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 September 30, 2022

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)

12780 El Camino Real
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 96,134,388 as of October 28, 2022.

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)	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 212.2	$ 340.8
Debt securities available-for-sale	587.2	370.5
Accounts receivable	301.2	185.5
Inventories	37.0	30.5
Other current assets	67.9	45.5
Total current assets	1,205.5	972.8
Deferred tax assets	319.4	315.1
Debt securities available-for-sale	362.6	560.7
Right-of-use assets	89.6	97.2
Equity securities	94.9	63.7
Property and equipment, net	60.9	58.6
Other assets	10.5	4.4
Total assets	$ 2,143.4	$ 2,072.5
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 297.8	$ 225.8
Convertible senior notes	169.2	—
Other current liabilities	18.1	20.0
Total current liabilities	485.1	245.8
Convertible senior notes	—	335.1
Operating lease liabilities	96.6	105.3
Other long-term liabilities	17.1	12.3
Total liabilities	598.8	698.5
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 million shares authorized; 96.1 million and 94.9 million shares issued and outstanding, respectively	0.1	0.1
Additional paid-in capital	2,054.3	2,011.4
Accumulated other comprehensive loss	(14.0)	(1.7)
Accumulated deficit	(495.8)	(635.8)
Total stockholders’ equity	1,544.6	1,374.0
Total liabilities and stockholders’ equity	$ 2,143.4	$ 2,072.5

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME
(unaudited)

(in millions, except per share data)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Revenues:				
Net product sales	$ 379.3	$ 288.8	$ 1,036.3	$ 786.6
Collaboration revenues	8.6	7.2	40.4	34.9
Total revenues	387.9	296.0	1,076.7	821.5
Operating expenses:				
Cost of revenues	6.1	4.2	15.5	10.2
Research and development	107.7	92.7	345.8	240.7
Acquired in-process research and development	—	—	—	5.0
Selling, general and administrative	186.3	154.6	569.8	426.8
Total operating expenses	300.1	251.5	931.1	682.7
Operating income	87.8	44.5	145.6	138.8
Other income (expense):				
Interest expense	(1.2)	(6.6)	(6.0)	(19.2)
Unrealized gain (loss) on equity securities	11.1	(8.2)	23.6	(7.5)
Loss on extinguishment of convertible senior notes	—	—	(70.0)	—
Investment income and other, net	0.2	0.8	2.8	3.1
Total other income (expense), net	10.1	(14.0)	(49.6)	(23.6)
Income before provision for income taxes	97.9	30.5	96.0	115.2
Provision for income taxes	29.4	8.0	30.5	18.3
Net income	68.5	22.5	65.5	96.9
Unrealized loss on debt securities available-for-sale, net of tax	(1.8)	(0.3)	(12.3)	(1.4)
Comprehensive income	$ 66.7	$ 22.2	$ 53.2	$ 95.5
Earnings per share:				
Basic	$ 0.72	$ 0.24	$ 0.69	$ 1.03
Diluted	$ 0.69	$ 0.23	$ 0.67	$ 0.99
Weighted-average shares outstanding:				
Basic	95.8	94.7	95.6	94.5
Diluted	99.0	97.7	98.3	97.9

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
Balances at June 30, 2022	95.6	$ 0.1	$ 1,999.8	$ (12.2)	$ (564.3)	$ 1,423.4
Net income	—	—	—	—	68.5	68.5
Unrealized loss on debt securities available-for-sale, net of tax	—	—	—	(1.8)	—	(1.8)
Stock-based compensation expense	—	—	43.1	—	—	43.1
Issuances of common stock under stock plans	0.5	—	11.4	—	—	11.4
Balances at September 30, 2022	96.1	$ 0.1	$ 2,054.3	$ (14.0)	$ (495.8)	$ 1,544.6
Balances at June 30, 2021	94.6	$ 0.1	$ 1,929.4	$ 0.7	$ (651.0)	$ 1,279.2
Net income	—	—	—	—	22.5	22.5
Unrealized loss on debt securities available-for-sale, net of tax	—	—	—	(0.3)	—	(0.3)
Stock-based compensation expense	—	—	37.1	—	—	37.1
Issuances of common stock under stock plans	0.2	—	7.5	—	—	7.5
Balances at September 30, 2021	94.8	$ 0.1	$ 1,974.0	$ 0.4	$ (628.5)	$ 1,346.0
Balance at December 31, 2021	94.9	$ 0.1	$ 2,011.4	$ (1.7)	$ (635.8)	$ 1,374.0
Net income	—	—	—	—	65.5	65.5
Unrealized loss on debt securities available-for-sale, net of tax	—	—	—	(12.3)	—	(12.3)
Cumulative-effect adjustment due to adoption of ASU 2020-06	—	—	(106.8)	—	74.5	(32.3)
Stock-based compensation expense	—	—	129.6	—	—	129.6
Issuances of common stock under stock plans	1.2	—	20.1	—	—	20.1
Balances at September 30, 2022	96.1	$ 0.1	$ 2,054.3	$ (14.0)	$ (495.8)	$ 1,544.6
Balance at December 31, 2020	93.5	$ 0.1	$ 1,849.7	$ 1.8	$ (725.4)	$ 1,126.2
Net income	—	—	—	—	96.9	96.9
Unrealized loss on debt securities available-for-sale, net of tax	—	—	—	(1.4)	—	(1.4)
Stock-based compensation expense	—	—	98.6	—	—	98.6
Issuances of common stock under stock plans	1.3	—	25.7	—	—	25.7
Balance at September 30, 2021	94.8	$ 0.1	$ 1,974.0	$ 0.4	$ (628.5)	$ 1,346.0

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

(in millions)	Nine Months Ended September 30, 2022	2021
Cash flows from operating activities:		
Net income	$ 65.5	$ 96.9
Adjustments to reconcile net income to net cash from operating activities:		
Stock-based compensation expense	129.6	98.6
Loss on extinguishment of convertible senior notes	70.0	—
Depreciation	11.2	7.9
Amortization of debt discount	—	12.1
Amortization of debt issuance costs	1.0	0.8
Change in fair value of equity security investments	(23.6)	7.5
Deferred income taxes	5.6	9.0
Other	3.0	7.7
Change in operating assets and liabilities:		
Accounts receivable	(115.7)	(6.7)
Inventories	(6.5)	2.5
Accounts payable and accrued liabilities	77.0	37.7
Other assets and liabilities, net	(20.7)	(21.7)
Cash flows from operating activities	196.4	252.3
Cash flows from investing activities:		
Purchases of debt securities available-for-sale	(387.9)	(658.7)
Sales and maturities of debt securities available-for-sale	348.8	523.9
Purchases of equity securities	(7.7)	(4.6)
Capital expenditures	(14.7)	(14.5)
Cash flows from investing activities	(61.5)	(153.9)
Cash flows from financing activities:		
Issuances of common stock under benefit plans	20.1	25.7
Repurchase of convertible senior notes	(279.0)	(0.1)
Cash flows from financing activities	(258.9)	25.6
Change in cash, cash equivalents and restricted cash	(124.0)	124.0
Cash, cash equivalents and restricted cash at beginning of period	344.0	190.3
Cash, cash equivalents and restricted cash at end of period	$ 220.0	$ 314.3
Supplemental disclosures:		
Non-cash capital expenditures	$ 0.7	$ 0.3
Right-of-use assets acquired through operating leases	$ —	$ 21.6
Cash paid for interest	$ 4.6	$ 4.3
Cash paid for income taxes	$ 4.3	$ 3.4

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, or GAAP, for interim financial information and with the instructions of the Securities and Exchange Commission, or 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, 2021, included in our Annual Report on Form 10-K, or the 2021 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, 2021, 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.

Recently Adopted Accounting Pronouncements.

ASU 2020-06. In August 2020, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Among other changes, ASU 2020-06 removed the separation models for convertible instruments with cash or beneficial conversion features. Instead, entities now account for convertible debt instruments wholly as debt, unless certain other conditions are met. The adoption of ASU 2020-06 prospectively reduces reported interest expense and increases (decreases) reported net income (loss), and resulted in a reclassification of certain conversion feature balance sheet amounts from stockholders’ equity to liabilities as it relates to the 2.25% fixed-rate convertible senior notes due May 15, 2024, or the 2024 Notes. We adopted ASU 2020-06 on January 1, 2022, using the modified retrospective transition method, which allowed for a cumulative-effect adjustment in the period of adoption and did not require restatement of prior period amounts. Under this transition method, the cumulative effect of the accounting change increased the carrying amount of the 2024 Notes by $42.2 million, reduced deferred tax liabilities by $9.9 million, reduced additional paid-in capital by $106.8 million and reduced the accumulated deficit by $74.5 million.

