7.0	$ (157.1)	$ 2,232.0
Net income	—	—	—	—	43.4	43.4
Other comprehensive loss, net of tax	—	—	—	(3.7)	—	(3.7)
Stock-based compensation expense	—	—	44.5	—	—	44.5
Issuances of common stock under stock plans	1.9	—	69.9	—	—	69.9
Balance at March 31, 2024	100.6	$ 0.1	$ 2,496.4	$ 3.3	$ (113.7)	$ 2,386.1
Balance at December 31, 2022	96.5	$ 0.1	$ 2,122.4	$ (7.9)	$ (406.8)	$ 1,707.8
Net loss	—	—	—	—	(76.6)	(76.6)
Other comprehensive income, net of tax	—	—	—	5.2	—	5.2
Stock-based compensation expense	—	—	39.9	—	—	39.9
Issuances of common stock under stock plans	1.0	—	8.2	—	—	8.2
Balance at March 31, 2023	97.5	$ 0.1	$ 2,170.5	$ (2.7)	$ (483.4)	$ 1,684.5

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

(in millions)	Three Months Ended March 31, 2024	2023
Cash flows from operating activities:		
Net income (loss)	$ 43.4	$ (76.6)
Adjustments to reconcile net income (loss) to net cash from operating activities:		
Stock-based compensation expense	44.5	39.9
Charges associated with convertible senior notes	88.7	—
Depreciation	5.3	4.1
Accretion of discount on investments, net	(7.1)	(2.1)
Amortization of intangible assets	0.9	0.9
Changes in fair value of equity investments	(1.6)	(2.2)
Deferred income taxes	(15.6)	(31.6)
Other	3.4	(0.1)
Change in operating assets and liabilities:		
Accounts receivable	(11.3)	(41.7)
Inventory	1.1	1.8
Accounts payable and accrued liabilities	(18.6)	6.7
Other assets and liabilities, net	(2.8)	(24.3)
Cash flows from operating activities	130.3	(125.2)
Cash flows from investing activities:		
Purchases of debt securities available-for-sale	(320.1)	(206.2)
Sales and maturities of debt securities available-for-sale	276.3	203.9
Purchases of equity investments	—	(31.3)
Capital expenditures	(11.2)	(8.5)
Cash flows from investing activities	(55.0)	(42.1)
Cash flows from financing activities:		
Issuances of common stock under benefit plans	69.9	8.2
Cash flows from financing activities	69.9	8.2
Change in cash, cash equivalents and restricted cash	145.2	(159.1)
Cash, cash equivalents and restricted cash at beginning of period	259.1	270.7
Cash, cash equivalents and restricted cash at end of period	$ 404.3	$ 111.6
Supplemental disclosures:		
Non-cash capital expenditures	$ 1.1	$ 0.6
Cash paid for income taxes	$ 0.2	$ 0.2

See accompanying notes to the condensed consolidated financial statements.

1. Organization and Significant Accounting Policies

Basis of Presentation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of our financial position and of the results of operations and cash flows for the periods presented. The accompanying unaudited condensed consolidated financial statements include the accounts of Neurocrine Biosciences and our wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2023, included in our Annual Report on Form 10-K, or the 2023 Form 10-K, filed with the SEC. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or the full year. The condensed consolidated balance sheet as of December 31, 2023, has been derived from the audited financial statements as of that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

There were no significant changes to our significant accounting policies as disclosed in the 2023 Form 10-K.

Recently Issued Accounting Pronouncements Not Yet Adopted.

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for annual reporting periods beginning after December 15, 2023, and for interim reporting periods beginning January 1, 2025, with early adoption permitted. We are currently evaluating the impact of adopting ASU 2023-07.

In December 2023, the FASB issued 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, with early adoption permitted. We are currently evaluating the impact of adopting ASU 2023-09.

2. Collaboration and License Agreements

Nxera Pharma UK Limited, or Nxera. In 2021, we entered into a collaboration and license agreement with Nxera (formerly Heptares Therapeutics Limited) 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.

Under the terms of the agreement, Nxera may be entitled to receive potential future payments of up to $2.6 billion upon the achievement of certain event-based milestones and would be 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.

We may terminate the agreement in its entirety or with respect to one or more targets upon 180 days' written notice to Nxera during the research collaboration term and upon 90 days' written notice to Nxera following the expiration of the research collaboration term. 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, or Takeda. In 2020, we entered into an exclusive license agreement with Takeda, pursuant to which we acquired the exclusive rights to develop and commercialize certain early to mid-stage psychiatry compounds, including luvadaxistat, NBI-1070770, NBI-1065845, NBI-1065846 and three non-clinical stage compounds. Luvadaxistat, NBI-1070770, and the three non-clinical stage compounds have each been designated as a royalty-bearing product. NBI-1065845 and NBI-1065846 are currently each designated as a profit-share product. We are responsible for all manufacturing, development and commercialization costs of any royalty-bearing product.

With respect to NBI-1065845 and NBI-1065846, we and Takeda will equally share in the operating profits and losses. Takeda retains the rights to opt-out of the profit-sharing arrangements, pursuant to which Takeda would be entitled to receive potential future payments upon the achievement of certain event-based milestones with respect to such compounds and receive royalties on the future net sales of such compounds (in lieu of equally sharing in the operating profits and losses). Takeda may elect to exercise such opt-out right for such compound immediately following the completion of a second Phase 2 clinical trial for such compound, or, under certain circumstances related to the development and commercialization activities to be performed by us, before the initiation of a Phase 3 clinical trial for such compound.

Under the terms of the agreement, Takeda may be entitled to receive potential future payments of up to $1.9 billion upon the achievement of certain event-based milestones and would be entitled to receive royalties on the future net sales of any royalty-bearing 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, (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 agreement in its entirety or in one or more (but not all) of the United States, 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 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 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 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 agreement in the event of any material breach, solely with respect to the target class of a licensed product to which such material breach relates, or in its entirety in the event of any material breach that relates to all licensed products.

Idorsia Pharmaceuticals Ltd., or Idorsia. In 2020, we entered into a collaboration and license agreement with Idorsia, pursuant to which we acquired the global rights to NBI-827104, a potent, selective, orally active and brain penetrating T-type calcium channel blocker in clinical development for the treatment of a rare pediatric epilepsy and other potential indications, including essential tremor. We are responsible for all manufacturing, development and commercialization costs of any collaboration product.

Under the terms of the agreement, Idorsia may be entitled to receive potential future payments of up to $1.7 billion upon the achievement of certain event-based milestones and would be entitled to receive royalties on the future net sales of any collaboration product.

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

Xenon Pharmaceuticals Inc., or 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. We are responsible for all development and manufacturing costs of any collaboration product, subject to certain exceptions.

In connection with entering the agreement in 2019, we purchased approximately 1.4 million shares (at $14.196 per share) of Xenon common stock (the 2019 Xenon Shares). The 2019 Xenon Shares were recorded at a fair value of $14.1 million after considering Xenon's stock price and certain transfer restrictions that were applicable to the shares on the measurement date.

In connection with the achievement of a development milestone in 2021, we purchased approximately 0.3 million shares (at $19.9755 per share) of Xenon common stock (the 2021 Xenon Shares). The 2021 Xenon Shares were recorded at a fair value of $4.6 million after considering Xenon's stock price and certain transfer restrictions that were applicable to the shares on the measurement date.

In connection with the achievement of a development milestone in 2022, we purchased approximately 0.3 million shares (at $31.855 per share) of Xenon common stock (the 2022 Xenon Shares). The 2022 Xenon Shares were recorded at a fair value of $7.7 million after considering Xenon's stock price on the measurement date.

Under the terms of the agreement, Xenon may be entitled to receive potential future payments of up to $1.7 billion upon the achievement of certain event-based milestones and would be 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 United States 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 United States.

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., or Voyager.

2019 Voyager Agreement. In 2019, we entered into a collaboration and license agreement with Voyager (the 2019 Voyager Agreement), pursuant to which we retain certain rights to develop and commercialize the Friedreich's ataxia (FA) program and two undisclosed programs. 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 approximately 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 for a period of up to three years from the effective date of the 2023 Voyager Agreement (defined below). The 2019 Voyager Shares were recorded at a fair value of $54.7 million after considering Voyager's stock price and certain transfer restrictions that were applicable to the shares on the measurement date.

