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, 2020

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 93,429,153 as of November 4, 2020.

NEUROCRINE BIOSCIENCES, INC.

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Item 1. Financial Statements

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

(in millions, except per share data)	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 425.3	$ 112.3
Debt securities available-for-sale, at fair value (amortized cost $517.3 million at September 30, 2020 and $557.3 million at December 31, 2019)	519.4	558.2
Accounts receivable	156.9	126.6
Inventories	20.6	17.3
Other current assets	34.7	16.6
Total current assets	1,156.9	831.0
Debt securities available-for-sale, at fair value (amortized cost $180.3 million at September 30, 2020 and $299.3 million at December 31, 2019)	181.4	299.7
Right-of-use assets	71.0	74.3
Equity securities	43.7	55.9
Property and equipment, net	43.0	41.9
Restricted cash	3.2	3.2
Other long-term assets	3.4	—
Total assets	$ 1,502.6	$ 1,306.0
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 170.5	$ 141.3
Convertible senior notes	425.0	408.8
Other current liabilities	15.5	15.2
Total current liabilities	611.0	565.3
Operating lease liabilities	83.0	86.7
Other long-term liabilities	4.3	17.1
Total liabilities	698.3	669.1
Stockholders’ equity:		
Preferred stock, $0.001 par value; 5.0 shares authorized; no shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 220.0 shares authorized; issued and outstanding shares were 93.4 at September 30, 2020 and 92.3 at December 31, 2019	0.1	0.1
Additional paid-in capital	1,874.3	1,768.1
Accumulated other comprehensive income	3.2	1.4
Accumulated deficit	(1,073.3)	(1,132.7)
Total stockholders’ equity	804.3	636.9
Total liabilities and stockholders’ equity	$ 1,502.6	$ 1,306.0

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions, except per share data)	**2020**	**2019**	**2020**	**2019**
Revenues:				
Product sales, net	$ 254.1	$ 198.1	$ 752.8	$ 515.0
Collaboration revenue	4.4	24.0	45.2	29.0
Total revenues	258.5	222.1	798.0	544.0
Operating expenses:				
Cost of sales	2.7	2.2	7.2	4.9
Research and development	69.1	45.3	208.3	144.7
Acquired in-process research and development	118.5	—	164.5	118.1
Selling, general and administrative	112.5	84.5	326.8	252.8
Total operating expenses	302.8	132.0	706.8	520.5
Operating (loss) income	(44.3)	90.1	91.2	23.5
Other (expense) income:				
Interest expense	(8.5)	(8.0)	(25.0)	(23.8)
Unrealized loss on equity securities	(7.0)	(28.5)	(12.2)	(5.8)
Investment income and other, net	2.7	4.8	11.0	14.0
Total other expense, net	(12.8)	(31.7)	(26.2)	(15.6)
(Loss) income before provision for income taxes	(57.1)	58.4	65.0	7.9
Provision for income taxes	0.5	4.6	5.6	4.9
Net (loss) income	(57.6)	53.8	59.4	3.0
Unrealized (loss) gain on debt securities available-for-sale, net of tax	(1.4)	1.0	1.8	3.6
Comprehensive (loss) income	$ (59.0)	$ 54.8	$ 61.2	$ 6.6
Net (loss) income per share, basic	$ (0.62)	$ 0.59	$ 0.64	$ 0.03
Net (loss) income per share, diluted	$ (0.62)	$ 0.56	$ 0.61	$ 0.03
Weighted average common shares outstanding, basic	93.3	91.9	93.0	91.4
Weighted average common shares outstanding, diluted	93.3	96.1	98.0	95.2

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, 2020	93.2	$ 0.1	$ 1,842.2	$ 4.6	$ (1,015.7)	$ 831.2
Net loss	—	—	—	—	(57.6)	(57.6)
Unrealized loss on debt securities available-for-sale, net of tax	—	—	—	(1.4)	—	(1.4)
Share-based compensation expense	—	—	26.7	—	—	26.7
Issuance of common stock for stock options	0.1	—	2.5	—	—	2.5
Issuance of common stock for employee stock purchase plan	0.1	—	2.9	—	—	2.9
Balances at September 30, 2020	93.4	$ 0.1	$ 1,874.3	$ 3.2	$ (1,073.3)	$ 804.3
Balances at June 30, 2019	91.5	$ 0.1	$ 1,703.5	$ 0.6	$ (1,220.5)	$ 483.7
Net income	—	—	—	—	53.8	53.8
Unrealized gain on debt securities available-for-sale, net of tax	—	—	—	1.0	—	1.0
Share-based compensation expense	—	—	20.3	—	—	20.3
Issuance of common stock for stock options	0.5	—	13.1	—	—	13.1
Issuance of common stock for employee stock purchase plan	0.1	—	2.6	—	—	2.6
Balances at September 30, 2019	92.1	$ 0.1	$ 1,739.5	$ 1.6	$ (1,166.7)	$ 574.5
Balance at December 31, 2019	92.3	$ 0.1	$ 1,768.1	$ 1.4	$ (1,132.7)	$ 636.9
Net income	—	—	—	—	59.4	59.4
Unrealized gain on debt securities available-for-sale, net of tax	—	—	—	1.8	—	1.8
Share-based compensation expense	—	—	79.0	—	—	79.0
Issuance of common stock for vested restricted stock options	0.5	—	—	—	—	—
Issuance of common stock for stock options	0.5	—	21.6	—	—	21.6
Issuance of common stock for employee stock purchase plan	0.1	—	5.6	—	—	5.6
Balances at September 30, 2020	93.4	$ 0.1	$ 1,874.3	$ 3.2	$ (1,073.3)	$ 804.3
Balance at December 31, 2018	90.8	$ 0.1	$ 1,660.4	$ (2.0)	$ (1,177.7)	$ 480.8
Net income	—	—	—	—	3.0	3.0
Unrealized gain on debt securities available-for-sale, net of tax	—	—	—	3.6	—	3.6
Share-based compensation expense	—	—	54.0	—	—	54.0
Issuance of common stock for vested restricted stock options	0.4	—	—	—	—	—
Issuance of common stock for stock options	0.8	—	20.0	—	—	20.0
Issuance of common stock for employee stock purchase plan	0.1	—	5.1	—	—	5.1
Cumulative-effect adjustment to equity due to adoption of ASU 2016-02	—	—	—	—	8.0	8.0
Balance at September 30, 2019	92.1	$ 0.1	$ 1,739.5	$ 1.6	$ (1,166.7)	$ 574.5