2. Collaboration and License Agreements

Heptares Therapeutics Limited, or Heptares. We entered into a collaboration and license agreement with Heptares, which became effective in December 2021, to develop and commercialize certain compounds containing sub-type selective muscarinic M1, M4, or dual M1/M4 receptor agonists, which compounds we have the exclusive rights to develop, manufacture and commercialize worldwide, excluding in Japan, where Heptares 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 Heptares, we retain the rights to opt in to profit sharing arrangements, pursuant to which we and Heptares 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 II clinical trial for such compound or following our receipt from Heptares 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.

In connection with the agreement, we paid Heptares $100.0 million upfront, which, including certain transaction-related costs, was expensed as in-process research and development, or IPR&D, in 2021. We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business.

In connection with the United States Food and Drug Administration's, or FDA's, acceptance of our investigational new drug application for NBI-1117568 for the treatment of schizophrenia in June 2022, we paid Heptares a milestone of $30.0 million, which was expensed as research and development, or R&D, in the second quarter of 2022.

Under the terms of the agreement, Heptares 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 Heptares during the research collaboration term and upon 90 days' written notice to Heptares following the expiration of the research collaboration term. Following the expiration of the research collaboration term, Heptares 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-1065845, NBI-1065846 and four non-clinical stage compounds. Luvadaxistat and the 4 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 II 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 III clinical trial for such compound.

In connection with the agreement, we paid Takeda $120.0 million upfront, which, including certain transaction-related costs, was expensed as IPR&D in 2020. We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. 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.

In connection with the approval of our clinical trial application for NBI-1070770 for the treatment of major depressive disorder in July 2022, a milestone of $5.0 million was expensed as R&D in the third quarter of 2022, which we expect to pay to Takeda in the fourth quarter of 2022.

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.

In connection with the agreement, we paid Idorsia $45.0 million upfront, which was expensed as IPR&D in 2020. We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. 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 the agreement, we paid Xenon $50.0 million upfront, including a purchase of approximately 1.4 million shares of Xenon common stock (at $14.196 per share). We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. The purchased shares were recorded at a fair value of $14.1 million after considering Xenon's stock price on the measurement date and certain transfer restrictions applicable to the shares. The remaining $36.2 million of the purchase price, which includes certain transaction-related costs, was expensed as IPR&D in 2019.

In connection with the European Union's approval of our clinical trial application for NBI-921352 for the treatment of focal onset seizures in adults in September 2021, we paid Xenon a regulatory milestone of $10.0 million, including a purchase of approximately 0.3 million shares of Xenon common stock (at $19.9755 per share). The purchased shares were recorded at a fair value of $4.6 million after considering Xenon's stock price on the measurement date and certain transfer restrictions applicable to the shares. The remaining $5.4 million of the milestone payment was expensed as R&D in 2021.

In connection with the FDA's acceptance of our amended KAYAK™ study protocol in January 2022, we paid Xenon a regulatory milestone of $15.0 million, including a purchase of approximately 0.3 million shares of Xenon common stock (at $31.855 per share). The purchased shares were recorded at a fair value of $7.7 million after considering Xenon's stock price on the measurement date. The remaining $7.3 million of the milestone payment was expensed as R&D in the first quarter of 2022.

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. In 2019, we entered into a collaboration and license agreement with Voyager, pursuant to which we acquired certain rights to develop and commercialize the NBIb-1817 for Parkinson's disease program, Friedreich's ataxia program and two undisclosed programs. We are responsible for all development costs of any collaboration product, subject to certain co-development and co-commercialization rights retained by Voyager. In February 2021, we notified Voyager of our termination of the NBIb-1817 for Parkinson's disease program, which became effective August 2, 2021. The termination did not apply to any program other than the NBIb-1817 for Parkinson's disease program.

In connection with the agreement, we paid Voyager $165.0 million upfront, including a purchase of approximately 4.2 million shares of Voyager common stock (at $11.9625 per share). We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. The purchased shares were recorded at a fair value of $54.7 million after considering Voyager's stock price on the measurement date and certain transfer restrictions applicable to the shares. The remaining $113.1 million of the purchase price, which includes certain transaction-related costs, was expensed as IPR&D in 2019. In addition, we paid Voyager $5.0 million upfront, which was expensed as IPR&D in 2019, to acquire the rights outside the United States to the Friedreich's ataxia program.

Under the terms of the 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.

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

BIAL – Portela & Ca, S.A., or BIAL. We acquired the United States and Canada rights to ONGENTYS® (opicapone) from BIAL in 2017, and launched ONGENTYS in the United States in September 2020 as an FDA-approved add-on treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing motor fluctuations. We are responsible for all commercialization costs of ONGENTYS in the United States and Canada and rely on BIAL for the commercial supply of ONGENTYS.

Under the terms of the license agreement, BIAL may be entitled to receive potential future payments of up to $75.0 million upon the achievement of certain event-based milestones. In addition, with respect to ONGENTYS, in the event we fail to meet certain minimum sales requirements for a particular year in comparison to our annual sales forecast for such year, we would be obligated to pay BIAL an amount equal to the difference between the actual net sales and minimum sales requirements for such year. Further, upon our written request to BIAL 12 months prior to the estimated expiration of the term of a licensed product, we will negotiate the continuation of BIAL's supply of such licensed product after the term. After the term, and if BIAL is no longer supplying such licensed product, BIAL would be entitled to receive a low double-digit royalty on our future quarterly net sales of such licensed product.

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

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

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

In June 2022, MTPC launched DYSVAL® (valbenazine) in Japan for the treatment of tardive dyskinesia. In connection with MTPC's first commercial sale of DYSVAL in Japan, we received a milestone payment of $20.0 million in the second quarter of 2022. ASC 606 provides a royalty exception for a sales-based or usage-based royalty promised in exchange for a license of intellectual property. Under the royalty exception, the milestone would be recognized as revenue only when the later of (1) the subsequent sale or usage occurs or (2) the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied). As the milestone related to a license of intellectual property and was contingent upon MTPC's first commercial sale of DYSVAL in Japan, the milestone was recognized as revenue in the second quarter of 2022. In addition, we receive royalties at tiered percentage rates on MTPC net sales of DYSVAL.

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. We out-licensed the global rights to elagolix to AbbVie in 2010. AbbVie is responsible for all development and commercialization costs of elagolix.

In August 2018, AbbVie launched ORILISSA® (elagolix tablets) in the United States for the treatment of moderate to severe pain associated with endometriosis. In June 2020, AbbVie launched ORIAHNN® (elagolix, estradiol and norethindrone acetate capsules and elagolix capsules) in the United States for the treatment of heavy menstrual bleeding related to uterine fibroids in premenopausal women. We receive royalties at tiered percentage rates on AbbVie net sales of elagolix and recognized elagolix royalty revenue of $6.1 million and $15.5 million, respectively, for the three and nine months ended September 30, 2022 and $5.9 million and $16.3 million, respectively, for the three and nine months ended September 30, 2021.

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.

		September 30, 2022				December 31, 2021			
(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	$ 97.9	$ —	$ (0.4)	$ 97.5	$ 204.8	$ —	$ —	$ 204.8
Corporate debt securities	0 to 1 years	260.5	—	(3.2)	257.3	128.2	—	(0.1)	128.1
Securities of government-sponsored entities	0 to 1 years	237.2	—	(4.8)	232.4	37.6	—	—	37.6
		$ 595.6	$ —	$ (8.4)	$ 587.2	$ 370.6	$ —	$ (0.1)	$ 370.5
Corporate debt securities	1 to 3 years	$ 270.8	$ —	$ (6.2)	$ 264.6	$ 358.9	$ —	$ (1.5)	$ 357.4
Securities of government-sponsored entities	1 to 3 years	102.3	—	(4.3)	98.0	204.3	—	(1.0)	203.3
		$ 373.1	$ —	$ (10.5)	$ 362.6	$ 563.2	$ —	$ (2.5)	$ 560.7

As of September 30, 2022, our security portfolio consisted of 193 debt securities available-for-sale, including 183 such securities that were in an unrealized loss position but of high credit quality. Unrealized losses on these investments were primarily due to changes in interest rates. We do not intend to sell these investments and it is not more likely than not that we will be required to sell these investments before recovery of their amortized cost basis. No allowance for credit losses was recognized as of September 30, 2022 or December 31, 2021.