In connection with the selection of a development candidate under the FA program pursuant to our collaboration with Voyager in February 2024, we paid Voyager a milestone of $5.0 million, which was expensed as research and development in the first quarter of 2024.

Under the terms of the 2019 Voyager Agreement, Voyager may be entitled to receive potential future payments of up to $1.3 billion upon the achievement of certain event-based milestones and would be 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 (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 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 approximately 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 for a period of up to three years from the effective date of the 2023 Voyager Agreement. 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. Mr. 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 the first quarter of 2023 as the license had no foreseeable alternative future use. We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business.

We recognized unrealized gains of $7.5 million and $9.3 million, respectively, on our equity investment in Voyager for the first quarter of 2024 and 2023. As of March 31, 2024, the fair value (Level 1) of our equity investment in Voyager was $79.8 million.

Under the terms of the 2023 Voyager Agreement, Voyager may be entitled to receive potential future payments of up to $6.1 billion upon the achievement of certain event-based milestones and would be 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.

Mitsubishi Tanabe Pharma Corporation, or MTPC. In 2015, we out-licensed the rights to valbenazine in Japan and other select Asian markets to MTPC. In 2020, we entered into a commercial supply agreement with MTPC, pursuant to which we supply MTPC with valbenazine drug product for commercial use in such markets. MTPC is responsible for all development, manufacturing and commercialization costs of valbenazine in such markets.

MTPC launched DYSVAL® (valbenazine) in Japan for the treatment of tardive dyskinesia in June 2022 and subsequently in other select Asian markets, where it is marketed as REMLEAS® (valbenazine). We receive royalties at tiered percentage rates on MTPC net sales of valbenazine.

Under the terms of our license agreement with MTPC, we may be entitled to receive potential future payments of up to $30.0 million upon the achievement of certain sales-based milestones and are entitled to receive royalties at tiered percentage rates on future MTPC net sales of valbenazine for the longer of 10 years or the life of the related patent rights. MTPC may terminate the agreement upon 180 days' written notice to us. In such event, all out-licensed product rights would revert to us.

AbbVie Inc., or AbbVie. In 2010, we out-licensed the global rights to elagolix to AbbVie. AbbVie is responsible for all development and commercialization costs of elagolix.

AbbVie launched ORILISSA® (elagolix tablets) in the U.S. for the treatment of moderate to severe pain associated with endometriosis in August 2018 and ORIAHNN® (elagolix, estradiol and norethindrone acetate capsules and elagolix capsules) in the U.S. for the treatment of heavy menstrual bleeding due to uterine fibroids in June 2020. We receive royalties at tiered percentage rates on AbbVie net sales of elagolix and recognized elagolix royalty revenue of $3.0 million and $3.7 million, respectively, for the first quarter of 2024 and 2023.

Under the terms of our license agreement with AbbVie, we may be entitled to receive potential future payments of up to $366.0 million upon the achievement of certain event-based milestones and are entitled to receive royalties at tiered percentage rates on future AbbVie net sales of elagolix for the longer of 10 years or the life of the related patent rights. AbbVie may terminate the agreement upon 180 days' written notice to us. In such event, all out-licensed product rights would revert to us.

3. Debt Securities

The following table presents the amortized cost, unrealized gain and loss recognized in accumulated other comprehensive income (loss) and fair value of debt securities available-for-sale, aggregated by major security type and contractual maturity.

		March 31, 2024				December 31, 2023			
(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	$ 58.0	$ —	$ —	$ 58.0	$ 53.5	$ —	$ —	$ 53.5
Corporate debt securities	0 to 1 years	419.4	0.1	(0.9)	418.6	382.1	0.1	(1.0)	381.2
Securities of government-sponsored entities	0 to 1 years	338.3	—	(0.6)	337.7	346.1	0.2	(0.5)	345.8
		$ 815.7	$ 0.1	$ (1.5)	$ 814.3	$ 781.7	$ 0.3	$ (1.5)	$ 780.5
Corporate debt securities	1 to 3 years	$ 530.0	$ 0.9	$ (1.3)	$ 529.6	$ 483.5	$ 2.9	$ (0.4)	$ 486.0
Securities of government-sponsored entities	1 to 3 years	171.4	—	(0.6)	170.8	201.1	0.5	(0.1)	201.5
		$ 701.4	$ 0.9	$ (1.9)	$ 700.4	$ 684.6	$ 3.4	$ (0.5)	$ 687.5

Unrealized losses on our available-for-sale debt security investments were primarily due to changes in interest rates. These investments 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 recovery of their amortized cost basis. No allowance for credit losses was recognized as of March 31, 2024 or December 31, 2023.

The following table presents debt securities available-for-sale that were in an unrealized loss position as of March 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	$ 555.2	$ (1.6)	$ 90.0	$ (0.6)	$ 645.2	$ (2.2)
Securities of government-sponsored entities	$ 383.3	$ (0.9)	$ 16.8	$ (0.3)	$ 400.1	$ (1.2)

The following table presents debt securities available-for-sale that were in an unrealized loss position as of December 31, 2023, 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	$ 265.1	$ (0.4)	$ 183.8	$ (1.0)	$ 448.9	$ (1.4)
Securities of government-sponsored entities	$ 214.6	$ (0.2)	$ 16.7	$ (0.4)	$ 231.3	$ (0.6)

Accrued interest receivables on debt securities available-for-sale totaled $12.6 million and $11.2 million, respectively, as of March 31, 2024 and December 31, 2023. We do not measure an allowance for credit losses for accrued interest receivables. For the purposes of identifying and measuring an impairment, accrued interest is excluded from both the fair value and amortized cost basis of the debt security. Uncollectible accrued interest receivables associated with an impaired debt security are reversed against interest income upon identification of the impairment. No accrued interest receivables were written off during the first three months of 2024 or 2023.

4. Fair Value Measurements

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.

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

	March 31, 2024			December 31, 2023		
	Fair Value	Leveling		Fair Value	Leveling	
(in millions)		Level 1	Level 2		Level 1	Level 2
Cash and money market funds	$ 396.3	$ 396.3	$ —	$ 251.1	$ 251.1	$ —
Restricted cash	8.0	8.0	—	8.0	8.0	—
Commercial paper	58.0	—	58.0	53.5	—	53.5
Corporate debt securities	948.2	—	948.2	867.2	—	867.2
Securities of government-sponsored entities	508.5	—	508.5	547.3	—	547.3
Equity security investments	163.5	163.5	—	161.9	161.9	—
	$ 2,082.5	$ 567.8	$ 1,514.7	$ 1,889.0	$ 421.0	$ 1,468.0

5. Other Balance Sheet Details

Inventory consisted of the following:

(in millions)	March 31, 2024	December 31, 2023
Raw materials	$ 18.1	$ 21.5
Work in process	12.0	9.7
Finished goods	7.5	12.3
	37.6	43.5
Less inventory reserves	(0.4)	(5.2)
Total inventory	$ 37.2	$ 38.3

Accounts payable and accrued liabilities consisted of the following:

(in millions)	March 31, 2024	December 31, 2023
Sales rebates and reserves	$ 185.9	$ 139.3
Accrued employee related costs	42.6	86.2
Current branded prescription drug fee	35.3	45.7
Accrued development costs	41.3	44.3
Current income taxes payable	24.8	24.4
Accounts payable and other accrued liabilities	87.3	108.9
Total accounts payable and accrued liabilities	$ 417.2	$ 448.8

Other noncurrent liabilities consisted of the following:

(in millions)	March 31, 2024	December 31, 2023
Noncurrent income taxes payable	$ 101.1	$ 96.0
Noncurrent branded prescription drug fee	19.4	10.3
Total other noncurrent liabilities	$ 120.5	$ 106.3

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

(in millions)	March 31, 2024	March 31, 2023
Cash and cash equivalents	$ 396.3	$ 103.8
Restricted cash included in other noncurrent assets	8.0	7.8
Total cash, cash equivalents and restricted cash	$ 404.3	$ 111.6

6. Goodwill and Intangible Assets

The following table presents the changes in the carrying amount of goodwill. Goodwill is included in other noncurrent assets in our condensed consolidated balance sheets.