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, 2020	2019
Cash Flows from Operating Activities:		
Net income	$ 59.4	$ 3.0
Reconciliation of net income to net cash provided by operating activities:		
Share-based compensation expense	79.0	54.0
Depreciation	6.4	5.4
Amortization of debt discount	15.2	14.1
Amortization of debt issuance costs	1.0	1.0
Change in fair value of equity security investments	12.2	5.8
Other	1.7	(0.7)
Change in operating assets and liabilities:		
Accounts receivable	(30.3)	(57.9)
Inventories	(3.4)	0.1
Accounts payable and accrued liabilities	28.1	12.3
Other assets and liabilities, net	(29.7)	12.4
Net cash provided by operating activities	139.6	49.5
Cash Flows from Investing Activities:		
Purchases of debt securities available-for-sale	(399.2)	(467.1)
Sales and maturities of debt securities available-for-sale	557.4	488.8
Purchases of equity securities	—	(54.7)
Purchases of property and equipment	(6.4)	(11.9)
Net cash provided by (used in) investing activities	151.8	(44.9)
Cash Flows from Financing Activities:		
Issuance of common stock	21.6	20.0
Net cash provided by financing activities	21.6	20.0
Change in cash, cash equivalents and restricted cash	313.0	24.6
Cash, cash equivalents and restricted cash at beginning of period	115.5	147.2
Cash, cash equivalents and restricted cash at end of period	$ 428.5	$ 171.8
Supplemental Disclosure:		
Non-cash capital expenditures	$ 1.1	$ 0.1
Cash paid for interest	$ 5.8	$ 5.8
Cash paid for income taxes	$ 0.4	$ 0.5

See accompanying notes to the condensed consolidated financial statements.

1. Organization and Significant Accounting Policies

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

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

Basis of Presentation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the US, 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, 2019, included in our Annual Report on Form 10-K, or the 2019 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 at December 31, 2019, has been derived from the audited financial statements as of that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

There were no significant changes to our significant accounting policies as disclosed in the 2019 Form 10-K, except as set forth below.

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

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

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

Accrued interest receivables on debt securities available-for-sale totaled $3.5 million at September 30, 2020. We do not measure an allowance for credit losses for accrued interest receivables. For the purposes of identifying and measuring an impairment, accrued interest is excluded from both the fair value and amortized cost basis of the debt security. Uncollectible accrued interest receivables associated with an impaired debt security are reversed against interest income upon identification of the impairment. No accrued interest receivables were written off during the nine months ended September 30, 2020.

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

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

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

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

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

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

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

Recently Adopted Accounting Pronouncements.

ASU 2016-13. On January 1, 2020, we adopted Accounting Standards Update, or ASU, 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* using the modified retrospective transition method. For debt securities available-for-sale, the standard requires an investor to determine whether a decline in the fair value below the amortized cost basis of the investment is due to credit-related factors. Credit-related impairment is recognized as an allowance for credit loss on the balance sheet with a corresponding adjustment to earnings. Credit losses are limited to the amount by which the investment's amortized cost basis exceeds its fair value and may be subsequently reversed if conditions change. Any impairment that is not credit related is recognized in other comprehensive income or loss, as applicable, net of applicable taxes.

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

Recently Issued Accounting Pronouncements.

ASU 2019-12. In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application of Topic 740. ASU 2019-12 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years, with early adoption permitted in any interim period for which financial statements have not yet been made available for issuance. We are currently evaluating the effect ASU 2019-12 will have on our condensed consolidated financial statements and related disclosures.

ASU 2020-06. In August 2020, the FASB issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments, and amends existing earnings-per-share, or EPS, guidance by requiring that an entity use the if-converted method when calculating diluted EPS for convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal

years, with early adoption permitted for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. We are currently evaluating the effect ASU 2020-06 will have on our condensed consolidated financial statements and related disclosures.

2. Significant Collaboration and Licensing Agreements

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

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

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

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

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

Idorsia. In May 2020, we entered a collaboration and licensing agreement with Idorsia to license 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. The agreement also included a research collaboration to discover and identify additional novel T-type calcium channel blockers as development candidates.

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

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

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

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

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

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

Voyager. In the first quarter of 2019, we entered into a collaboration and license agreement with Voyager, a clinical-stage gene therapy company. The agreement is focused on the development and commercialization of four programs using Voyager's proprietary gene therapy platform. The four programs consist of the NBIb-1817 program for Parkinson's disease, the Friedreich's ataxia program and the rights to two undisclosed programs.

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

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

BIAL – Portela & Ca, S.A. In the first quarter of 2017, we entered into an exclusive license agreement with BIAL – Portela & Ca, S.A., or BIAL, for the development and commercialization of ONGENTYS for the treatment of human diseases and conditions, including Parkinson's disease, in the US and Canada.

In April 2020, we received FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients, which was commercialized by our commercial team in late September 2020. FDA approval for ONGENTYS for Parkinson's disease triggered a milestone payment of $20.0 million, which was expensed

as R&D in the second quarter of 2020. Pursuant to the terms of the agreement, BIAL may also be entitled to receive up to $75.0 million upon the achievement of certain commercial milestones.

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

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

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

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

Mitsubishi Tanabe Pharma Corporation. In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation, or MTPC, for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets.

For the three and nine months ended September 30, 2020, we recognized revenue of $0.5 million and $1.8 million, respectively, in connection with the ongoing KINECT-HD study, a placebo-controlled Phase III study of valbenazine in adult Huntington's disease patients with chorea. In accordance with our continuing performance obligations, $7.6 million of the $30.0 million upfront payment received from MTPC in connection with the agreement is being deferred and will be recognized as revenue over the KINECT-HD study period using an input method according to costs incurred to-date relative to estimated total costs associated with the study.