The following table presents debt securities available-for-sale that were in an unrealized loss position as of September 30, 2022, 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
Commercial paper	$ 52.9	$ (0.4)	$ —	$ —	$ 52.9	$ (0.4)
Corporate debt securities	$ 251.1	$ (4.8)	$ 263.7	$ (4.6)	$ 514.8	$ (9.4)
Securities of government-sponsored entities	$ 235.0	$ (6.0)	$ 92.9	$ (3.1)	$ 327.9	$ (9.1)

The following table presents debt securities available-for-sale that were in an unrealized loss position as of December 31, 2021, 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	$ 428.6	$ (1.6)	$ —	$ —	$ 428.6	$ (1.6)
Securities of government-sponsored entities	$ 230.5	$ (1.0)	$ —	$ —	$ 230.5	$ (1.0)

Accrued interest receivables on debt securities available-for-sale totaled $3.9 million and $2.2 million, respectively, as of September 30, 2022 and December 31, 2021. 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 nine months ended September 30, 2022 or 2021.

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 investments, which were measured at fair value on a recurring basis.

(in millions)	September 30, 2022				December 31, 2021			
	Fair Value	Leveling			Fair Value	Leveling		
		Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
Cash and cash equivalents:								
Cash and money market funds	$ 212.2	$ 212.2	$ —	$ —	$ 340.8	$ 340.8	$ —	$ —
Restricted cash:								
Certificates of deposit	7.8	7.8	—	—	3.2	3.2	—	—
Debt securities available-for-sale:								
Commercial paper	97.5	—	97.5	—	204.8	—	204.8	—
Corporate debt securities	521.9	—	521.9	—	485.5	—	485.5	—
Securities of government-sponsored entities	330.4	—	330.4	—	240.9	—	240.9	—
Equity securities:								
Equity securities–biotechnology industry	94.9	94.9	—	—	63.7	52.7	—	11.0
	$ 1,264.7	$ 314.9	$ 949.8	$ —	$ 1,338.9	$ 396.7	$ 931.2	$ 11.0

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

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Balance at beginning of period	$ —	$ 38.9	$ 11.0	$ 38.2
Purchases	—	4.6	—	4.6
Unrealized gain (loss) included in earnings [1]	—	(8.2)	20.8	(7.5)
Transfers out of Level 3 [2]	—	—	(31.8)	—
Balance at end of period	$ —	$ 35.3	$ —	$ 35.3

(1) Unrealized gains and losses on restricted equity security investments were measured at fair value on a recurring basis using significant unobservable inputs (Level 3) and are included in other income (expense), net.

(2) In the first quarter of 2022, our equity security investment in Voyager was transferred from Level 3 to Level 1 as the associated holding period restriction expired.

5. Inventories

Inventories consisted of the following:

(in millions)	September 30, 2022	December 31, 2021
Raw materials	$ 15.0	$ 11.2
Work in process	5.0	3.6
Finished goods	17.0	15.7
Total inventories	$ 37.0	$ 30.5

6. Cash, Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash and 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)	September 30, 2022	September 30, 2021
Cash and cash equivalents	$ 212.2	$ 311.1
Restricted cash included in other assets	7.8	3.2
Total cash, cash equivalents and restricted cash	$ 220.0	$ 314.3

7. Leases

Our operating leases that have commenced have terms that expire beginning 2024 through 2031 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 operating lease right-of-use, or ROU, assets or operating lease liabilities.

On February 8, 2022, we entered into a lease agreement for a four-building campus facility to be constructed in San Diego, California, pursuant to which we also secured a six-year option for the construction of a fifth building and an option to purchase the entire campus facility, which will consist of office space and research and development laboratories, in the future. Upon completion of construction, we expect to utilize the campus facility as our new corporate headquarters. This lease has not commenced for accounting purposes. Under the terms of the lease, on a building-by-building basis, base rent will be subject to a 10-month rent abatement period following the respective lease commencement date, which dates will be determined in the future based upon achievement of substantial completion of construction with respect to each such building in the condition suitable for the installation of our furniture, fixtures, and equipment, and on which date we will record a lease liability, corresponding right-of-use asset, and begin lease expense recognition with respect to each such building. After the rent abatement period, monthly base rent will be $6 per square foot, subject to annual escalations of 3% during the initial 13.6-year lease term, which term we have the option to renew for two additional terms of five years each.

In connection with our operating leases, in lieu of a cash security deposits, Wells Fargo Bank, N.A., issued letters of credit on our behalf, which are secured by deposits totaling $7.8 million.

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

	Nine Months Ended September 30,	
(in millions, except weighted average data)	**2022**	**2021**
Operating lease cost	$ 12.5	$ 11.2
Cash paid for amounts included in the measurement of operating lease liabilities	$ 12.2	$ 9.1

	September 30, 2022	**September 30, 2021**
Weighted average remaining lease term	8.1 years	9.0 years
Weighted average discount rate	5.3 %	5.3 %

The following table presents approximate non-cancelable future minimum lease payments under operating leases as of September 30, 2022.

(in millions)	**Amount** [1]
2022 (3 months remaining)	$ 4.4
2023	17.9
2024	17.4
2025	15.9
2026	15.7
Thereafter	70.4
Total operating lease payments	141.7
Less accreted interest	27.8
Total operating lease liabilities	113.9
Less current operating lease liabilities included in other current liabilities	17.3
Noncurrent operating lease liabilities	$ 96.6

(1) Amounts presented in the table above exclude $17.2 million for 2024, $33.3 million for 2025, $41.9 million for 2026, and $479.7 million thereafter of approximate non-cancelable future minimum lease payments under operating leases that have not yet commenced.

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 accordance with authoritative guidance in effect at the time of issuance, we were required to separately account for the liability and equity components of the 2024 Notes. The initial carrying value of the liability component of $368.3 million was calculated using a 7.50% assumed borrowing rate, which reflected the market interest rate for a similar non-convertible instrument at the date of issuance. The equity component of $149.2 million, which was treated as a discount on the liability component and amortized over the seven-year term of the 2024 Notes using the effective interest rate method, was determined by deducting the fair value of the liability component from the par value of the 2024 Notes and recorded as an increase to additional paid-in capital on the issuance date. In addition, we allocated transaction costs of $14.7 million related to the issuance of the 2024 Notes to the liability and equity components based on their relative values on the issuance date. Transaction costs attributable to the liability component were being amortized over the seven-year term of the 2024 Notes using the effective interest rate method, while transaction costs attributable to the equity component were recorded as a reduction to additional paid-in capital on the issuance date.

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

On January 1, 2022, we adopted ASU 2020-06 using the modified retrospective transition method, which allowed for a cumulative-effect adjustment in the period of adoption and did not require restatement of prior period amounts. Under this transition method, the cumulative effect of the accounting change increased the carrying amount of the 2024 Notes by $42.2 million, reduced deferred tax liabilities by $9.9 million, reduced additional paid-in capital by $106.8 million, and reduced the accumulated deficit by $74.5 million.

In the second quarter of 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. We accounted for the partial repurchase of the 2024 Notes as a debt extinguishment, which resulted in the recognition of a $70.0 million loss on extinguishment in the second quarter of 2022.

The following table presents a summary of the 2024 Notes as of September 30, 2022.

(in millions)	Principal Amount	Unamortized Debt		Net Carrying Amount	Fair Value	
		Discount	Issuance Costs		Amount	Leveling
2024 Notes	$ 170.4	$ —	$ (1.2)	$ 169.2	$ 238.3	Level 2

The following table presents a summary of the 2024 Notes as of December 31, 2021.

(in millions)	Principal Amount	Unamortized Debt		Net Carrying Amount	Fair Value	
		Discount	Issuance Costs		Amount	Leveling
2024 Notes	$ 381.2	$ (43.2)	$ (2.9)	$ 335.1	$ 464.7	Level 2

The following table presents a summary of the interest expense of the 2024 Notes.