(in millions)	Amount
Balance as of December 31, 2023	$ 5.8
Foreign currency translation adjustments	(0.1)
Balance as of March 31, 2024	$ 5.7

The following table presents information relating to our recognized intangible assets as of March 31, 2024.

(dollars in millions)	Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Developed product rights	10 years	$ 35.8	$ 5.0	$ 30.8
Acquired IPR&D	Indefinite	$ 3.5	$ —	3.5
Total intangible assets, net				$ 34.3

The following table presents approximate future annual amortization expense for our finite-lived intangible assets as of March 31, 2024.

(in millions)	Amount
2024 (9 months remaining)	$ 2.7
2025	$ 3.6
2026	$ 3.6
2027	$ 3.6
2028	$ 3.6
Thereafter	$ 13.7

7. Leases

Our operating leases that have commenced have terms that expire beginning 2025 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 right-of-use (ROU) assets or operating lease liabilities.

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

	Three Months Ended March 31,	
(in millions, except weighted average data)	2024	2023
Operating lease cost	$ 9.4	$ 4.1
Sublease income	(0.4)	—
Net operating lease cost	$ 9.0	$ 4.1
Cash paid for amounts included in the measurement of operating lease liabilities	$ 6.1	$ 4.4

	March 31, 2024	March 31, 2023
Weighted average remaining lease term	10.6 years	7.7 years
Weighted average discount rate	5.1 %	5.3 %
Restricted cash related to letters of credit issued in lieu of cash security deposits	$ 7.8	$ 7.8

The following table presents approximate future non-cancelable minimum lease payments under operating leases and sublease income as of March 31, 2024.

(in millions)	Operating Leases [1]	Sublease Income
2024 (9 months remaining)	$ 26.9	$ (1.3)
2025	34.7	(1.7)
2026	34.0	(1.7)
2027	34.8	(1.7)
2028	35.6	(1.7)
Thereafter	211.4	(4.3)
Total operating lease payments (sublease income)	377.4	$ (12.4)
Less accreted interest	89.5	
Total operating lease liabilities	287.9	
Less current operating lease liabilities included in other current liabilities	35.0	
Noncurrent operating lease liabilities	$ 252.9	

(1) Amounts presented in the table above exclude $15.4 million for 2025, $23.6 million for 2026, $24.3 million for 2027, $25.1 million for 2028 and $223.5 million thereafter of approximate non-cancelable future minimum lease payments under operating leases related to our new campus facility that have not yet commenced.

New Campus Facility. On February 8, 2022, we entered into a lease agreement for a four-building campus facility to be constructed in San Diego, California, including a six-year option for the construction of a fifth building. This campus facility, comprised of office space and research and development laboratories, now serves as our corporate headquarters.

The construction of the campus facility is phased. The first phase of construction, consisting of two buildings relating to office space, was completed in December 2023 and resulted in the recognition of ROU assets and operating lease liabilities totaling $199.0 million and $189.8 million, respectively.

As we begin to occupy our new campus facility, we will sublease certain of our existing leased premises when we determine there is excess leased capacity. Certain of these subleases contain both lease and non-lease components. Sublease income is recognized as an offset to operating expense on a straight-line basis over the lease term. Income related to non-lease components is recognized in operating expenses as a reduction to costs we incur in relation to the primary lease.

Further, 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 identified 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.

8. Convertible Senior Notes

On May 2, 2017, we completed a private placement of $517.5 million in aggregate principal amount of 2.25% fixed-rate convertible senior notes due May 15, 2024, or the 2024 Notes, and entered into the 2017 Indenture with respect to the 2024 Notes. Interest on the 2024 Notes is due semi-annually on May 15 and November 15 of each year.

In 2020, we repurchased $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. In 2022, we repurchased $210.8 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $279.0 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. 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 will be 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 debt discount will be recorded in other income (expense), net in our condensed consolidated statements of operations.

The following table presents a reconciliation of the beginning and ending balances for the derivative liability measured at fair value using significant unobservable inputs (Level 3).

(in millions)	**Amount**
Balance as of December 31, 2023	$ —
Initial fair value	126.6
Change in fair value	9.6
Balance as of March 31, 2024	$ 136.2

The following table presents a summary of charges recognized in connection with the bifurcation of the conversion feature of the 2024 Notes in the first quarter of 2024.

(in millions)	**Amount**
Accretion of debt discount	$ 79.1
Change in fair value	9.6
Charges associated with convertible senior notes	$ 88.7

The following table presents a summary of the 2024 Notes as of March 31, 2024.

(in millions)	Principal Amount	Unamortized Debt		Net Carrying Amount	Fair Value	
		Issuance Costs	Discount		Amount	Leveling
Convertible senior notes	$ 170.4	$ (0.1)	$ (47.5)	$ 122.8	$ 309.5	Level 2

The following table presents a summary of the 2024 Notes as of December 31, 2023.

(in millions)	Principal Amount	Unamortized Debt		Net Carrying Amount	Fair Value	
		Issuance Costs	Discount		Amount	Leveling
Convertible senior notes	$ 170.4	$ (0.3)	$ —	$ 170.1	$ 295.7	Level 2

The initial conversion rate for the 2024 Notes, which is subject to adjustment in some events (as provided for in the 2017 Indenture), is 13.1711 shares of common stock per $1,000 principal amount and equivalent to an initial conversion price of approximately $75.92 per share, reflecting a conversion premium of approximately 42.5% above the closing price of $53.28 per share of our common stock on April 26, 2017.

On or after May 15, 2021, we had the ability to redeem for cash all or part of the 2024 Notes if the last reported sale price (as defined in the 2017 Indenture) of our common stock had been at least 130% of the conversion price then in effect (equal to $98.70 as of March 31, 2024) for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending on, and including, the trading day immediately before the date which we provide a notice of redemption.

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

(i) during any calendar quarter (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than 130% of the conversion price (equal to $98.70 as of March 31, 2024) on each applicable trading day;

(ii) during the five business-day period immediately after any five consecutive trading-day period (the measurement period) in which the trading price (as defined in the 2017 Indenture) per $1,000 principal amount of the 2024 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day;

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

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

Until the close of business on the scheduled trading day immediately preceding May 15, 2024, holders of the 2024 Notes may convert the 2024 Notes at any time. Upon conversion, holders of the 2024 Notes will receive the principal amount of their 2024 Notes and any conversion premium, calculated based on the per share volume-weighted average price (VWAP) for each of the 30 consecutive trading days during the observation period (as more fully described in the 2017 Indenture), in cash.

If we undergo a fundamental change (as defined in the 2017 Indenture), subject to certain conditions, holders of the 2024 Notes may require us to repurchase for cash all or part of their 2024 Notes at a repurchase price equal to 100% of the principal amount of the 2024 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, if a make-whole fundamental change (as defined in the 2017 Indenture) occurs prior to January 15, 2024, we would, in certain circumstances, increase the conversion rate for a holder who elects to convert their notes in connection with the make-whole fundamental change.

The 2024 Notes are our general unsecured obligations that rank senior in right of payment to all of our indebtedness that is expressly subordinated in right of payment to the 2024 Notes, and equal in right of payment to our unsecured indebtedness. The 2024 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by us. The 2017 Indenture contains customary events of default with respect to the 2024 Notes, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the 2024 Notes will automatically become due and payable.

9. Earnings (Loss) per Share

Earnings (loss) per share were calculated as follows:

(in millions, except per share data)	Three Months Ended March 31, 2024	2023
Net income (loss) - basic and diluted	$ 43.4	$ (76.6)
Weighted-average common shares outstanding:		
Basic	99.8	97.1
Effect of dilutive securities	3.8	—
Diluted	103.6	97.1
Earnings (loss) per share:		
Basic	$ 0.43	$ (0.79)
Diluted	$ 0.42	$ (0.79)
Shares excluded from diluted per share amounts because their effect would have been anti-dilutive	1.7	15.5

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations section contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in Part II, Item 1A under the caption "Risk Factors." The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2023 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2023.