Since inception of the agreement, we have recognized revenue of $19.8 million associated with the delivery of a technology license and existing know-how, $15.0 million associated with the achievement of a certain development milestones, and $2.6 million associated with our performance of the ongoing KINECT-HD study. Pursuant to the terms of the agreement, we may also be entitled to receive payments of up to $70.0 million upon the achievement of certain regulatory and commercial milestones, receive payments for the manufacture of certain pharmaceutical products, as well as receive royalties on the net sales of collaboration products in select territories in Asia.

Under the terms of the agreement, MTPC is responsible for all third-party development, marketing, and commercialization costs in Japan and other select Asian markets and we would be entitled to a percentage of sales of INGREZZA in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights. Further, the collaboration effort between the parties to advance INGREZZA towards commercialization in Japan and other select Asian markets is governed by joint steering and development committees with representatives from both parties. There are no performance, cancellation, termination, or refund provisions in the agreement that would have a material financial consequence to us. We do not directly control when event-based payments will be achieved or when royalty payments will begin. MTPC may terminate the agreement at its discretion upon 180 days' written notice to us. In such event, all INGREZZA product rights for Japan and other select Asian markets would revert to us.

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

AbbVie received approval of ORILISSA for the management of moderate to severe endometriosis pain in women from the FDA in July 2018 and Health Canada in October 2018.

In May 2020, AbbVie received approval from the FDA for ORIAHNN for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. FDA approval for ORIAHNN for uterine fibroids resulted in the achievement of a $30.0 million regulatory milestone, which was recognized as collaboration revenue in the second quarter of 2020.

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

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

3. Debt Securities

The following table summarizes the amortized cost, unrealized gain and loss recognized in accumulated other comprehensive income (loss), allowance for credit losses, and fair value of debt securities available-for-sale at September 30, 2020, aggregated by major security type and contractual maturity:

(in millions)	Contractual Maturity	Amortized Cost	Unrealized Gain	Unrealized Loss	Allowance for Credit Losses	Fair Value
Commercial paper	Within 1 year	$ 104.8	$ —	$ —	—	$ 104.8
Corporate debt securities	Within 1 year	283.6	1.7	—	—	285.3
Securities of government-sponsored entities	Within 1 year	128.9	0.4	—	—	129.3
		$ 517.3	$ 2.1	$ —	$ —	$ 519.4
Corporate debt securities	1 to 2 years	$ 142.8	$ 1.2	$ (0.1)	—	$ 143.9
Securities of government-sponsored entities	1 to 2 years	37.5	—	—	—	37.5
		$ 180.3	$ 1.2	$ (0.1)	$ —	$ 181.4

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

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

The following table summarizes debt securities available-for-sale in an unrealized loss position for which an allowance for credit losses has not been recorded at September 30, 2020, aggregated by major security type and length of time in a continuous unrealized loss position:

	Less Than 12 Months		12 Months or Longer		Total	
(in millions)	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate Debt Securities	$ 39.8	$ (0.1)	$ —	$ —	$ 39.8	$ (0.1)

At September 30, 2020, our security portfolio consisted of 143 securities related to investments in debt securities available-for-sale, of which 14 securities were in an unrealized loss position.

Our investments in corporate debt securities in an unrealized loss position at September 30, 2020 are of high credit quality (rated A- or higher). Unrealized losses on these investments were primarily due to changes in interest rates. We do not intend

to sell these investments and it is not more likely than not that we will be required to sell these investments before recovery of their amortized cost basis.

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

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

4. Fair Value Measurements

Investments at September 30, 2020, which were measured at fair value on a recurring basis, consisted of the following:

		Fair Value Measurements Using		
(in millions)	Fair Value	Level 1	Level 2	Level 3
Cash and cash equivalents:				
Cash and money market funds	$ 425.3	$ 425.3	$ —	$ —
Total cash and cash equivalents	425.3	425.3	—	—
Restricted cash:				
Certificates of deposit	3.2	3.2	—	—
Total restricted cash	3.2	3.2	—	—
Debt securities available-for-sale:				
Commercial paper	104.8	—	104.8	—
Corporate debt securities	429.2	—	429.2	—
Securities of government-sponsored entities	166.8	—	166.8	—
Total debt securities available-for-sale	700.8	—	700.8	—
Equity securities:				
Equity securities–biotechnology industry	43.7	—	—	43.7
Total equity securities	43.7	—	—	43.7
Total recurring fair value measurements	$ 1,173.0	$ 428.5	$ 700.8	$ 43.7

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2020	2019	2020	2019
Balance at beginning of period	$ 50.7	$ 77.4	$ 55.9	$ —
Purchases	—	—	—	54.7
Unrealized loss included in earnings	(7.0)	(28.5)	(12.2)	(5.8)
Balance at end of period	$ 43.7	$ 48.9	$ 43.7	$ 48.9

At September 30, 2020, the discount for lack of marketability used in the valuation analysis of equity securities ranged from 16.0% to 31.5% (weighted average of 26.8%). The discount for lack of marketability was weighted by the relative fair value of the instruments. A significant increase (decrease) in the discount for lack of marketability in isolation would result in a significantly lower (higher) fair value measurement. Unrealized gains and losses on equity securities are included in other income (expense), net.