(in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Coupon interest	$ 1.0	$ 2.2	$ 5.0	$ 6.3
Amortization of debt discount and issuance costs	0.2	4.4	1.0	12.9
Total	$ 1.2	$ 6.6	$ 6.0	$ 19.2

In December 2021, we entered into the First Supplemental Indenture to the 2017 Indenture, pursuant to which we irrevocably elected to settle the principal amount of the 2024 Notes in cash upon conversion and to settle any conversion premium, calculated based on the per share volume-weighted average price for each of the 30 consecutive trading days during the observation period (as more fully described in the 2017 Indenture), in either cash or shares of our common stock.

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.

We may 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 has been at least 130% of the conversion price then in effect (equal to $98.70 as of September 30, 2022) for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending on, and including, the trading day immediately before the date which we provide notice of redemption.

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 September 30, 2022) 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.

On or after January 15, 2024, 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.

As the conditional conversion feature described under (i) above was triggered as of September 30, 2022, holders of the 2024 Notes may convert the 2024 Notes at any time during the period beginning on October 3, 2022, and ending at the close of business on December 30, 2022. Accordingly, the 2024 Notes have been classified as a current liability as of September 30, 2022. The future conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of our common stock during the prescribed measurement periods.

Upon conversion, holders will receive the principal amount of their 2024 Notes in cash and any excess conversion value, calculated based on the per share volume-weighted average price for each of the 30 consecutive trading days during the observation period (as more fully described in the 2017 Indenture), in either cash or shares of our common stock.

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 per Share

Earnings per share was calculated as follows:

(in millions, except per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income - basic and diluted	$ 68.5	$ 22.5	$ 65.5	$ 96.9
Weighted-average shares outstanding:				
Basic	95.8	94.7	95.6	94.5
Effect of dilutive securities:				
Stock options	1.9	1.8	1.7	1.9
Restricted stock	0.8	0.2	0.5	0.3
2024 Notes	0.6	1.0	0.5	1.1
Diluted	99.0	97.7	98.3	97.9
Earnings per share, basic	$ 0.72	$ 0.24	$ 0.69	$ 1.03
Earnings per share, diluted	$ 0.69	$ 0.23	$ 0.67	$ 0.99
Shares excluded from diluted per share amounts because their effect would have been anti-dilutive	4.9	4.5	5.5	4.0

10. Subsequent Events

On November 1, 2022, we acquired Diurnal Group plc in an all-cash transaction, for an aggregate value of approximately £48.3 million GBP, or approximately $56 million USD. We believe the transaction presents an opportunity to accelerate the establishment of our clinical development and commercial capabilities in the United Kingdom to the benefit of patient communities and other stakeholders. We are currently in the process of finalizing the accounting for this transaction.

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, 2021 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, 2021 and our Quarterly Report on Form 10-Q for the six months ended June 30, 2022.

Overview

At Neurocrine Biosciences, our purpose is simple: to relieve suffering for people with great needs, but few options. For three decades, we have applied our unique insight into neuroscience to advance medicines for neurology, neuroendocrinology and neuropsychiatry-related disorders and diseases. Our efforts have resulted in United States Food and Drug Administration, or FDA, approved treatments for tardive dyskinesia, Parkinson's disease, endometriosis* and uterine fibroids* and a diversified portfolio of investigational therapies with the potential to address unmet clinical needs of patients worldwide living with neurological, endocrine and psychiatric disorders. *(*in collaboration with AbbVie Inc., or AbbVie)*

We launched INGREZZA® (valbenazine) in the United States in May 2017 as the first FDA-approved drug for the treatment of tardive dyskinesia and launched ONGENTYS® (opicapone) in the United States in September 2020 as an FDA-approved add-on treatment for levodopa/carbidopa in patients with Parkinson's disease experiencing motor fluctuations. INGREZZA net product sales represent the significant majority of our total net product sales.

Our partner Mitsubishi Tanabe Pharma Corporation, or MTPC, launched DYSVAL® (valbenazine) in Japan in June 2022 for the treatment of tardive dyskinesia. We receive royalties at tiered percentage rates on MTPC net sales of DYSVAL.

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

Business Highlights

- In October 2022, we submitted a supplemental new drug application, or sNDA, with the FDA for valbenazine for the treatment of chorea associated with Huntington disease.
- On November 1, 2022, we acquired Diurnal Group plc in an all-cash transaction, for an aggregate value of approximately £48.3 million GBP, or approximately $56 million USD. We believe the transaction presents an opportunity to accelerate the establishment of our clinical development and commercial capabilities in the United Kingdom to the benefit of patient communities and other stakeholders.

Impacts of Macro-Economic Factors on Our Business

COVID-19 Global Pandemic.

We continue to monitor the impact of the COVID-19 pandemic on our business, including our clinical trials, third-party manufacturers, suppliers and service providers. The extent to which COVID-19 may impact our financial condition and results of operations remains uncertain and is dependent on numerous evolving factors, including the measures being taken by authorities to mitigate against the spread of COVID-19, the emergence of new variants and the availability and successful administration of effective vaccines. For more information on the risks and uncertainties associated with the evolving effects of COVID-19 on our business, our ability to generate sales of and revenues from our approved products and our clinical development and regulatory efforts, refer to Part II Item 1A. Risk Factors.

Russia/Ukraine Conflict.

In February 2022, Russia commenced a military invasion of Ukraine. The ongoing geopolitical turmoil and continuing military action in the region, together with widening sanctions imposed on Russia, have caused us to suspend all planned clinical trial activities for valbenazine and luvadaxistat in Russia and Ukraine.

The duration and impact of the conflict between Russia and Ukraine is highly unpredictable and the extent to which the conflict may impact certain of our clinical development and regulatory efforts remains uncertain. For more information on the risks and uncertainties associated with the evolving effects of the conflict between Russia and Ukraine on our business and certain of our clinical development and regulatory efforts, refer to Part II Item 1A. Risk Factors.

Results of Operations for the Three and Nine Months Ended September 30, 2022 and 2021

Revenues

Net Product Sales by Sales Product.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
INGREZZA net product sales	$ 376.4	$ 286.5	$ 1,028.6	$ 780.9
ONGENTYS net product sales	2.9	2.3	7.7	5.7
Total net product sales	$ 379.3	$ 288.8	$ 1,036.3	$ 786.6

Compared with the comparable periods last year, the increase in INGREZZA net product sales was driven by increased new patient starts and record total prescriptions, reflecting higher customer demand and increased commercial activities.

Collaboration Revenues by Category.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
Royalty revenue	$ 6.1	$ 5.9	$ 15.5	$ 16.3
Milestone revenue	—	—	20.0	15.0
Other	2.5	1.3	4.9	3.6
Total collaboration revenues	$ 8.6	$ 7.2	$ 40.4	$ 34.9

Royalty revenue. Consists of royalties earned at tiered percentage rates on AbbVie net sales of elagolix and, beginning in June 2022, MTPC net sales of DYSVAL.

Milestone revenue. Consists of license fees earned under the terms of our license agreements with AbbVie and MTPC.

Milestone revenue for the nine months ended September 30, 2022 reflected the achievement of a $20.0 million milestone in connection with MTPC's first commercial sale of DYSVAL in Japan in June 2022. For the comparable period last year, milestone revenue reflected the achievement of a $15.0 million milestone in connection with MTPC's submission of a marketing authorization application for valbenazine for the treatment of tardive dyskinesia with the Ministry of Health and Welfare in Japan in April 2021.

Operating Expenses

Cost of Revenues.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2022**	**2021**	**2022**	**2021**
Cost of revenues	$ 6.1	$ 4.2	$ 15.5	$ 10.2

Compared with the comparable periods last year, the increase in cost of revenues primarily reflected increased manufacturing costs in connection with our supply of valbenazine drug product under our collaboration with MTPC and increased INGREZZA net product sales driven by increased new patient starts and record total prescriptions, reflecting higher customer demand and increased commercial activities.

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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2022	2021	2022	2021
Late stage	$ 18.1	$ 15.8	$ 48.2	$ 41.9
Early stage	18.1	13.9	56.4	27.8
Research and discovery	13.5	14.8	45.2	35.9
Milestone	5.0	5.4	42.7	5.4
Payroll and benefits	41.6	32.4	119.7	97.0
Facilities and other	11.4	10.4	33.6	32.7
Total research and development	$ 107.7	$ 92.7	$ 345.8	$ 240.7

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

Compared with the comparable periods last year, late-stage expenses primarily reflected increased investment in our Phase III programs for valbenazine in schizophrenia and crinecerfont in classic congenital adrenal hyperplasia, partially offset by lower spend related to the completion of the Phase III KINECT-HD study in the first quarter of 2022.