Overview

Neurocrine Biosciences is a neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine and neuropsychiatric disorders. The Company's diverse portfolio includes U.S. Food and Drug Administration (FDA) approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, adrenal insufficiency, and endometriosis and uterine fibroids in collaboration with AbbVie Inc. (AbbVie), a European Medicines Agency (EMA) approved treatment for classic congenital adrenal hyperplasia (CAH) and a diversified portfolio of advanced clinical-stage programs in multiple therapeutic areas.

We launched INGREZZA® (valbenazine) in the U.S. as the first FDA-approved drug for the treatment of tardive dyskinesia in May 2017 and for the treatment of adults with chorea associated with Huntington's disease in August 2023.

Our partner Mitsubishi Tanabe Pharma Corporation (MTPC) launched DYSVAL® (valbenazine) in Japan for the treatment of tardive dyskinesia in June 2022 and subsequently in other select Asian markets, where it is marketed as REMLEAS® (valbenazine). We receive royalties at tiered percentage rates on MTPC net sales of valbenazine.

Our partner AbbVie launched ORILISSA® (elagolix tablets) in the U.S. for the treatment of moderate to severe pain associated with endometriosis in August 2018 and ORIAHNN® (elagolix, estradiol and norethindrone acetate capsules and elagolix capsules) in the U.S. for the treatment of heavy menstrual bleeding due to uterine fibroids in June 2020. We receive royalties at tiered percentage rates on AbbVie net sales of elagolix.

Business Highlights

January 2024:

- Elected to settle all conversions of the convertible senior notes due May 15, 2024 in cash.

April 2024:

- Reported positive Phase 2 data for the completed Phase 2 study of NBI-1065845 in adult subjects with major depressive disorder. The study met its primary and key secondary endpoints.
- Submitted two New Drug Applications to the FDA for crinecerfont as a treatment for adult and pediatric patients with classic congenital adrenal hyperplasia.
- Received approval from the FDA for INGREZZA® SPRINKLE (valbenazine) capsules, a new oral granules formulation of INGREZZA capsules.

Results of Operations for the Three Months Ended March 31, 2024 and 2023

Revenues

Net Product Sales by Sales Product.

	Three Months Ended March 31,	
(in millions)	**2024**	**2023**
INGREZZA	$ 506.0	$ 410.4
Other	3.0	4.9
Total net product sales	$ 509.0	$ 415.3

Compared with the comparable period last year, the increase in total net product sales primarily reflected increased INGREZZA net product sales driven by strong underlying patient demand and improved gross-to-net dynamics.

Collaboration Revenues by Category.

(in millions)	Three Months Ended March 31, 2024	2023
Royalty revenue	$ 4.1	$ 4.2
Other	2.2	0.9
Total collaboration revenues	$ 6.3	$ 5.1

Total collaboration revenues for all periods presented primarily reflected royalty revenue earned on AbbVie net sales of elagolix and MTPC net sales of DYSVAL.

Operating Expenses

Cost of Revenues.

(in millions)	Three Months Ended March 31, 2024	2023
Cost of revenues	$ 7.5	$ 8.5

Compared with the comparable period last year, the change in cost of revenues primarily reflected increased INGREZZA net product sales, offset by decreased costs due to the termination of our license agreement with BIAL, which became effective in December 2023, to commercialize and market ONGENTYS® (opicapone) in the U.S. and Canada.

Research and Development by Category.

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.

(in millions)	Three Months Ended March 31, 2024	2023
Late stage	$ 24.2	$ 30.1
Early stage	27.2	28.9
Research and discovery	26.2	20.8
Milestone	6.1	—
Payroll and benefits	57.6	47.8
Facilities and other	18.1	11.9
Total research and development	$ 159.4	$ 139.5

Late Stage. Consists of expenses incurred for product candidates in Phase II registrational studies and all subsequent activities.

Compared with the comparable period last year, the decrease in late-stage expenses primarily reflected the successful completion of the Phase 3 programs for crinecerfont in CAH in the third quarter of 2023.

Early Stage. Consists of expenses incurred for product candidates after the approval of an investigational new drug application by the applicable regulatory agency through Phase II non-registrational studies.

Compared with the comparable period last year, the change in early-stage expenses primarily reflected increased investment in advancing Phase 2 programs in psychiatry, offset by decreased spend on early stage programs in epilepsy.

Research and Discovery. Consists of expenses incurred prior to the approval of an investigational new drug application by the applicable regulatory agency.

Compared with the comparable period last year, the increase in research and discovery expenses primarily reflected increased investment in preclinical development programs.

Milestone. Consists of milestone expenses incurred in connection with our collaborative arrangements.

Milestone expense for the first quarter of 2024 primarily reflected $5.0 million of expense recognized in connection with our selection of a development candidate under the Friedreich's ataxia program pursuant to our collaboration with Voyager Therapeutics, Inc. (Voyager).

Payroll and Benefits. Consists 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.

Compared with the comparable period last year, the increase in payroll and benefits expenses primarily reflected higher headcount, including an increase of $3.2 million in non-cash stock-based compensation expense.

Facilities and Other. Consists of indirect costs incurred for the benefit of multiple programs, including depreciation, information technology, and other facility-based expenses, such as rent expense.

Acquired In-Process Research and Development, or IPR&D.

	Three Months Ended March 31,	
(in millions)	**2024**	**2023**
Acquired in-process research and development	$ 6.0	$ 143.9

In the first quarter of 2024, we recognized $6.0 million of IPR&D expense in connection with the payment of the upfront fee pursuant to our collaboration with Biocytogen Pharmaceuticals (Beijing) Co., Ltd. In the first quarter of 2023, we recognized $143.9 million of IPR&D expense in connection with the payment of the upfront fee pursuant to the expansion of our collaboration with Voyager.

Selling, General and Administrative, or SG&A.

	Three Months Ended March 31,	
(in millions)	**2024**	**2023**
Selling, general and administrative	$ 243.1	$ 242.7

Compared with the comparable period last year, the change in SG&A expenses primarily reflected continued investment in our commercial organization, including pre-launch crinecerfont activities, offset by decreases in other general and administrative costs.

Other (Expense) Income, Net.

	Three Months Ended March 31,	
(in millions)	**2024**	**2023**
Interest expense	$ (1.1)	$ (1.1)
Unrealized gain on equity securities	1.6	2.2
Charges associated with convertible senior notes	(88.7)	—
Investment income and other, net	23.4	9.8
Total other (expense) income, net	$ (64.8)	$ 10.9

Compared with the comparable period last year, the change in total other (expense) income, net, primarily reflected $88.7 million of expense recognized in connection with the bifurcation of the embedded conversion option of the convertible senior notes, partially offset by increased interest income on our debt security investments.

Benefit from Income Taxes.

(in millions)	Three Months Ended March 31, 2024	2023
Benefit from income taxes	$ (8.9)	$ (26.7)

The effective tax rate for the first quarter of 2024 varied from the federal and state statutory rates primarily due to credits generated for research activities, certain nondeductible expenses including debt extinguishment, 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. For the comparable period last year, the effective tax rate varied from the federal and state statutory rates primarily due to excess tax benefits related to stock-based compensation.

Net Income (Loss).

(in millions)	Three Months Ended March 31, 2024	2023
Net income (loss)	$ 43.4	$ (76.6)

Compared with the comparable period last year, the change in net income (loss) primarily reflected increased INGREZZA net product sales and decreased IPR&D expense in connection with our collaborations, partially offset by $88.7 million of expense recognized in connection with the bifurcation of the embedded conversion option of the convertible senior notes and increased investment in our expanded clinical portfolio.

Liquidity and Capital Resources

Sources of Liquidity

We believe that our existing capital resources, funds generated by anticipated INGREZZA net product sales and investment income will be sufficient to satisfy our current and projected funding requirements for at least the next 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 additional 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)	March 31, 2024	December 31, 2023
Total cash, cash equivalents and marketable securities	$ 1,911.0	$ 1,719.1
Working Capital:		
Total current assets	$ 1,799.0	$ 1,607.0
Less total current liabilities	712.9	654.8
Total working capital	$ 1,086.1	$ 952.2

Information Regarding Our Cash Flows.