5. Inventories

Inventories consisted of the following:

(in millions)	September 30, 2020	December 31, 2019
Raw materials	$ 14.8	$ 14.1
Work in process	1.0	1.5
Finished goods	4.8	1.7
Total inventories	$ 20.6	$ 17.3

6. Cash, Cash Equivalents and Restricted Cash

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

(in millions)	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 425.3	$ 112.3
Restricted cash	3.2	3.2
Total cash, cash equivalents and restricted cash	$ 428.5	$ 115.5

7. Leases

Operating leases consisted of the following:

Address	Type	Square Feet	Commencement Date	Expiration Date
12780 El Camino Real [(1)]	Office/Laboratory	141,000	August 7, 2019	July 31, 2031
12790 El Camino Real, Suite 130 [(1)]	Office	2,000	December 1, 2019	July 31, 2031
12790 El Camino Real, Suite 150 [(1)]	Office	8,000	August 7, 2019	July 31, 2031
12790 El Camino Real, Suite 300 [(1)]	Office	28,000	December 1, 2019	July 31, 2031
12777 High Bluff Drive	Office	45,000	July 1, 2018	July 31, 2029
12790 El Camino Real, Suite 200 [(1)]	Office	28,000	February 1, 2021	July 31, 2031
12790 El Camino Real, Suite 100 [(1)]	Office	17,000	February 1, 2021	July 31, 2031

(1) Under the terms of the 12780/12790 El Camino Real master lease, we have two options to extend the term of the lease for a period of ten years each. We were not reasonably certain to exercise either of these options at lease commencement. As such, neither option was recognized as part of the associated operating lease right-of-use asset or liability.

Note: In connection with our operating leases, in lieu of cash security deposits, Wells Fargo Bank, N.A., issued letters of credit on our behalf, which are secured by deposits totaling $3.2 million.

Our operating lease cost was $7.4 million and $5.9 million for the nine months ended September 30, 2020 and 2019, respectively. Cash paid for amounts in the measurement of lease liabilities for operating cash flows from operating leases was $6.4 million and $5.5 million for the nine months ended September 30, 2020 and 2019, respectively.

Our operating leases had a weighted average remaining lease term of approximately 10.5 years and 11.2 years at September 30, 2020 and December 31, 2019, respectively, and a weighted average discount rate of 5.8% at September 30, 2020 and December 31, 2019, respectively.

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

(in millions)	September 30, 2020
Year ending December 31, 2020 (3 months remaining)	$ 2.1
Year ending December 31, 2021	10.6
Year ending December 31, 2022	10.9
Year ending December 31, 2023	11.2
Year ending December 31, 2024	11.6
Thereafter	79.7
Total operating lease payments	126.1
Less accreted interest	33.4
Total operating lease liabilities	92.7
Less current operating lease liabilities	9.7
Noncurrent operating lease liabilities	$ 83.0

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

8. Convertible Senior Notes

On May 2, 2017, we completed a private placement of $517.5 million in aggregate principal amount of 2.25% convertible senior notes due 2024 and entered into an indenture agreement, or the 2024 Indenture, with respect to the 2024 Notes. The 2024 Notes accrue interest at a fixed rate of 2.25% per year, payable semiannually in arrears on May 15 and November 15 of each year, beginning on November 15, 2017. The 2024 Notes mature on May 15, 2024. The net proceeds from the issuance of the 2024 Notes were approximately $502.8 million, after deducting commissions and the offering expenses payable by us.

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

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

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

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

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

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

As the conditional conversion feature described under (i) above had been triggered as of September 30, 2020, holders of the 2024 Notes may convert the 2024 Notes at any time during the period beginning on October 1, 2020 and ending at the close of business on December 31, 2020. Accordingly, the 2024 Notes have been classified as a current liability as of September 30, 2020. The future conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of our common stock during the prescribed measurement periods.

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

It is our intent and policy to settle conversions through combination settlement, which essentially involves repayment of an amount of cash equal to the "principal portion" and delivery of the "share amount" in excess of the principal portion in shares of common stock or cash. In general, for each $1,000 in principal, the "principal portion" of cash upon settlement is defined as the lesser of $1,000, and the conversion value during the 25-day observation period as described in the 2024 Indenture. The conversion value is the sum of the daily conversion value which is the product of the effective conversion rate divided by 25 days and the daily volume weighted average price, or VWAP, of our common stock. The "share amount" is the cumulative "daily share amount" during the observation period, which is calculated by dividing the daily VWAP into the difference between the daily conversion value (i.e., conversion rate x daily VWAP) and $1,000.

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

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

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

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

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

We are required to separately account for the liability and equity components of the 2024 Notes as they may be settled entirely or partially in cash upon conversion in a manner that reflects our economic interest cost. The liability component of the instrument was valued in a manner that reflects the market interest rate for a similar nonconvertible instrument at the date of issuance. The initial carrying value of the liability component of $368.3 million was calculated using a 7.5% assumed borrowing rate. The equity component of $149.2 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the 2024 Notes and was recorded in additional paid-in capital on the consolidated balance sheet at the issuance date. That equity component is treated as a discount on the liability component of the 2024 Notes, which is amortized over the seven-year term of the 2024 Notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. At September 30, 2020, the remaining period over which the discount on the liability component will be amortized was approximately 3.6 years.

We allocated the total transaction costs of approximately $14.7 million related to the issuance of the 2024 Notes to the liability and equity components of the 2024 Notes based on their relative values. Transaction costs attributable to the liability

component are amortized to interest expense over the seven-year term of the 2024 Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity.

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

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

(in millions)	September 30, 2020	December 31, 2019
Principal	$ 517.5	$ 517.5
Deferred financing costs	(5.9)	(6.9)
Debt discount, net	(86.6)	(101.8)
Net carrying amount	$ 425.0	$ 408.8

The 2024 Notes were recorded at the estimated value of a similar non-convertible instrument on the date of issuance and accretes to the face value of the 2024 Notes over their seven-year term. The fair value of the 2024 Notes, which was estimated utilizing market quotations from an over-the-counter trading market (Level 2), was $713.0 million at September 30, 2020 and $596.8 million at December 31, 2019.