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 periods last year, early-stage expenses primarily reflected increased investment in support of our advancing Phase II programs in epilepsy and luvadaxistat and NBI-1117568 in schizophrenia.

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 periods last year, research and discovery expenses primarily reflected increased investment in our preclinical development programs.

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

Milestone expenses for the nine months ended September 30, 2022 primarily reflected $5.0 million of expense recognized in connection with the approval of our clinical trial application for NBI-1070770 for the treatment of major depressive disorder in July 2022, $30.0 million of expense recognized in connection with the FDA's acceptance of our investigational new drug application for NBI-1117568 for the treatment of schizophrenia in June 2022 and $7.3 million of expense recognized in connection with the FDA's acceptance of our amended KAYAK™ study protocol in January 2022. For the nine months ended September 30, 2021, milestone expenses reflected $5.4 million of expense recognized in connection with the European Union's approval of our clinical trial application for NBI-921352 for the treatment of focal onset seizures in adults in September 2021.

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 to the comparable period last year, payroll and benefits expenses for the nine months ended September 30, 2022 primarily reflected higher headcount and an increase of $7.4 million in non-cash stock-based compensation expense primarily related to an August 2021 equity grant of approximately 0.5 million restricted stock units to our full-time employees other than our executive officers, which are vesting over a 2-year period, and unvested performance-based restricted stock units to our executive officers for which attainment of the performance-based criteria was determined to be probable. The nine months ended September 30, 2021 included a non-cash stock-based compensation charge of $6.4 million related to the modification of certain stock-based awards.

Selling, General and Administrative.

(*in millions*)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Sales, general and administrative	$ 186.3	$ 154.6	$ 569.8	$ 426.8

Compared with the comparable periods last year, the increase in sales, general and administrative expense was primarily driven by increased investment in ongoing commercial initiatives, including our TD Spotlight-branded direct-to-consumer INGREZZA advertising campaign, which launched in May 2021, and deployment of our expanded sales force. Compared with the comparable period last year, sales, general and administrative expense for the nine months ended September 30, 2022, also reflected increased personnel expenses driven by higher headcount and an increase of $23.6 million in non-cash stock-based compensation expense primarily related to an August 2021 equity grant of approximately 0.5 million restricted stock units to our full-time employees other than our executive officers, which are vesting over a 2-year period, and unvested performance-based restricted stock units to our executive officers for which attainment of the performance-based criteria was determined to be probable.

Other Income (Expense), Net.

(*in millions*)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Interest expense	$ (1.2)	$ (6.6)	$ (6.0)	$ (19.2)
Unrealized gain (loss) on equity securities	11.1	(8.2)	23.6	(7.5)
Loss on extinguishment	—	—	(70.0)	—
Investment income and other, net	0.2	0.8	2.8	3.1
Total other income (expense), net	$ 10.1	$ (14.0)	$ (49.6)	$ (23.6)

Compared with the comparable periods last year, the change in other income (expense), net, was driven by periodic fluctuations in the fair values of our equity security investments and decreased interest expense in connection with our adoption of ASU 2020-06 on January 1, 2022. Compared with the comparable period last year, other expense, net, for the nine months ended September 30, 2022, also reflected a $70.0 million loss on extinguishment in connection with the repurchase of $210.8 million aggregate principal amount of our convertible senior notes for an aggregate repurchase price of $279.0 million in cash in the second quarter of 2022.

Provision for Income Taxes.

(*in millions*)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Provision for income taxes	$ 29.4	$ 8.0	$ 30.5	$ 18.3

The provision for income taxes for the three and nine months ended September 30, 2022, reflected an effective tax rate that differs from the federal and state statutory rates primarily due to credits generated for research activities and certain nondeductible expenses, including the premium paid on the repurchase of our convertible senior notes. The provision for income taxes for the three and nine months ended September 30, 2021, reflected an effective tax rate that was lower than the federal and statutory rates primarily due to excess tax benefits related to stock-based compensation. Based upon available Federal net operating losses and tax credits, we expect to begin making cash payments for Federal income tax beginning in 2022.

Net Income.

(in millions)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Net income	$ 68.5	$ 22.5	$ 65.5	$ 96.9

Compared with the comparable periods last year, the change in net income primarily reflected increased INGREZZA net product sales driven by increased new patient starts and record total prescriptions, reflecting higher customer demand and increased commercial activities, partially offset by increased investments in ongoing commercial initiatives and our expanded clinical portfolio. Compared to the comparable period last year, net income for the nine months ended September 30, 2022, also reflected a $70.0 million loss on extinguishment recognized in connection with the repurchase of our convertible senior notes in the second quarter of 2022 and increased milestone expenses incurred in connection with certain of our collaborative arrangements.

Liquidity and Capital Resources

Sources of Liquidity

We believe that our existing capital resources and anticipated revenues 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. In addition, the disruption of global financial markets caused by the COVID-19 pandemic, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity.

Information Regarding Our Financial Condition.

(in millions)	September 30, 2022	December 31, 2021
Total cash, cash equivalents and marketable securities	$ 1,162.0	$ 1,272.0
Working Capital:		
Total current assets	$ 1,205.5	$ 972.8
Less total current liabilities	485.1	245.8
Total working capital	$ 720.4	$ 727.0

Information Regarding Our Cash Flows.

(in millions)	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Cash flows from operating activities	$ 196.4	$ 252.3
Cash flows from investing activities	(61.5)	(153.9)
Cash flows from financing activities	(258.9)	25.6
Change in cash, cash equivalents and restricted cash	$ (124.0)	$ 124.0

Cash Flows from Operating Activities.

Compared with the comparable period last year, cash flows from operating activities primarily reflected increased INGREZZA net product sales driven by increased new patient starts and record total prescriptions, reflecting higher customer demand and increased commercial activities, partially offset by increased investments in ongoing commercial initiatives and our expanded clinical portfolio. In addition, we experienced an increase in accounts receivable due to extended customer payment terms attributed to the expansion of our distribution network at the end of fiscal 2021.

Cash Flows from Investing Activities.

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

Cash Flows from Financing Activities.

Compared with the comparable period last year, cash flows from financing activities primarily reflected the repurchase of $210.8 million aggregate principal amount of our convertible senior notes for an aggregate repurchase price of $279.0 million in cash in the second quarter of 2022.

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, ONGENTYS, 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;
- developments related to any future litigation; and
- the impact of the COVID-19 pandemic on our business.

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 $10.8 billion upon the achievement of certain event-based milestones.

On November 1, 2022, we acquired Diurnal Group plc in an all-cash transaction, for an aggregate value of approximately £48.3 million GBP, or approximately $56 million USD. We believe the transaction presents an opportunity to accelerate the establishment of our clinical development and commercial capabilities in the United Kingdom to the benefit of patient communities and other stakeholders.

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

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, or the 2024 Notes. In the fourth quarter of 2020 and second quarter of 2022, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million and $210.8 million, respectively, aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million and $279.0 million, respectively, in cash. As of September 30, 2022, $170.4 million aggregate principal amount of the 2024 Notes remained outstanding.

At our election, we may redeem all or any portion of the 2024 Notes under certain circumstances. Further, as the conditional conversion feature of the 2024 Notes was triggered as of September 30, 2022, holders of the 2024 Notes may convert the 2024 Notes at any time during the period beginning on October 3, 2022, and ending at the close of business on December 30, 2022. With respect to the 2024 Notes, unless earlier converted, redeemed, or repurchased, we would be required to pay interest of $1.9 million in 2022, $3.8 million in 2023, and $1.9 million in 2024 and pay the aggregate principal amount outstanding of $170.4 million upon maturity of the 2024 Notes.

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 notes would become due and payable.

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

Leases. Our operating leases that have commenced have terms that expire beginning 2024 through 2031 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, pursuant to which we also secured a six-year option for the construction of a fifth building and an option to purchase the entire campus facility, which will consist of office space and research and development laboratories, in the future. Upon completion of construction, we expect to utilize the campus facility as our new corporate headquarters and expect to begin subleasing our existing leased facilities.

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.

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, 2021.