(in millions)	Three Months Ended March 31, 2024	2023
Cash flows from operating activities	$ 130.3	$ (125.2)
Cash flows from investing activities	(55.0)	(42.1)
Cash flows from financing activities	69.9	8.2
Change in cash, cash equivalents and restricted cash	$ 145.2	$ (159.1)

Cash Flows from Operating Activities. Compared with the comparable period last year, the change in cash flows from operating activities primarily reflected increased INGREZZA net product sales and lower upfront payments in connection with our collaborations, partially offset by $88.7 million of expense recognized in connection with the bifurcation of the embedded conversion option of the convertible senior notes and increased investment in our expanded clinical portfolio.

Cash Flows from Investing Activities. Periodic fluctuations in cash flows from investing activities primarily reflect timing differences related to our purchases, sales, and maturities of debt security investments and changes in our portfolio-mix.

Cash flows from investing activities for the comparable period last year also reflected an equity investment of $31.3 million in Voyager in connection with the expansion of our collaboration in the first quarter of 2023.

Cash Flows from Financing Activities. Cash flows from financing activities reflected proceeds from issuances of our common stock for all periods presented.

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, ORILISSA, ORIAHNN and/or DYSVAL;
- 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 cost of commercialization activities and arrangements, including our advertising campaigns;
- the cost of manufacturing of our product candidates;
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- competing technological and market developments; and
- developments related to any future litigation.

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 approximately $17.5 billion upon the achievement of certain milestones.

Refer to Note 2 to the condensed consolidated financial statements for more information on our significant collaboration and license agreements.

Leases. Our operating leases that have commenced have terms that expire beginning 2025 through 2036 and consist of office space and research and development laboratories, including our corporate headquarters.

On February 8, 2022, we entered into a lease agreement for a four-building campus facility to be constructed in San Diego, California, including a six-year option for the construction of a fifth building. This campus facility, comprised of office space and research and development laboratories, now serves as our corporate headquarters.

The construction of the campus facility is phased. The first phase of construction, consisting of two buildings relating to office space, was completed in December 2023. As we begin to occupy our new campus facility, we will sublease certain of our existing leased premises when we determine there is excess leased capacity.

Refer to Note 7 to the condensed consolidated financial statements for more information on our leases, including a presentation of our approximate future minimum lease payments under non-cancelable operating leases.

Convertible Senior Notes. On May 2, 2017, we completed a private placement of $517.5 million in aggregate principal amount of 2.25% fixed-rated convertible senior notes due May 15, 2024 (the 2024 Notes). In 2020, we repurchased $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. In 2022, we repurchased $210.8 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $279.0 million in cash. As of March 31, 2024, $170.4 million aggregate principal amount of the 2024 Notes remained outstanding.

Until the close of business on the scheduled trading day immediately preceding May 15, 2024, holders of the 2024 Notes may convert the 2024 Notes at any time. 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. As a result, upon conversion, holders of the 2024 Notes will receive the principal amount of their 2024 Notes and any conversion premium, calculated based on the per share volume-weighted average price (VWAP) for each of the 30 consecutive trading days during the observation period (as more fully described in the 2017 Indenture), in cash. As of March 31, 2024, the fair value of the 2024 Notes was $309.5 million.

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

Refer to Note 8 to the condensed consolidated financial statements for more information on the 2024 Notes.

Critical Accounting Policies and Estimates

There were no changes to our critical accounting policies as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023.

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 March 31, 2024, it would not have had a material effect on the fair value of our investment portfolio as of that date.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve a number of risks and uncertainties. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, these forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as “believes,” “expects,” “hopes,” “may,” “will,” “plan,” “intends,” “estimates,” “could,” “should,” “would,” “continue,” “seeks,” “proforma,” or “anticipates,” or other similar words (including their use in the negative), or by discussions of future matters such as the development of new products, technology enhancements, possible changes in legislation and other statements that are not historical. These statements include but are not limited to statements under the captions “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading in Part II titled “Item 1A. Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

A discussion of our exposure to, and management of, market risk appears in Part I, Item 2 of this Quarterly Report on Form 10-Q under the heading “Interest Rate Risk.”

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports required by the Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the timelines specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes to our internal control over financial reporting that occurred during the quarter ended March 31, 2024, and that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

During the quarter ended March 31, 2024, we implemented a new company-wide enterprise resource planning (ERP) system. As part of the system implementation, we assessed the impact to the control environment and modified internal controls where necessary. There were no other significant changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the quarter ended March 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

From time to time, we may become subject to 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 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations. The risk factors set forth below with an asterisk (*) contain changes to the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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 other products, or any of our product candidates if they are approved in the future.
- If physicians and patients do not continue to accept INGREZZA or do not accept any of our other products, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.
- Enacted healthcare reform, drug pricing measures and other recent legislative initiatives, including the Inflation Reduction Act of 2022, could adversely affect our business.
- We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced.
- 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.
- 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.
- We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.
- Use of our approved products or those of our collaborators could be associated with side effects or adverse events.
- We have increased the size of our organization and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.
- 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 or any of our other products, or any product candidate approved by the FDA in the future.
- We currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA or any of our other products, or any of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed, and our costs may rise.
- We currently depend on a limited number of third-party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA or any of our other products, could materially and adversely affect our ability to successfully commercialize INGREZZA or any of our other products.
- We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, or violate the terms of these licenses, we could lose our rights to those technologies and drug candidates or be forced to pay damages.
- 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.

- 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 that regarding the status of our products that could limit our product revenues and delay sustained profitability.
- Our indebtedness could expose us to risks that could adversely affect our business, financial condition and results of operations.
- We have a history of losses and expect to increase our expenses for the foreseeable future, and we may not be able to sustain profitability.
- 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.

Risks Related to Our Company

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

Our ability to produce INGREZZA revenues consistent with expectations ultimately depends on our ability to continue to successfully commercialize INGREZZA and secure adequate third-party reimbursement. Our experience in marketing and selling pharmaceutical products began with INGREZZA's approval in 2017, when we hired our sales force and established our distribution and reimbursement capabilities, all of which are necessary to successfully commercialize our current and future products. We have continued to invest in our commercial infrastructure and distribution capabilities, including the expansion of our specialty sales force, which we announced in the third quarter of 2021 and completed in April 2022. 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 of our other products, or any product candidate approved by the FDA, or equivalent foreign authorities, in the future.

In addition, our business has been and may continue to be adversely affected by the effects of health pandemics or epidemics. In parts of the country, some hospitals, community mental health facilities, and other healthcare facilities continue to have policies that limit access of our sales representatives, medical affairs personnel and patients to such facilities. In addition, many healthcare practitioners have adopted telehealth for patient interactions, which may impact the ability of the healthcare practitioner to screen for and diagnose tardive dyskinesia or chorea associated with Huntington's disease.

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

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

The market acceptance of INGREZZA or any of our other products could be affected by a number of factors, including:

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

If the medical community, 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 endometriosis, tardive dyskinesia, chorea associated with Huntington's disease, uterine fibroids, classic congenital adrenal hyperplasia, pain, Parkinson's disease and other neurology, neuroendocrinology and neuropsychiatry-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 tardive dyskinesia 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 tardive dyskinesia off-label, such as XENAZINE® (tetrabenazine) and generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin. In addition, there are several programs in clinical development by other companies targeting Huntington's disease.
- ORILISSA and ORIAHNN each compete with several FDA-approved products for the treatment of endometriosis, uterine fibroids, infertility and central precocious puberty. Additionally, there is also competition from surgical intervention, including hysterectomies and ablations. Separate from these options, there are many programs in clinical development which serve as potential future competition. Lastly, there are numerous medicines used to treat the symptoms of disease (vs. endometriosis or uterine fibroids directly) which may also serve as competition: oral contraceptives, NSAIDs and other pain medications, including opioids.
- For CAH, high doses of corticosteroids are the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive adrenocorticotropic hormone levels. 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 epilepsy may in the future compete with numerous approved anti-seizure medications and development-stage programs being pursued by several other companies. Commonly used anti-seizure medications include phenytoin, levetiracetam, brivaracetam, cenobamate, carbamazepine, clobazam, lamotrigine, valproate, oxcarbazepine, topiramate, lacosamide, perampanel and cannabidiol, among others. There are currently no FDA-approved treatments specifically indicated for the early infantile epileptic encephalopathy SCN8A-DEE; however, a number of different anti-seizure medications are currently used in these patient populations.
- Our investigational treatments for potential use in schizophrenia, anhedonia and depression may in the future compete with several development-stage programs being pursued by other companies. Currently, there are no FDA-approved treatments specifically indicated for anhedonia or cognitive impairment associated with schizophrenia; however, there are a number of different anti-psychotic medications currently used in these patient populations.
- Our investigational treatments for potential use in neurology, neuroendocrinology and neuropsychiatry 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 resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical testing experience;
- manufacturing, marketing and distribution experience; and
- production facilities.