9. Net (Loss) Income Per Share

Net (loss) income per share was calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions, except per share data)	2020	2019	2020	2019
Net (loss) income - basic and diluted	$ (57.6)	$ 53.8	$ 59.4	$ 3.0
Weighted-average common shares outstanding:				
Basic	93.3	91.9	93.0	91.4
Effect of dilutive securities:				
Stock options	—	2.5	2.5	2.6
Restricted stock	—	0.5	0.5	0.4
2024 Notes	—	1.3	2.0	0.8
Diluted	93.3	96.1	98.0	95.2
Net (loss) income per share:				
Basic	$ (0.62)	$ 0.59	$ 0.64	$ 0.03
Diluted	$ (0.62)	$ 0.56	$ 0.61	$ 0.03

Convertible debt instruments that may be settled entirely or partly in cash (such as the 2024 Notes) may, in certain circumstances where the borrower has the ability and intent to settle in cash, be accounted for under the treasury stock method. We issued the 2024 Notes with a combination settlement feature, which we have the ability and intent to use upon conversion of the 2024 Notes, to settle the principal amount of debt for cash and the excess of the principal portion in shares of our common stock. As a result, of the approximately 6.8 million shares underlying the 2024 Notes, only the shares required to settle the excess of the principal portion are considered under the treasury stock method.

Shares which have been excluded from diluted per share amounts because their effect would have been anti-dilutive were 10.9 million and 1.8 million for the three and nine months ended September 30, 2020, respectively, and 2.3 million and 2.2 million for the three and nine months ended September 30, 2019, respectively.

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, 2019 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, 2019 and our Quarterly Report on Form 10-Q for the six months ended June 30, 2020.

Overview

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

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

In April 2020, we received FDA approval for ONGENTYS® (opicapone) as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients, which was commercialized by our commercial team in late September 2020.

Our collaboration partner, AbbVie Inc., or AbbVie, received approval of ORILISSA® (elagolix) for the management of moderate to severe endometriosis pain in women from the FDA in July 2018 and Health Canada in October 2018. In May 2020, AbbVie received approval from the FDA for ORIAHNN™ (elagolix) for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. We receive royalties at tiered percentage rates on any net sales of ORILISSA and ORIAHNN.

Also in May 2020, we entered into a collaboration and licensing agreement with Idorsia Pharmaceuticals Ltd, or Idorsia. In connection with the agreement, we paid Idorsia $45.0 million upfront to gain a license 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. The agreement includes a research collaboration to discover and identify additional novel T-type calcium channel blockers as development candidates.

In June 2020, we entered into an exclusive license agreement with Takeda Pharmaceutical Company Limited, or Takeda, which became effective in July 2020. The agreement is focused on the development and commercialization of certain compounds in Takeda's early to mid-stage psychiatry pipeline. In connection with the agreement, we paid Takeda $120.0 million upfront to gain an exclusive license to seven of Takeda's pipeline programs, including three clinical-stage assets for schizophrenia, treatment-resistant depression, and anhedonia. The collaboration also includes a cost-sharing arrangement for certain collaboration activities.

Our late-stage pipeline includes valbenazine for the treatment of chorea in adult patients with Huntington's disease, or HD, crinecerfont (NBI-74788) for the treatment of congenital adrenal hyperplasia, or CAH, in adult patients, and NBIb-1817 (VY-AADC) for the treatment of advanced Parkinson's disease patients with motor fluctuations that are refractory to medical management. Our product candidate for advanced Parkinson's disease is partnered with Voyager Therapeutics, Inc., or Voyager.

Our early-stage clinical pipeline includes crinecerfont for the treatment of CAH in pediatric patients, elagolix for the treatment of polycystic ovary syndrome, or PCOS, in women, NBI-1065844 (TAK-831) for the treatment of schizophrenia, NBI-1065845 (TAK-653) for the treatment of treatment-resistant depression, NBI-1065846 (TAK-041) for the treatment of anhedonia in depression, NBI-921352 (XEN901) for the treatment of epilepsy, and NBI-827104 (ACT-709478) for the treatment of a rare pediatric epilepsy. Our product candidate for PCOS is partnered with AbbVie.

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

COVID-19

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

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

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

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

Results of Operations for the Three and Nine Months Ended September 30, 2020 and 2019

Revenues

The following table presents revenues by category.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2020**	**2019**	**2020**	**2019**
Product sales, net	$ 254.1	$ 198.1	$ 752.8	$ 515.0
Collaboration revenue	4.4	24.0	45.2	29.0
Total revenues	$ 258.5	$ 222.1	$ 798.0	$ 544.0

Product Sales, Net. Net product sales were $254.1 million and $752.8 million for the three and nine months ended September 30, 2020, respectively, compared with $198.1 million and $515.0 million in the comparable periods last year, reflecting increased INGREZZA net product sales primarily driven by new patient additions. ONGENTYS net product sales were $0.1 million for the three and nine months ended September 30, 2020.

Collaboration Revenue. Collaboration revenue reflects the achievement of certain development, regulatory and commercial milestones, royalties received on any net sales of ORILISSA and ORIAHNN and license fees earned under our collaboration agreements with AbbVie and Mitsubishi Tanabe Pharma Corporation, or MTPC. Collaboration revenue was $4.4 million and $45.2 million for the three and nine months ended September 30, 2020, respectively, compared with $24.0 million and $29.0 million in the comparable periods last year, primarily reflecting the achievement of a $30.0 million regulatory milestone associated with AbbVie's receipt of FDA approval for ORIAHNN for uterine fibroids in May 2020.

Operating Expenses

Cost of Sales. Cost of sales was $2.7 million and $7.2 million for the three and nine months ended September 30, 2020, respectively, compared with $2.2 million and $4.9 million in the comparable periods last year.

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

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

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

The following table presents R&D expense by category:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	**2020**	**2019**	**2020**	**2019**
Late stage	$ 15.3	$ 10.5	$ 41.4	$ 29.6
Early stage	9.8	5.4	20.0	18.0
Research and discovery	11.7	6.0	31.6	16.8
Milestone expenses	—	—	20.0	10.0
Payroll and benefits	24.8	17.9	73.9	50.7
Facilities and other	7.5	5.5	21.4	19.6
Total R&D expense	$ 69.1	$ 45.3	$ 208.3	$ 144.7

R&D expense was $69.1 million and $208.3 million for the three and nine months ended September 30, 2020, respectively, compared with $45.3 million and $144.7 million in the comparable periods last year, primarily reflecting increased investment to support advancing our expanded clinical portfolio and increased personnel expenses on higher headcount.