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 September 30, 2022, 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 our last fiscal quarter and that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Our evaluation did not identify 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 September 30, 2022, 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

In the second, third and fourth quarters of 2021 and the first, second and third quarters of 2022, we received notices from (i) Teva Pharmaceuticals Development, Inc., (ii) Lupin Limited, (iii) Crystal Pharmaceutical (Suzhou) Co. Ltd., (iv) Sandoz Inc. and (v) Zydus Pharmaceuticals (USA) Inc. that each company had filed an abbreviated new drug application, or ANDA, with the FDA seeking approval of a generic version of INGREZZA. These companies represented that their respective ANDAs each contained a Paragraph IV Patent Certification alleging that certain of our patents covering INGREZZA are invalid and/or will not be infringed by the manufacture, use or sale of the medicine for which the ANDA was submitted.

We filed suit in the United States District Court for the District of Delaware in July, August and October 2021 and January, April, May, July, August and September 2022, against (i) Teva Pharmaceuticals, Inc., Teva Pharmaceuticals Development, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (entity dismissed), (ii) Lupin Limited, Lupin Pharmaceuticals, Inc., Lupin Inc. and Lupin Atlantis Holdings S.A., (iii) Crystal Pharmaceutical (Suzhou) Co., Ltd., Crystal Pharmatech Co., Ltd., (iv) Sandoz Inc., Sandoz International GmbH (entity dismissed) and Sandoz AG (entity dismissed) and (v) Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited d/b/a Zydus Cadila) and Zydus Healthcare (USA) LLC (entity dismissed). Sandoz Inc. has been joined in the cases against Crystal Pharmaceutical (Suzhou) Co., Ltd. and Crystal Pharmatech Co., Ltd. The cases filed in July, August and October 2021 and January and August 2022 have been consolidated in the United States District Court for the District of Delaware and the trial is currently scheduled for January 2, 2024.

We also filed suit in the United States District Court for the District of New Jersey in July and October 2021 and April 2022 against Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited d/b/a Zydus Cadila) and Zydus Healthcare (USA) LLC and these cases were dismissed in favor of continued prosecution of the Delaware proceedings against the same entities.

Further, we filed suit in the United States District Court for the District of Delaware and in the United States District Court for the District of New Jersey in September 2022, against Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited d/b/a Zydus Cadila) and Zydus Healthcare (USA) LLC.

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

Item 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, 2021.

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, ONGENTYS, or any of our product candidates if they are approved in the future.
- If physicians and patients do not continue to accept INGREZZA or do not accept ONGENTYS, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.
- Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products that could limit our product revenues and delay sustained profitability.
- Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic, which could also cause significant disruption in the operations of third-party manufacturers, contract research organizations, or CROs, or other third parties upon whom we rely.

- We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced.
- Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.
- Our clinical trials may be delayed for safety or other reasons, or fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.
- Several of our planned clinical trial sites have been impacted and could be delayed or suspended as a result of the conflict between Russia and Ukraine.
- 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 recently increased the size of our organization and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.
- 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, ONGENTYS or any product candidate approved by the FDA.
- We currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA, ONGENTYS or any of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed, and our costs may rise.
- We currently depend on a limited number of third-party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA or ONGENTYS, could materially and adversely affect our ability to successfully commercialize INGREZZA or ONGENTYS.
- 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.
- Health care reform measures and other recent legislative initiatives could adversely affect our business.
- Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations.
- We have a history of losses and expect to increase our expenses for the foreseeable future, and we may not be able to sustain profitability.
- Our customers are concentrated and therefore the loss of a significant customer may harm our business.
- If we cannot raise additional funding, we may be unable to complete development of our product candidates or establish commercial and manufacturing capabilities in the future.

Risks Related to Our Company

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

Our ability to produce INGREZZA revenues consistent with expectations ultimately depends on our ability to 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 in the past four years, 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 to successfully commercialize ONGENTYS or any product candidate approved by the FDA in the future.

In addition, our business has been and may continue to be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic. In parts of the country where the pandemic is having a greater impact, 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. These policies are likely to change from time to time as communities or regions grapple with outbreaks. These facilities also may be facing staffing shortages that impact their ability to see patients and conduct necessary screenings. In addition, many health care practitioners have adopted telehealth for patient interactions, which may impact the ability of the health care practitioner to screen for and diagnose tardive dyskinesia. Further, during the COVID-19 pandemic, the use of physician telehealth services increased significantly, fueled by an expansion of coverage and reimbursement from government and other payors. The limitations that telehealth places on the ability to conduct a thorough visual and physical examination may impact the ability of providers to screen for movement disorders, leading to potentially fewer patients to be diagnosed and referred for treatment. The ultimate impact of the COVID-19 pandemic, including any lasting effects on the way we conduct our business, is highly uncertain and subject to continued change. If we fail to maintain successful marketing, sales and reimbursement capabilities, our product revenues may suffer.

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

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

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

- the timing of receipt of marketing approvals for 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.

Governmental 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 that could limit our product revenues and delay sustained profitability.

Our ability to continue to commercialize INGREZZA successfully or to successfully commercialize ONGENTYS, will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available. The continuing efforts of government and third-party payors to contain or reduce the costs of health care and the price of prescription drugs through various means may 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 payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the 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 United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. In addition, communications from government officials regarding health care costs and pharmaceutical pricing could have a negative impact on our stock price, even if such communications do not ultimately impact coverage or reimbursement decisions for our products.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs 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. 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.

If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize INGREZZA, ONGENTYS or any other product candidate for which we obtain marketing approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Further, a majority of our current revenue is derived from federal healthcare program payors, including Medicare and Medicaid. Thus, changes in government reimbursement policies, 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 has rapidly increased, fueled by an unprecedented expansion of coverage and reimbursement across 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.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic, 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 of the ongoing COVID-19 pandemic, we may experience disruptions that could severely impact our supply chain, ongoing and future clinical trials and commercialization of INGREZZA and ONGENTYS. For example, the COVID-19 pandemic has resulted in travel restrictions and the shutdown or delay of business activities in various regions. 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. Most of our field-based employees have resumed in-person interactions in accordance with location-specific guidance. Our office-based employees have returned to the office under flexible work guidelines to help balance business needs, employee health, well-being and safety and the evolving work environment. However, as the effects of the pandemic continue to rapidly evolve with the emergence of new COVID-19 variants and spikes or surges in infection and hospitalization rates, 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, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, we may face several challenges or disruptions upon a return back to the workplace, including re-integration challenges by our employees and distractions to management related to such transition. These and similar, and perhaps more severe, disruptions in our operations due to the COVID-19 pandemic could negatively impact our business, operating results and financial condition. We continue to evaluate the impact of the COVID-19 pandemic on our business and will update our plans and policies as needed going forward.

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

In addition, clinical site initiation and patient enrollment may be delayed due to concerns for patient safety and prioritization of healthcare resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient travel or interrupt healthcare services. Similarly, our ability to recruit and retain patients, principal investigators and site staff may be hindered, which would adversely impact our clinical trial operations. Increases in COVID-19 cases or hospitalizations in the future could cause us or any of our clinical sites to again limit or suspend our patient enrollment and screening activities.

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

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

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, uterine fibroids, essential tremor, 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), which was approved by the FDA for the treatment of tardive dyskinesia in adults in August 2017 and is marketed by Teva Pharmaceutical Industries, and several clinical development-stage programs targeting tardive dyskinesia and related movement disorders. Additionally, there are a number of commercially available medicines used to treat tardive dyskinesia off-label, such as XENAZINE® (tetrabenazine) and generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin.
- ONGENTYS competes with two other FDA-approved COMT inhibitors and their generic equivalents. Additionally, there are a number of alternative adjunctive treatment options (FDA-approved and in clinical development) for Parkinson's patients which compete with ONGENTYS, including various L-dopa preparations, dopamine agonists, MAO-B inhibitors and others. In terms of potential future competition, there are several programs in late-stage clinical development.
- 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 ACTH levels. In the United States alone, there are more than two dozen companies manufacturing steroid-based products. In addition, there are several programs in clinical development targeting CAH and several companies developing medicinal treatments for CAH.
- Our investigational treatments for potential use in epilepsy may in the future compete with numerous approved anti-seizure medications 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 encephalopathies SCN8A-DEE and EE-CSWS; however, a number of different anti-seizure medications are currently used in these patient populations.
- Our investigational treatments for potential use in schizophrenia and depression may in the future compete with several development-stage programs being pursued by other companies. Currently, there are no FDA-approved treatments specifically indicated for cognitive impairment associated with schizophrenia, or CIAS; 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.