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

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 the results of previous trials;
- the FDA or similar foreign regulatory authorities may require use of new or experimental endpoints that may prove insensitive to treatment effects;
- we or the FDA or similar foreign regulatory authorities may suspend 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.;
- patients may drop out of the trials;
- unforeseen disruptions or delays may occur, caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the conflict between Russia and Ukraine and the conflict in the Middle East; and
- regulatory requirements may change.

These risks and uncertainties impact all of our clinical programs and any of the clinical, regulatory or operational events described above could change our planned clinical and regulatory activities. For example, the conflict between Russia and Ukraine, together with sanctions imposed on Russia, caused us to suspend all planned clinical trial activities in Russia and Ukraine. As a result, our planned clinical development timelines for valbenazine and luvadaxistat were significantly delayed while we identified and operationalized alternative clinical trial sites, which we have now done. Additionally, any of these events described above could result in suspension of a program and/or obviate any filings for necessary regulatory approvals.

In addition, late-stage clinical trials are often conducted with patients having the most advanced stages of disease. During the course of treatment, these patients can die or suffer other adverse medical effects for reasons that may not be related to the pharmaceutical agent being tested but which can nevertheless adversely affect clinical trial 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.

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.

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

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

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

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

****We depend on our current collaborators for the development and commercialization of 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 MTPC for the commercialization of DYSVAL in Japan and for the continued development and commercialization of valbenazine for movement disorders in other select Asian markets. Our additional collaborators include Xenon Pharmaceuticals, Inc., Idorsia Pharmaceuticals Ltd., Takeda Pharmaceutical Company Limited, Nxera Pharma UK Limited (formerly Heptares Therapeutics Limited) and Voyager Therapeutics, Inc.

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; and
- strategic collaborators could develop, either alone or with others, products or product candidates that may compete with ours.

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

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

As of March 31, 2024, we had approximately 1,448 full-time employees. 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 are in the process of implementing a new company-wide enterprise resource planning (ERP) system 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. Any disruptions, delays, or deficiencies in the implementation or design 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 and any of our other products, 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, 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.

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 or any of our other products, 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 or any of our other products, or any product candidate approved by the FDA in the future, including crinecerfont. 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, 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.

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

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the commercialization of our products. We have limited experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Establishing internal commercial manufacturing capabilities would require significant time and resources, and we may not be able to timely or successfully establish such capabilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes, including INGREZZA. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products, including INGREZZA. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA and equivalent foreign regulations, including current Good Manufacturing Practice 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; 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. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

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, 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 man-made or natural disasters, pandemics or epidemics, or other business interruptions. We depend on a limited number of suppliers for the production and packaging of INGREZZA and its API. If our third-party suppliers for INGREZZA encounter these or any other manufacturing, quality or compliance difficulties, we may be unable to meet commercial demand for INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA.

In addition, if our suppliers fail or refuse to supply us with INGREZZA or its API for any reason, it would take a significant amount of time and expense to qualify a new supplier. The FDA and similar 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, which could materially and adversely affect our ability to successfully commercialize INGREZZA.

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

We are dependent on licenses from third parties for some of our key technologies. These licenses typically subject us to various commercialization, reporting and other obligations. If we fail to comply with these obligations, we could lose important rights. If we were to default on our obligations under any of our licenses, we could lose some or all of our rights to develop, market and sell products covered by these licenses. 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.

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 successfully or any of our other products 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, manufacture, 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 or any of our other products, or any other product candidate 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, during the COVID-19 pandemic, the use of physician telehealth services rapidly increased, fueled by an unprecedented 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 movement disorders, leading to fewer patients being diagnosed and/or treated.

Outside the United States, 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 HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This regulation, which entered into force in January 2022 will apply as of January 2025. The regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain 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.

In light of the fact that the UK has left the EU, Regulation No 2021/2282 on HTA will not apply in the UK. However, the MHRA is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium, the National Institute for Health and Care Excellence, and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products.

Legislators, policymakers and healthcare insurance funds in the EU and the UK may continue to propose and implement cost-containing measures to keep healthcare costs down, particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of European countries. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign 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.

Our indebtedness could expose us to risks that could adversely affect our business, financial condition and results of operations.

In May 2017, we sold $517.5 million aggregate principal amount of the 2024 Notes. In 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. In 2022, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $210.8 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $279.0 million in cash. As of March 31, 2024, $170.4 million aggregate principal amount of the 2024 Notes remained outstanding.

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. Although we have sufficient cash reserves to fully repay and settle the 2024 Notes at their scheduled maturity on May 15, 2024, we may incur additional indebtedness in the future. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay any additional indebtedness that we may incur. In addition, any future indebtedness that we may incur may contain financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

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

Since our inception, we have incurred significant net losses and negative cash flow from operations. As of March 31, 2024, we had an accumulated deficit of $113.7 million as a result of historical operating losses.

We received FDA approval for INGREZZA for tardive dyskinesia in April 2017 and for chorea associated with Huntington's disease in August 2023. 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 MTPC received Japanese Ministry of Health, Labour and Welfare approval for DYSVAL for the treatment of tardive dyskinesia 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 developing and commercializing any of our other product candidates, we may not be able to sustain profitability. We also expect to continue to incur significant operating and capital expenditures as we:

- commercialize INGREZZA for tardive dyskinesia and chorea associated with Huntington's disease;
- 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 and marketing 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. Our failure to maintain or increase profitability on a sustained basis could negatively impact the market price of our common stock.

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, and all of our product sales of INGREZZA are to these customers. Four of these customers represented approximately 94% of our total product sales for the three months ended March 31, 2024 and approximately 97% of our accounts receivable balance as of March 31, 2024. If any of these significant customers becomes subject to bankruptcy, is unable to pay us for our products or is acquired by a company that wants to terminate the relationship with us, or if we otherwise lose any of these significant customers, our revenue, results of operations and cash flows would be adversely affected. Even if we replace the loss of a significant customer, we cannot predict with certainty that such transition would not result in a decline in our revenue, results of operations and cash flows.

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, ORILISSA, ORIAHNN, DYSVAL, and/or any of our other products;
- debt services obligations on the 2024 Notes;
- continued scientific progress in our R&D and clinical development programs;

- the magnitude and complexity of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the 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 commercialization activities and arrangements, including advertising campaigns;
- the cost of manufacturing our product candidates;
- the impact of the COVID-19 pandemic or a future pandemic or epidemic on our business; and
- the cost of any strategic alliances, collaborations, product in-licensing, or acquisitions.

We intend to seek additional funding through strategic alliances and may seek additional funding through public or private sales of our securities, including equity securities. In addition, during the second quarter of 2017, we issued the 2024 Notes and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. In 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. In 2022, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $210.8 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $279.0 million in cash. As of March 31, 2024, $170.4 million aggregate principal amount of the 2024 Notes remained outstanding. Additional equity or debt financing might not be available on reasonable terms, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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 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 products. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may compete with us. If independent investigators and CROs assist our competitors at our expense, it could harm our competitive position.