Acquired In-Process Research and Development. In connection with the payment of the upfront fee pursuant to our collaboration and license agreement with Idorsia, we recorded a charge of $46.0 million, accounted for as in-process research and development, or IPR&D, in the second quarter of 2020. In the third quarter of 2020, we recorded a charge of $118.5 million, accounted for as IPR&D, in connection with the payment of the upfront fee pursuant to our exclusive license agreement with Takeda. In connection with the payments of the upfront fees pursuant to our collaboration and license agreement with Voyager, we recorded charges of $118.1 million, accounted for as IPR&D, in the first nine months of 2019.

Sales, General and Administrative. Sales, general and administrative, or SG&A, expense was $112.5 million and $326.8 million for the three and nine months ended September 30, 2020, respectively, compared with $84.5 million and $252.8 million in the comparable periods last year, primarily reflecting increased personnel expenses on higher headcount and continued investment in INGREZZA marketing.

Other Expense, Net

Other expense, net, was $12.8 million and $31.7 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020, other expense, net, was $26.2 million, compared with $15.6 million in the comparable period last year. Periodic fluctuations in other expense, net, primarily reflect unrealized gains or losses recognized to adjust our equity investments in Voyager and Xenon Pharmaceuticals Inc. to fair value.

Provision for Income Taxes

Our provision for income taxes was $0.5 million and $5.6 million for the three and nine months ended September 30, 2020, respectively, compared with $4.6 million and $4.9 million in the comparable periods last year. At September 30, 2020 and 2019, we had full valuation allowances against our net deferred tax assets as realization was uncertain. As a result, tax expense for the three and nine months ended September 30, 2020 and 2019, respectively, varies from the statutory tax rate primarily due to changes in our valuation allowances, net of other permanent book/tax differences, tax credits generated and impacts of changes in tax laws.

Net (Loss) Income

We incurred a net loss of $57.6 million, or $0.62 diluted net loss per share, for the three months ended September 30, 2020, compared with net income of $53.8 million, or $0.56 diluted earnings per share, in the comparable period last year. For the

nine months ended September 30, 2020, net income was $59.4 million, or $0.61 diluted earnings per share, compared with $3.0 million, or $0.03 diluted earnings per share, in the comparable period last year.

Liquidity and Capital Resources

At September 30, 2020, our cash and cash equivalents and debt securities available-for-sale totaled $1.1 billion compared with $970.2 million at December 31, 2019.

Net cash provided by operating activities was $139.6 million for the nine months ended September 30, 2020, compared with $49.5 million in the comparable period last year, primarily reflecting increased INGREZZA net product sales offset partially by increased upfront payments in connection with our collaborations with Idorsia and Takeda.

Net cash provided by investing activities was $151.8 million for the nine months ended September 30, 2020, compared with net cash used in investing activities of $44.9 million in the comparable period last year, reflecting timing differences related to purchases, sales and maturities of debt securities available-for-sale, changes in our portfolio-mix, and an equity investment of $54.7 million in Voyager in March 2019.

Net cash provided by financing activities was $21.6 million for the nine months ended September 30, 2020, compared with $20.0 million in the comparable period last year, reflecting proceeds from issuances of our common stock.

Convertible Senior Notes. In May 2017, we issued $517.5 million of 2.25% convertible senior notes due May 15, 2024.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements at September 30, 2020 or 2019.

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, 2019.

Interest Rate Risk

We are exposed to interest rate risk on our short-term investments. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high-quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum average maturity of our investments does not exceed twelve months. If a 1% change in interest rates were to have occurred on September 30, 2020, it would not have had a material effect on the fair value of our investment portfolio as of that date. Due to the short holding period of our investments, we have concluded that we do not have a material financial market risk exposure.

Recently Issued Accounting Pronouncements

For a summary of new accounting pronouncements which may be applicable to us, see Note 1 to the condensed consolidated financial statements included in this report.

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, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

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, 2019.

Summary Risk Factors

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

- We may not be able to successfully commercialize INGREZZA, ONGENTYS, or any of our product candidates if they are approved in the future.
- If physicians and patients do not continue to accept INGREZZA or do not accept ONGENTYS or any of our other products, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.
- Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products that could limit our product revenues and delay sustained profitability.
- Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have significant sales and marketing efforts or manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.
- Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.
- Our clinical 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.
- 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, including INGREZZA, ONGENTYS, ORILISSA, and ORIAHNN could be associated with side effects or adverse events.
- We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced.
- We currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA, ONGENTYS or any of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed, and our costs may rise.
- We currently depend on a limited number of third-party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA or ONGENTYS, could materially and adversely affect our ability to successfully commercialize INGREZZA or ONGENTYS.
- If we are unable to retain and recruit qualified scientists or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts or impact our commercialization of INGREZZA, ONGENTYS or any product candidate approved by the FDA.
- We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, or violate the terms of these licenses, we could lose our rights to those technologies and drug candidates or be forced to pay damages.
- Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations.

- We have a history of losses and expect to increase our expenses for the foreseeable future, and we may not be able to sustain profitability.
- We have recently increased the size of our organization and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.
- Our customers are concentrated and therefore the loss of a significant customer may harm our business.
- If we cannot raise additional funding, we may be unable to complete development of our product candidates or establish commercial and manufacturing capabilities in the future.
- Health care reform measures and other recent legislative initiatives could adversely affect our business.
- If we are unable to protect our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

Risks Related to Our Company

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

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

In addition, our business has been and may continue to be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic. Most hospitals, community mental health facilities, and other healthcare facilities have implemented policies that limit access of our sales representatives, medical affairs personnel, and patients to such facilities. Due to these closures and our work from home decisions, our field force is currently functioning utilizing digital and telephonic engagement tools and tactics, which may be less effective than our ordinary course sales and marketing programs. 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 any of our other products, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.

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

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

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

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

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

Our ability to commercialize any products successfully, including INGREZZA and 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 through various means may reduce our potential revenues. These payors' efforts could decrease the price that we receive for any products we may develop and sell in the future.