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.

****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 may require additional preclinical studies as a condition of the initiation of Phase I clinical studies, or additional clinical studies for progression from Phase I to Phase II, or Phase II to Phase III, or for NDA approval;
- the product candidate may not prove to be effective or as effective as other competing product candidates;
- we may discover that a product candidate may cause harmful side effects or results of required toxicology or other studies may not be acceptable to the FDA;
- 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 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 may not accept the data from any trial or trial site outside of the United States;
- patients may drop out of the trials;
- unforeseen disruptions or delays may occur, caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic and the conflict between Russia and Ukraine; 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. In addition, due to the impact of the COVID-19 pandemic, clinical site initiation and new patient enrollment has been negatively impacted. 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 foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Several of our planned clinical trial sites have been impacted and could be delayed or suspended as a result of the conflict between Russia and Ukraine.

In February 2022, Russia commenced a military invasion of Ukraine. We have planned clinical trial sites in both Russia and Ukraine, but no patients yet enrolled. Ongoing geopolitical turmoil and continuing military action in the region, together with widening sanctions imposed on Russia, have caused us to suspend all planned clinical trial activities in Russia and Ukraine. Alternative clinical trial sites that would fully and timely compensate for our planned clinical trial activities in Ukraine and Russia may not be available and we may need to find other countries in which to conduct such activities. Our planned clinical development timelines for valbenazine and luvadaxistat could be significantly delayed, which would increase our development costs and delay the development and/or regulatory approval process of such product candidates and jeopardize our ability to commence product sales and generate revenues.

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. We also rely on BIAL for the commercial supply of ONGENTYS. In addition, we collaborate with Xenon Pharmaceuticals, Inc. for the development of NBI-921352, Idorsia Pharmaceuticals Ltd for the development of NBI-827104, Takeda Pharmaceutical Company Limited for the development of luvadaxistat, NBI-1065845 and NBI-1065846 and Heptares Therapeutics Limited for the development of NBI-1117568.

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;
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and commercialization and may increase the cost of developing and commercializing our products or product candidates; and
- strategic collaborators could develop, either alone or with others, products or product candidates that may compete with ours.

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

We may not be able to successfully commercialize ONGENTYS.

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

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

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

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

As of September 30, 2022, we had more than 1,150 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 may take time away from running other aspects of our business, including development and commercialization of our product candidates.

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

- manage our development efforts effectively;
- integrate additional management, administrative and manufacturing personnel;
- further develop our marketing and sales organization;
- 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, ONGENTYS or any product candidate approved by the FDA.

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, ONGENTYS or any product candidate approved by the FDA. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future, along with personnel with experience marketing and selling pharmaceutical products, is critical to our success. We may be unable to attract and retain personnel on acceptable terms given effects of the COVID-19 pandemic, as well as the competition among biotechnology, pharmaceutical and health care companies, universities and non-profit research institutions for experienced scientists and individuals with experience marketing and selling pharmaceutical products. We may face particular retention challenges in light of the recent rapid growth in our personnel and infrastructure and the perceived impact of those changes upon our corporate culture. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy and our commercialization strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

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

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the commercialization of our products. We have limited experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Establishing internal commercial manufacturing capabilities would require significant time and resources, and we may not be able to timely or successfully establish such capabilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes, including INGREZZA and ONGENTYS. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products, including INGREZZA and ONGENTYS. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations, including current Good Manufacturing Practice regulations. Our third-party manufacturers, including BIAL and its suppliers, might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. Our reliance on contract manufacturers also exposes us to the following risks:

- contract manufacturers may encounter difficulties in achieving volume production, quality control or quality assurance, and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical schedules or adequately manufacture our products in commercial quantities when required;
- switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all;
- our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store or distribute our products; and
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the United States Drug Enforcement Administration, and other agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the active pharmaceutical ingredients, or API, 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 United States, state and non-United States regulations, and disruptions or delays 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. 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, under the terms of our agreement with BIAL, although we are responsible for the management of all ONGENTYS commercialization activities, we rely on BIAL and its suppliers to supply all drug product for the commercialization of ONGENTYS. BIAL relies on third-party contract manufacturers to produce ONGENTYS. These contract manufacturers may encounter difficulties in achieving volume production, quality control, or quality assurance. As a result, these contract manufacturers may not be able to adequately produce ONGENTYS in commercial quantities when required, which may impact our ability to deliver ONGENTYS on a timely basis.

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

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

We depend on independent clinical investigators and CROs to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If our independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, or not in compliance with Good Clinical Practices, it may delay or prevent the approval of our 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 do not and will not have access to all information regarding the products and product candidates we licensed to AbbVie.

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

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

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

- restrictions on the marketing or manufacturing of the product, changes in the product's label, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- 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, ONGENTYS and our other product candidates are being developed to address are in underserved and underdiagnosed populations. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who will seek treatment utilizing our products or product candidates, may not be accurate. If our estimates of the prevalence or number of patients potentially on therapy prove to be inaccurate, the market opportunities for INGREZZA, ONGENTYS and our other product candidates may be smaller than we believe they are, our prospects for generating expected revenue may be adversely affected and our business may suffer.

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

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

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

As of September 30, 2022, the conditional conversion feature of the 2024 Notes had been triggered, allowing holders of 2024 Notes to convert their 2024 Notes at any time during the period beginning on October 3, 2022 and ending at the close of business on December 30, 2022. The future conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of our common stock during the prescribed measurement periods, and as a result, it is possible that holders of 2024 Notes will continue to be entitled to convert their 2024 Notes at any time during specified periods at their option. If one or more of the holders of the 2024 Notes elects to convert their 2024 Notes, we would be required to settle the principal amount of our conversion obligation in cash, which could adversely affect our liquidity.

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

In May 2017, we sold $517.5 million aggregate principal amount of the 2024 Notes. In the fourth quarter of 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 the second quarter of 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 September 30, 2022, $170.4 million aggregate principal amount of the 2024 Notes remained outstanding. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

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

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

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

Since our inception, we have incurred significant net losses and negative cash flow from operations. As of September 30, 2022, we had an accumulated deficit of $495.8 million as a result of historical operating losses.

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

- commercialize INGREZZA for tardive dyskinesia;
- commercialize ONGENTYS for Parkinson's disease;
- seek regulatory approvals for our product candidates 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.

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

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

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

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to seasonality and timing of customer purchases and commercial sales of INGREZZA, impact of the commercial launch of ONGENTYS and ORIAHNN, royalties from out-licensed products, the impact of Medicare Part D coverage, our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing, contract research payments, fluctuations in our effective tax rate, and disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic and the conflict between Russia and Ukraine. 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, 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 United States and over 15 years for research activities conducted outside the United States. Unless the United States 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 United States.

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, changed, modified or applied adversely to us. For example, Tax Cut 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 United States tax expense.

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

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

As a result, our pre-2018 NOL carryforwards may expire prior to being used and our NOL carryforwards generated in tax years beginning after December 31, 2017, will be subject to a percentage limitation and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

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

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

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

The price of our common stock is volatile.

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market for these securities has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The COVID-19 pandemic, for example, has negatively affected the stock market and investor sentiment and has resulted in significant volatility. Furthermore, especially as we and our market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts' forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, which is based on assumptions that may be incorrect or that may change from quarter to quarter, the market price of our common stock could decline. Over the course of the last twelve months, the price of our common stock has ranged from approximately $72 per share to approximately $116 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 status and cost of our post-marketing commitments for INGREZZA;
- the results of our clinical trials;
- reports of safety issues related to INGREZZA, ONGENTYS, ORILISSA, ORIAHNN, or DYSVAL;
- developments concerning new and existing collaboration agreements;
- announcements of technological innovations or new therapeutic products by us or others;
- general economic and market conditions, including economic and market conditions affecting the biotechnology industry;
- developments in patent or other proprietary rights;
- developments related to the FDA and foreign regulatory agencies;
- 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 and developments in existing litigation matters, such as the ANDA litigation matters;
- government regulation;
- government and third-party payor coverage and reimbursement;
- failure of any of our product candidates, if approved, to achieve commercial success;
- disruptions caused by man-made or natural disasters, 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.