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

Regulatory approvals for any of our product candidates, including crinecerfont, 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. In addition, with respect to INGREZZA, and any product candidate that the FDA or a comparable foreign regulatory authority approves, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with GCPs for any clinical trials that we conduct post-approval. Failure to comply with these ongoing regulatory requirements, or later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, changes in the product's label, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning 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 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.

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

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, royalties from out-licensed products, the impact of Medicare Part D coverage, including redesign of the Part D benefit enacted as part of the Inflation Reduction Act, our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing, contract research payments, fluctuations in our effective tax rate, and disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the conflict between Russia and Ukraine, or in the Middle East. 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 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.

Effective January 1, 2022, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the U.S. and over 15 years for research activities conducted outside the U.S. Unless the U.S. Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is deferred, modified, or repealed by Congress, we expect a material decrease in our cash flows from operations and an offsetting similarly sized increase in our net deferred tax assets over these amortization periods. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur and whether we conduct our research and development activities inside or outside the U.S.

In addition, new income, sales, use, excise or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act of 2017, the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Furthermore, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Our ability to use tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use certain pre-change federal tax attributes such as research and development tax credits to offset its post-change income or taxes may be limited. Based on completed Section 382 analysis done annually, we do not believe we have experienced any previous ownership changes, but the determination is complex and there can be no assurance we are correct. Furthermore, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control.

Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes, including net operating loss (NOL) carryforwards. In addition, at the state level, there may be periods during which the use of NOLs or credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOLs, research and development credits, and other tax attributes, which could adversely affect our future cash flows.

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

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

****The price of our common stock is volatile.***

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market for these securities has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The COVID-19 pandemic, for example, negatively affected the stock market and investor sentiment and resulted in significant volatility, as has the applicability of the Medicare drug price negotiation provisions in the Inflation Reduction Act. 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 $89 per share to approximately $148 per share.

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

- sales of INGREZZA and our other products;
- the results of our clinical trials;
- reports of safety issues related to INGREZZA, ORILISSA, ORIAHNN, DYSVAL, or any of our other products;
- any delay in filing an IND, NDA, marketing authorization application (MAA), or other regulatory submission for any of our product candidates, including crinecerfont, 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;
- 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, CMS and foreign regulatory agencies;
- government regulation, including the Inflation Reduction Act;
- future sales of our common stock by us or our stockholders;

- comments by securities analysts;
- additions or departures of key personnel;
- fluctuations in our operating results;
- potential litigation matters;
- government and third-party payor coverage and reimbursement;
- failure of any of our product candidates, including crinecerfont, to achieve commercial success even if approved;
- disruptions caused by man-made or natural disasters, pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic and the conflict between Russia and Ukraine; 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.

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

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

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

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

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.

Our business could be adversely affected by the effects of health pandemics or epidemics, which could also cause significant disruption in the operations of third-party manufacturers, CROs, or other third parties upon whom we rely.

Our business could be adversely affected by the effects of health pandemics or epidemics, which could also cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. As a result, we may experience disruptions that could severely impact our supply chain, ongoing and future clinical trials and commercialization of INGREZZA or any of our other products. In response to the COVID-19 pandemic, we implemented a remote work model for all employees except certain key essential members involved in business-critical activities. Our employees have resumed in-person interactions and have returned to the office under flexible work guidelines. However, a remote work model may nevertheless need to be reinstated at some point in the future. The effects of a remote and flexible work model may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend on our ability to conduct our business in the ordinary course. Remote work may also create increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. In addition, we may face several challenges or disruptions upon a return back to the workplace, including re-integration challenges by our employees and distractions to management related to such transition. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

In addition, clinical site initiation and patient enrollment may be delayed due to concerns for patient safety. Some patients may not be able to comply with clinical trial protocols and our ability to recruit and retain patients, principal investigators and site staff may be hindered, which would adversely impact our clinical trial operations.

The ultimate effects of health pandemics or epidemics is highly uncertain and subject to change and these effects could have a material impact on our operations, or the operations of third parties on whom we rely.

Risks Related to Our Industry

****Enacted healthcare reform, drug pricing measures and other recent legislative initiatives, including the Inflation Reduction Act of 2022, 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, in August 2022, President Biden signed into law the Inflation Reduction Act of 2022, or the IRA, which, among other things: (1) directs the Secretary of the 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. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in the ACA marketplaces through plan year 2025 and beginning in 2025, eliminates the “donut hole” under the Medicare Part D program and creates a new, permanent cap on beneficiary out-of-pocket spending, in addition to a newly established manufacturer discount program. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued and updated and will continue to issue and update guidance as these programs are implemented. These provisions take effect progressively starting in 2023. On August 29, 2023, HHS announced the list of the first 10 drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently uncertain how the IRA will be implemented over time; however, it is likely to have a significant impact on the pharmaceutical industry and prescription drug pricing.

While the IRA drug price negotiation program targets high-expenditure drugs that have been on the market for several years without generic or biosimilar competition, we believe we will qualify for the small biotech exception from negotiation that is set to expire in 2029.

Additionally, beginning on January 1, 2025, the Centers for Medicare & Medicaid Services (CMS) will implement 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 will be $2,000 beginning in 2025). 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, the Company was notified by CMS that it qualified as a "specified small manufacturer" and will receive the discount phase-in discussed above. 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, marketed by Teva Pharmaceuticals Industries. 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 our expected qualification under 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 potential acquisition or strategic transaction, could have an adverse impact on our business.

Prior to the IRA's enactment, the most significant recent federal legislation impacting the pharmaceutical industry occurred in March 2010, when the ACA was signed into law. The ACA was intended to broaden access to health insurance and reduce the number of uninsured individuals, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms.

Other legislative changes have been adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act and Consolidated Appropriations Act of 2023, will remain in effect until 2032. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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. For example, on January 5, 2024, the FDA approved Florida's SIP proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. 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 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;
- 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.

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. In addition, 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. For example, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

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. 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, 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. If our operations or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

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

We could face liability if a regulatory authority determines that we are promoting INGREZZA or any of our product candidates that receives regulatory approval, for "off-label" uses.

A company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the U.S. or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions.

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, 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. 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 become more common and has increased risks to our information technology systems and data, as more 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.

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 and are planning to implement 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 adverse consequences. Such 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.

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 new drug is clinically superior to the orphan product or a market shortage occurs.

In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is "clinically superior" to the original orphan drug.

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 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, 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 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, 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, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—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 (CPRA) (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 (up to $7,500 per intentional violation). 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. 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 impose 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 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 United States, 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.

Our employees and personnel may 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, any 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. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, 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 5. Other Information

During the period from January 1, 2024, to March 31, 2024, our executive officers and directors adopted or terminated contracts, instructions or written plans for the purchase or sale of our securities as noted below:

Name and Title	Action	Date	Trading Arrangement		Total Shares Authorized to be Sold	Expiration Date
			Rule 10b5-1*	Non-Rule 10b5-1**		
Julie S. Cooke Chief Human Resources Officer	Adopt	3/17/2024	X		88,495	6/13/2025
Kyle W. Gano Chief Business Development & Strategy Officer	Adopt	3/15/2024	X		101,400	5/10/2025
Matthew C. Abernethy Chief Financial Officer	Adopt	2/13/2024	X		45,000	2/15/2025
Gary A. Lyons Director	Adopt	2/13/2024	X		25,000	5/27/2025

_____

* Intended to satisfy the affirmative defense of Rule 10b5-1(c)

** Not intended to satisfy the affirmative defense of Rule 10b5-1(c)

Item 6. 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 August 1, 2023
4.1	Description:	Form of Common Stock Certificate
	Reference:	Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-03172)
4.2	Description:	Indenture, dated as of May 2, 2017, by and between the Company and U.S. Bank National Association, as Trustee
	Reference:	Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on May 2, 2017
4.3	Description:	First Supplemental Indenture, dated as of December 22, 2021, by and between the Company and U.S. Bank National Association, as Trustee
	Reference:	Incorporated by reference to Exhibit 4.3 of the Company's Annual Report on Form 10-K filed on February 11, 2022
4.4	Description:	Form of Note representing the Company's 2.25% Convertible Notes due 2024
	Reference:	Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on May 2, 2017
10.1+	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
10.2+	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
31.1	Description:	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Description:	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Description:	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Description:	Inline XBRL Instance Document. – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Description:	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Description:	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Description:	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Description:	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Description:	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Description:	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101)

+ Management contract or compensatory arrangement.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Neurocrine Biosciences, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Except as specifically noted above, the Company's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K have a Commission File Number of 000-22705.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NEUROCRINE BIOSCIENCES, INC.