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

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the US. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. In addition, communications from government officials regarding health care costs and pharmaceutical pricing could have a negative impact on our stock price, even if such communications do not ultimately impact coverage or reimbursement decisions for our products.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, gene therapy treatments, which we are developing pursuant to our collaboration and license agreement with Voyager, face additional uncertainty related to pricing and reimbursement. As an example, there are a limited number of gene therapy products currently approved for coverage and reimbursement by the Centers for Medicare & Medicaid Services, or CMS.

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

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

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

conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations due to COVID-19 could negatively impact our business, operating results and financial condition.

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

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

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

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

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

All of our product candidates are currently in research or clinical development with the exceptions of INGREZZA, which has been approved by the FDA for TD, ONGENTYS, which has been approved by the FDA for Parkinson's disease, ORILISSA (partnered with AbbVie), which has been approved by the FDA for the management of moderate to severe endometriosis pain in women, and ORIAHNN (partnered with AbbVie), which has been approved by the FDA for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. Only a small number of research and development programs ultimately result in commercially successful drugs. In addition, to date the FDA has granted regulatory approval for only a very limited number of gene therapy products. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

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

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

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

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

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

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

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

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

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

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

Our strategy for fully developing and commercializing ORILISSA and ORIAHNN is dependent upon maintaining our current collaboration agreement with AbbVie. This collaboration agreement provides for significant future payments should certain development, regulatory and commercial milestones be achieved, and royalties on future sales of elagolix. Under this agreement, AbbVie is responsible for, among other things, conducting clinical trials and obtaining required regulatory approvals for elagolix; as well as manufacturing and commercialization of ORILISSA and ORIAHNN.

Because of our reliance on AbbVie for the commercialization and continued development of ORILISSA and ORIAHNN, there could be substantial impairments if AbbVie:

- does not successfully commercialize ORILISSA for endometriosis or ORIAHNN for uterine fibroids;
- does not conduct its collaborative activities in a timely manner;
- does not devote sufficient time and resources to our partnered programs;

- terminates its agreement with us;
- develops, either alone or with others, products that may compete with elagolix;
- disputes our respective allocations of rights to any products or technology developed during our collaboration; or
- merges with a third party that wants to terminate our agreement.

In addition, we are a party to several other collaboration and license agreements, including our agreements with BIAL, MTPC, Voyager, Xenon, Idorsia and Takeda. These collaborations are subject to risks and uncertainties similar to those described above. In some situations, we may not be able to influence our collaboration partners' decisions regarding the development and collaboration of our partnered product products 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. We may also need to enter into other licensing collaborations to assist in the development and commercialization of other product candidates we are developing now or may develop in the future, and any such future collaborations would be subject to similar risks and uncertainties.

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

We may not be able to successfully commercialize ONGENTYS.

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

Use of our approved products or those of our collaborators, including INGREZZA, ONGENTYS, ORILISSA, and ORIAHNN could be associated with side effects or adverse events.

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

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

Gene therapy remains a novel technology, with few gene therapy products approved to date in the US. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the

medical community. As part of our collaboration and license agreement with Voyager, RESTORE-1, a Phase II clinical trial of NBIb-1817, is being conducted. There is no guarantee that this program or other collaboration gene therapy product candidates will not be placed on clinical hold by the FDA, as has been the case for many gene therapy clinical programs. In November 2020, the Drug Safety Monitoring Board reviewed certain patient imaging data, and asked for additional patient data as well as recommended that we discontinue dosing of subjects in the RESTORE-1 clinical trial until these additional data can be reviewed. Based in part on the data, we are preparing an expedited IND safety report. Even if we are able to successfully complete clinical development of a gene therapy product and obtain commercial approval, the success of our collaboration with Voyager will depend upon physicians who specialize in the treatment of genetic diseases targeted by gene therapy product candidates, prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations, negative public opinion related to gene therapy products, or safety issues identified in our clinical trials may delay or impair the development and commercialization of our gene therapy product candidates or demand for any gene therapy products we develop.

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

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

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

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

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

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

Competition may also arise from, among other things:

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

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

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

- With respect to INGREZZA for TD, we compete with Teva Pharmaceutical Industries, which received FDA approval for AUSTEDO to treat TD in August 2017, and several clinical development-stage programs targeting TD and related movement disorders. Additionally, there are a number of commercially available medicines used to treat TD off-label, such as Xenazine (tetrabenazine) and generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin.
- In endometriosis, ORILISSA and ORIAHNN each compete with several FDA-approved products for the treatment of endometriosis, uterine fibroids, infertility, and central precocious puberty. Additionally, there is also competition

from surgical intervention, including hysterectomies and ablations. Separate from these options, there are many programs in clinical development which serve as potential future competition. Lastly, there are numerous medicines used to treat the symptoms of disease (vs. endometriosis or uterine fibroids directly) which may also serve as competition: oral contraceptives, NSAIDs and other pain medications including opioids.

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

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

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

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

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

- contract manufacturers may encounter difficulties in achieving volume production, quality control or quality assurance, and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical schedules or adequately manufacture our products in commercial quantities when required;
- switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly on acceptable terms, or at all;

- our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to successfully produce, store or distribute our products; and
- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the US Drug Enforcement Administration, and other agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

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

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

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

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, changes in the product's label, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- product injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

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

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

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

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

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

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

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

The conditional conversion feature of the 2024 Notes was triggered as of September 30, 2020, meaning holders of 2024 Notes are entitled to convert their 2024 Notes at any time during the period beginning on October 1, 2020, and ending at the close of business on December 31, 2020. The conditional conversion feature may also be triggered again in the future. If one or more of the holders of the 2024 Notes elects to convert their notes, unless we satisfy our conversion obligation by

delivering only shares of our common stock, we would be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. The 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.

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

Since our inception, we have incurred significant net losses and negative cash flow from operations. At December 31, 2019, we had an accumulated deficit of $1.1 billion as a result of historical operating losses.