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 89% of our total product revenue for the nine months ended September 30, 2022 and approximately 95% of our accounts receivable balance as of September 30, 2022. If any of these significant customers becomes subject to bankruptcy, is unable to pay us for our products or is acquired by a company that wants to terminate the relationship with us, or if we otherwise lose any of these significant customers, our revenue, results of operations and cash flows would be adversely affected. Even if we replace the loss of a significant customer, we cannot predict with certainty that such transition would not result in a decline in our revenue, results of operations and cash flows.

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

We may require additional funding to continue our research and development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, and the cost of product in-licensing and any possible acquisitions. In addition, we may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources and anticipated revenues will be sufficient to satisfy our current and projected funding requirements for at least the next 12 months. However, these resources might be insufficient to conduct research and development programs, the cost of product in-taking and possible acquisitions, fully commercialize products and operate the company to the full extent currently planned. If we cannot obtain adequate funds, we may be required to significantly curtail our commercial plans or one or more of our research and development programs or obtain funds through additional arrangements with corporate collaborators or others that may require us to relinquish rights to some of our technologies or product candidates.

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

- the commercial success of INGREZZA, ONGENTYS, ORILISSA, ORIAHNN and/or DYSVAL;
- 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;
- 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 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 the fourth quarter of 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 the second quarter of 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 September 30, 2022, $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. In addition, disruptions due to the COVID-19 pandemic could make it more difficult for us to access capital. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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

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

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

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

Risks Related to Our Industry

****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 United States and internationally.

Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Accordingly, we intend to seek patent protection for our proprietary technology and compounds. However, we face the risk that we may not obtain any of these patents and that the breadth of claims we obtain, if any, may not provide adequate protection of our proprietary technology or compounds.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our commercial collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our commercial collaborators and consultants. However, if our employees, commercial collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors.

In addition, although we own a number of patents, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. In addition, potential competitors have in the past and may in the future file an 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. For example, we are currently engaged in various intellectual property litigation matters against potential competitors related to INGREZZA. Refer to Item 1. Legal Proceedings for a more detailed description of these matters. 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 United States 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 United States.

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

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care and to lower drug prices. In the United States, comprehensive health care reform legislation has been enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the United States will continue to put pressure on the pricing and reimbursement of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. Additionally, other federal and state legislation impose obligations on manufacturers of pharmaceutical products, among others, related to disclosure of new drug products introduced to the market and increases in drug prices above a specified threshold.

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

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

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive legal and political challenges to certain aspects of the ACA. For example, on June 17, 2021 the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress.

Further, prior to the United States Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and any additional healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequestration. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule finalizing the changes to the Quality Payment Program. At this time, it remains unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, on July 24, 2020, and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the United States Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of which has been delayed until January 1, 2027.

In addition, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Additionally, the IRA will, among other things, allow the Secretary of HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare Part B and Medicare Part D, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain sustained profitability or commercialize our drugs, particularly since the majority of our current revenue is derived from federal healthcare programs, including Medicare and Medicaid.

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

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

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

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal civil False Claims Act, and Civil Monetary Penalties Laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the Health Insurance Portability and Accountability Act, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses, as well as their business associates and their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), 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 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 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 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 United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

A company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of our products, including INGREZZA and ONGENTYS, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations.

If the FDA or any other governmental agency initiates an enforcement action against us, or if we are the subject of a *qui tam* suit brought by a private plaintiff on behalf of the government, and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

If our information technology systems or 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, 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 collect, use, safeguard, share, transfer and otherwise process confidential and sensitive electronic information on our networks and in our data centers. This information includes, among other things, our intellectual property and proprietary information, the confidential information of our collaborators and licensees, and the 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 breakdown, malicious intrusion, security breaches, ransomware attacks, social engineering attacks, supply-chain attacks, and other cyber-attacks. Ransomware attacks are becoming increasingly prevalent and severe. 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 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. Furthermore, if the COVID-19 pandemic requires us to reinstate a remote workforce model, our information technology systems and data will be at increased risk as more of our employees work from home, utilizing network connections outside our premises.

Additionally, natural disasters, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), terrorism, war and geopolitical conflicts (including, for example, the conflict between Russia and Ukraine) 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. Information security risks have significantly increased in recent years in part due to the proliferation of new technologies and the increased sophistication and activities of organized crime, hackers, terrorists and other external parties, including foreign private parties and state actors.

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. Our efforts to identify and remediate such vulnerabilities may not be successful and we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Further, we may be unable to detect such vulnerabilities in the future because such threats and techniques change frequently, are often sophisticated in nature and may not be detected until after a security breach has occurred.

Although to our knowledge we have not experienced any material incident or disruption to date, we and our vendors have been the target of cybersecurity incidents of this nature and expect them to continue. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events.

If we (or a third party upon whom we rely) experience a security breach or are perceived to have experienced a security breach, 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; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; 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.

Our contracts 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.

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 United States for seven years and the European Union 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 European Union, orphan exclusivity may be reduced to 6 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. For example, we are currently engaged in various intellectual property litigation matters against potential competitors related to INGREZZA. Refer to Item 1. Legal Proceedings for a more detailed description of these matters.

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

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners and vendors, or by employees of our commercial partners could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately, to maintain the confidentiality of our trade secrets or the trade secrets of our commercial partners, or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any action against our employees, independent contractors, principal investigators, consultants, commercial partners or vendors for violations of these laws could result in significant civil, criminal and administrative penalties, fines and imprisonment.

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

The use of any of our potential products in clinical trials, and the sale of any approved products, including INGREZZA and ONGENTYS, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have product liability insurance coverage for our clinical trials in the amount of $45.0 million per occurrence and $45.0 million in the aggregate. In addition, we have product liability insurance related to the sale of INGREZZA and ONGENTYS in the amount of $45.0 million per occurrence and $45.0 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability from any current or future clinical trials or approved products. A successful product liability claim, or series of claims, brought against us would decrease our cash reserves and could cause our stock price to fall. Furthermore, regardless of the eventual outcome of a product liability claim, any product liability claim against us may decrease demand for our approved products, including INGREZZA and ONGENTYS, damage our reputation, result in regulatory investigations that could require costly recalls or product modifications, cause clinical trial participants to withdrawal, result in costs to defend the related litigation, decrease our revenue, and divert management’s attention from managing our business.

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

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

****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, the number and scope of which are expanding, changing, subject to differing applications and interpretations, and may be inconsistent among countries. 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 in Europe regarding privacy, data protection, information security and the processing of personal data have been significantly reformed and continue to undergo reform. For example, the European Union's General Data Protection Regulation, or the EU GDPR, and the United Kingdom's GDPR, or the UK GDPR, impose strict requirements for processing the personal data of individuals located, respectively, within the European Economic Area, or EEA, and the United Kingdom, or the UK. The EU GDPR and the UK GDPR enhance 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 EU GDPR and the UK GDPR impose substantial fines for breaches of data protection requirements. For example, under the EU GDPR, such fines can be up to four percent of global revenue or 20 million euros, whichever is greater, and also confer a private right of action on data subjects for breaches of data protection requirements. The EU GDPR, the UK 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.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfers laws. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA, such as the United States, which the European Commission does not consider to provide an adequate level of personal data protection. If we cannot implement a valid compliance mechanism for cross-border personal data transfers, 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 United States 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.

Laws regarding privacy, data protection, information security and the processing of personal data are also becoming increasingly common in the United States at both the federal and state level. For example, the California Consumer Privacy Act, or CCPA, which went into effect in 2020, imposes obligations on businesses to which it applies. These obligations include, without limitation, providing specific disclosures in privacy notices, affording California residents certain rights related to their personal data, and requiring businesses subject to the CCPA to implement certain measures to effectuate California residents' personal data rights. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). In addition, it is anticipated that the California Privacy Rights Act of 2020, or the CPRA, effective January 1, 2023, will expand the CCPA. For example, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CCPA (as amended), which could increase the risk of an enforcement action. Other states have also enacted data privacy laws. For example, Virginia passed its Consumer Data Protection Act, Colorado passed the Colorado Privacy Act, and Utah passed the Utah Consumer Privacy Act, all of which become effective in 2023.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion. 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 to 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, additional reporting requirements and/or oversight, bans on processing personal data and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, financial condition or results of operations.

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 May 5, 2021
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
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)

* 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: November 1, 2022

/s/ Matthew C. Abernethy

Matthew C. Abernethy

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

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: November 1, 2022

/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: November 1, 2022

/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 September 30, 2022 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.

November 1, 2022

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 September 30, 2022 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.

November 1, 2022

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