Dated: May 1, 2024

/s/ Matthew C. Abernethy

Matthew C. Abernethy

Chief Financial Officer
(Duly authorized officer and Principal Financial Officer)

Neurocrine Biosciences, Inc.
2020 Equity Incentive Plan

RSU Award Grant Notice

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

Participant: __
Date of Grant: __
Vesting Commencement Date: __
Number of RSUs: __

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

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

Withholding Obligation: To the fullest extent permitted under the Plan and Applicable Law, any Withholding Obligation (as set forth in Section 6 of the Agreement) will be satisfied through a "Sell to Cover" procedure as described in Section 6 of the Agreement. ***The sale of shares to satisfy the Withholding Obligation is a condition of this RSU Award and further described in Section 6 of the Agreement.***

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

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

Neurocrine Biosciences, Inc.
2020 Equity Incentive Plan

RSU Award Agreement

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

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

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

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

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

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

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

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

3. Vesting.

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

(b) If you are an Employee or Director, in each case as of the date of termination of your Continuous Service, then in the event of a termination of your Continuous Service due to your death or Disability, your RSU Award will become vested, as of the date of such termination, in accordance with the vesting schedule set forth in the Grant Notice as if you had provided an additional six months of Continuous Service as of the date of such termination.

(c) If you are a Director as of the date of a Transaction, then in the event of a Transaction during your Continuous Service, your RSU Award will become fully vested as of the date of such Transaction.

4. Date of Issuance.

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

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

(c) Notwithstanding the foregoing, if:

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

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

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

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

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

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

6. Withholding Obligations.

(a) As provided in Section 8 of the Plan, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for, any sums required to satisfy the federal, state, local and foreign tax withholding obligations, if any, which arise in connection with your RSU Award (the "***Withholding Obligation***") in accordance with the withholding procedures established by the Company.

(b) The Company shall arrange a mandatory sale (on your behalf pursuant to your authorization under this section and without further consent) of the shares of Common Stock issued in settlement upon the vesting of your RSUs in an amount necessary to satisfy the Withholding Obligation and shall satisfy the Withholding Obligation by withholding from the proceeds of such sale (the "***Sell to Cover***"). You hereby acknowledge and agree that the Company shall have the authority to administer the Sell to Cover arrangement in its sole discretion with a registered broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") as the Company may select as the agent (the "***Agent***") who will sell on the open market at the then prevailing market price(s), as soon as practicable on or after each date on which your RSUs vest and in accordance with the issuance schedule set forth in Section 4 of this Agreement, the number (rounded up to the next whole number) of the shares of Common Stock to be delivered to you in connection with the vesting of the RSUs sufficient to generate proceeds to cover (A) the Withholding Obligation that you are required to pay pursuant to the Plan and this Agreement as a result of the vesting of the RSUs (or shares being issued thereunder, as applicable) and, to the extent applicable (B) fees and commissions due to, or required to be collected by, the Agent with respect thereto, with any remaining funds remitted to you.

(c) If, for any reason, the Sell to Cover does not result in sufficient proceeds to satisfy the Withholding Obligation, the Company or an Affiliate (as applicable) may, in its sole discretion, satisfy all or any portion of the Withholding Obligation by any of the following means or by a combination of such means: (i) causing you to tender a cash payment; (ii) subject to approval by the Company and/or the Committee, as applicable, and in compliance with any applicable legal conditions or restrictions, by withholding from the shares of Common Stock otherwise issuable to you in connection with your RSU Award a number of whole shares of Common Stock with a Fair Market Value on the date of issuance not in excess of the maximum amount of tax that may be required to be withheld by law (or such other amount as may be permitted while still avoiding classification of your RSU Award as a liability for financial accounting purposes); or (iii) such other method permitted under the Plan.

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

(e) You acknowledge that the Sell to Cover is one of the terms and conditions of this RSU Award. You further understand and acknowledge that the Agent is under no obligation to arrange for the sale of Common Stock at any particular price and may effect sales pursuant to the Sell to Cover in one or more sales and that the average price for executions resulting from bunched orders will be assigned to your account. In addition, you acknowledge that it may not be possible to sell shares of Common Stock as provided in this Section 6 due to (i) a legal or contractual restriction applicable to you or the Agent, (ii) a market disruption, (iii) rules governing order execution priority on the national exchange where the Common Stock may be traded or (iv) the Company's determination that sales may not be effected. Further, you agree to execute and deliver to the Agent or the Company any other agreements or documents as the Agent or Company reasonably deems necessary or appropriate to carry out the purposes and intent of the Sell to Cover under this Section 6.

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

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

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

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

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

Neurocrine Biosciences, Inc.
2020 Equity Incentive Plan

Option Grant Notice

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

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

Type of Grant: You have been granted an Incentive Stock Option. However, due to the $100,000 Rule (as described below), the Option (or a certain portion thereof) may be treated as a Nonstatutory Stock Option. Please log into your E*TRADE account to see the exact details of your grant.

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

Exercise Schedule: Same as Vesting Schedule

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

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

Neurocrine Biosciences, Inc.
2020 Equity Incentive Plan

Option Agreement

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

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

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

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

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

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

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

2. Vesting.

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

(b) If you are an Employee or Director, in each case as of the date of termination of your Continuous Service, then in the event of a termination of your Continuous Service due to your death or Disability, your Option will become vested, as of the date of such termination, in accordance with the vesting schedule set forth in the Grant Notice as if you had provided an additional six months of Continuous Service as of the date of such termination.

(c) If you are a Director as of the date of a Transaction, then in the event of a Transaction during your Continuous Service, your Option will become fully vested as of the date of such Transaction.

3. Exercise.

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

(b) To the extent permitted by Applicable Law, you may pay the exercise price of your Option by cash or check or as follows:

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

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

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

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

(a) immediately upon the termination of your Continuous Service for Cause;

(b) if you are an Employee as of the date of termination of your Continuous Service, then three months after the termination of your Continuous Service for any reason other than Cause, Disability or death;

(c) if you are a Director as of the date of termination of your Continuous Service, then three years after the termination of your Continuous Service for any reason other than Cause;

(d) if you are a Consultant as of the date of termination of your Continuous Service, then 30 days after the termination of your Continuous Service for any reason other than Cause;

(e) if you are an Employee as of the date of termination of your Continuous Service, then 12 months after the termination of your Continuous Service due to your Disability;

(f) if you are an Employee as of the date of termination of your Continuous Service, then 18 months after your death if you die during your Continuous Service;

(g) immediately upon a Transaction if the Board has determined that your Option will terminate in connection with such Transaction;

(h) the Expiration Date set forth in the Grant Notice; or

(i) the day before the 10th anniversary of the Date of Grant.

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

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

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

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

6. Withholding Obligations.

(a) As provided in Section 8 of the Plan, at the time you exercise your Option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "cashless exercise" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations, if any, which arise in connection with your Option (the "***Withholding Obligation***") in accordance with the withholding procedures established by the Company.

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

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

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

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

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

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

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

* * * *

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin C. Gorman, Chief Executive Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neurocrine Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 1, 2024

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew C. Abernethy, Chief Financial Officer of Neurocrine Biosciences, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Neurocrine Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 1, 2024

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

Exhibit 32

CERTIFICATIONS OF
CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Neurocrine Biosciences, Inc. (Company) on Form 10-Q for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (Report), I, Kevin C. Gorman, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and

(2) That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 1, 2024

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

In connection with the Quarterly Report of Neurocrine Biosciences, Inc. (Company) on Form 10-Q for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (Report), I, Matthew C. Abernethy, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), of the Securities Exchange Act of 1934; and

(2) That information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

May 1, 2024

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