In April 2017, we received FDA approval of INGREZZA for TD. In July 2018, our partner AbbVie received FDA approval for ORILISSA for the management of moderate to severe endometriosis pain in women. In April 2020, we received FDA approval of ONGENTYS for Parkinson's disease. In May 2020, our partner AbbVie received FDA approval for ORIAHNN for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. 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 TD;
- commercialize ONGENTYS for Parkinson's disease;
- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our product candidates;
- in-license or acquire new product development opportunities;
- implement additional internal systems and infrastructure; and
- hire additional clinical, scientific, sales and marketing personnel.

We expect to increase our expenses and other investments in the coming years as we fund our operations, in-licensing or acquisition opportunities, and capital expenditures. While we were profitable for the nine months ended September 30, 2020, we were not profitable for the three months ended September 30, 2020, and our future operating results and profitability may fluctuate from period to period due to the factors described above, and we will need to generate significant revenues to achieve and maintain profitability and positive cash flow on a sustained basis. We may not be able to generate these revenues, and we may never achieve profitability on a sustained basis in the future. Our failure to maintain or increase profitability on a sustained basis could negatively impact the market price of our common stock.

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

At September 30, 2020, we had approximately 825 full-time employees. Although we have substantially increased the size of our organization, we may need to add additional qualified personnel and resources, especially now that we have a commercial sales force. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates.

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

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

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

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

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

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

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to seasonality and timing of customer purchases and commercial sales of INGREZZA, impact of the commercial launch of ONGENTYS and ORIAHNN, royalties from out-licensed products, the impact of Medicare Part D coverage, our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing, contract research payments and disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic. A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect financial results in a quarter. While we were not profitable for the three months ended September 30, 2020, our future operating results and profitability may fluctuate from period to period, and even if we become profitable on a quarterly or annual basis, we may not be able to sustain or increase our profitability. Moreover, as our company and our market capitalization have grown, our financial performance has become increasingly subject to quarterly and annual comparisons with the expectations of securities analysts or investors. The failure of our financial results to meet these expectations, either in a single quarterly or annual period over a sustained period time, could cause our stock price to decline.

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

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

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

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

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

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

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

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

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

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

- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic; and
- public concern as to the safety of our drugs.

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

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

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

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

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

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

We intend to seek additional funding through strategic alliances and may seek additional funding through public or private sales of our securities, including equity securities. In addition, during the second quarter of 2017, we issued the 2024 Notes and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. 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 sales, general and administrative expenses and management time related to compliance activities. If we fail to comply with these laws, regulations and standards, our reputation may be harmed, and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

Risks Related to Our Industry

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

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the US, comprehensive health care reform legislation was enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the US will continue to put pressure on the rate of adoption and pricing of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. Additionally, other federal and state legislation imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers are required to provide certain information regarding the drug product provided to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding distribution of the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, notification and purchaser license verification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

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

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

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

There remain legal and political challenges to certain aspects of the ACA. Since January 2017, several executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA have been put into place. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a US District Court Judge in Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the US Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. However, the Medicare sequester reductions under the BBA will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the current presidential administration's budget proposal for the 2021 fiscal year includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the current presidential administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The US Department of Health and Human Services, or HHS, has solicited feedback on certain of these measures and, additionally, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, the Trump

administration announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their business

associates and their 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, as defined by such law, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; state and local "drug take back" laws and regulations; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

In addition, any sales of our product once commercialized outside the US 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 US or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of our products, including INGREZZA and ONGENTYS, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated their restrictions. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations. If the FDA or any other governmental agency initiates an enforcement action against us, or if we are the subject of a *qui tam* suit brought by a private plaintiff on behalf of the government, and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing

scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects, and reputation.

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

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

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

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

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

In addition, although we own a number of patents, the issuance of a patent is not conclusive as to its validity or enforceability, and third parties may challenge the validity or enforceability of our patents. We cannot assure you how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings. It is possible that a competitor may successfully challenge our patents or that challenges will result in limitations of their coverage. Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement claims, which are expensive and time-consuming. In addition, in an infringement proceeding a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. Interference proceedings declared by the US Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications or those of our licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to management. We cannot assure you that we will be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the US.

If we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed.

A product candidate that receives orphan drug designation can benefit from a streamlined regulatory process as well as potential commercial benefits following approval. Currently, this designation provides market exclusivity in the US and the EU for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs.

In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug. We may not be successful obtaining orphan drug designations for any indications and, even if we succeed, such orphan drug designations may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position.

The technologies we use in our research as well as the drug targets we select may infringe the patents or violate the proprietary rights of third parties.

We cannot assure you that third parties will not assert patent or other intellectual property infringement claims against us or our collaborators with respect to technologies used in potential products. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party's intellectual property unless that party grants us or our collaborators rights to use its intellectual property. In such cases, we could be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if our collaborators or we were able to obtain rights to the third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

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

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

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

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

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

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

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

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

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

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

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. For example, the EU's General Data Protection Regulation, or GDPR, imposes strict obligations on the processing of personal data, including personal health data, and the free movement of such data. The GDPR applies to any company established in the EU as well as any company outside the EU that processes personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, obligations relating to: processing health and other sensitive data; obtaining consent of individuals; providing notice to individuals regarding data processing activities; responding to data subject requests; taking certain measures when engaging third-party processors; notifying data subjects and regulators of data breaches; implementing safeguards to protect the security and confidentiality of personal data; and transferring personal data to countries outside the EU, including the US. The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue or 20 million euros, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices or lead to government enforcement actions, private litigation or significant penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

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

CCPA could mark the beginning of a trend toward more stringent privacy legislation in the US, which could increase our potential liability and adversely affect our business.

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:	Certificate of Amendment of Bylaws
	Reference:	Incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed on August 28, 2020
4.1	Description:	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:	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
4.4	Description:	Description of Common Stock of the Company
	Reference:	Incorporated by reference to Exhibit 4.4 of the Company's Annual Report on Form 10-K filed on February 7, 2020
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 9, 2020

/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 9, 2020

/s/ Kevin C. Gorman

Kevin C. Gorman
Chief Executive Officer

Exhibit 31.2

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

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

1. I have reviewed this 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 9, 2020

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

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, 2020 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 9, 2020

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, 2020 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 9, 2020

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