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 June 30, 2021

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 94,646,427 as of July 28, 2021.

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)	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 368.0	$ 187.1
Debt securities available-for-sale, at fair value (amortized cost $516.3 million at June 30, 2021 and $612.4 million at December 31, 2020)	516.9	613.9
Accounts receivable	158.5	157.1
Inventories	28.3	28.0
Other current assets	38.4	30.1
Total current assets	1,110.1	1,016.2
Deferred tax assets	316.1	319.4
Debt securities available-for-sale, at fair value (amortized cost $337.9 million at June 30, 2021 and $226.7 million at December 31, 2020)	337.8	227.1
Right-of-use assets	100.3	82.8
Equity securities	38.9	38.2
Property and equipment, net	50.0	44.6
Other assets	3.2	6.4
Total assets	$ 1,956.4	$ 1,734.7
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 190.9	$ 168.7
Other current liabilities	22.0	17.8
Total current liabilities	212.9	186.5
Convertible senior notes	326.3	317.9
Operating lease liabilities	109.0	94.4
Other long-term liabilities	29.0	9.7
Total liabilities	677.2	608.5
Stockholders’ equity:		
Preferred stock, $0.001 par value; 5.0 shares authorized; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 220.0 shares authorized; issued and outstanding shares were 94.6 at June 30, 2021 and 93.5 at December 31, 2020	0.1	0.1
Additional paid-in capital	1,929.4	1,849.7
Accumulated other comprehensive income	0.7	1.8
Accumulated deficit	(651.0)	(725.4)
Total stockholders’ equity	1,279.2	1,126.2
Total liabilities and stockholders’ equity	$ 1,956.4	$ 1,734.7

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions, except per share data)	**2021**	**2020**	**2021**	**2020**
Revenues:				
Product sales, net	$ 266.8	$ 267.6	$ 497.8	$ 498.7
Collaboration revenue	22.1	34.8	27.7	40.8
Total revenues	288.9	302.4	525.5	539.5
Operating expenses:				
Cost of sales	3.1	2.4	6.0	4.5
Research and development	74.8	80.9	148.0	139.2
Acquired in-process research and development	5.0	46.0	5.0	46.0
Selling, general and administrative	143.2	96.5	272.2	214.3
Total operating expenses	226.1	225.8	431.2	404.0
Operating income	62.8	76.6	94.3	135.5
Other (expense) income:				
Interest expense	(6.2)	(8.3)	(12.6)	(16.5)
Unrealized gain (loss) on equity securities	—	11.3	0.7	(5.2)
Investment income and other, net	0.9	3.6	2.3	8.3
Total other (expense) income, net	(5.3)	6.6	(9.6)	(13.4)
Income before provision for income taxes	57.5	83.2	84.7	122.1
Provision for income taxes	15.2	3.6	10.3	5.1
Net income	42.3	79.6	74.4	117.0
Unrealized (loss) gain on debt securities available-for-sale, net of tax	(0.3)	6.0	(1.1)	3.2
Comprehensive income	$ 42.0	$ 85.6	$ 73.3	$ 120.2
Net income per share, basic	$ 0.45	$ 0.86	$ 0.79	$ 1.26
Net income per share, diluted	$ 0.43	$ 0.81	$ 0.76	$ 1.20
Weighted average common shares outstanding, basic	94.6	93.0	94.4	92.8
Weighted average common shares outstanding, diluted	97.7	98.2	98.0	97.6

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 March 31, 2021	94.5	$ 0.1	$ 1,897.8	$ 1.0	$ (693.3)	$ 1,205.6
Net income	—	—	—	—	42.3	42.3
Unrealized loss on debt securities available-for-sale, net of tax	—	—	—	(0.3)	—	(0.3)
Share-based compensation expense	—	—	28.6	—	—	28.6
Issuances of common stock under stock plans	0.1	—	3.0	—	—	3.0
Balances at June 30, 2021	94.6	$ 0.1	$ 1,929.4	$ 0.7	$ (651.0)	$ 1,279.2
Balances at March 31, 2020	92.8	$ 0.1	$ 1,796.9	$ (1.4)	$ (1,095.3)	$ 700.3
Net income	—	—	—	—	79.6	79.6
Unrealized gain on debt securities available-for-sale, net of tax	—	—	—	6.0	—	6.0
Share-based compensation expense	—	—	29.5	—	—	29.5
Issuances of common stock under stock plans	0.4	—	15.8	—	—	15.8
Balances at June 30, 2020	93.2	$ 0.1	$ 1,842.2	$ 4.6	$ (1,015.7)	$ 831.2
Balance at December 31, 2020	93.5	$ 0.1	$ 1,849.7	$ 1.8	$ (725.4)	$ 1,126.2
Net income	—	—	—	—	74.4	74.4
Unrealized loss on debt securities available-for-sale, net of tax	—	—	—	(1.1)	—	(1.1)
Share-based compensation expense	—	—	61.5	—	—	61.5
Issuances of common stock under stock plans	1.1	—	18.2	—	—	18.2
Balances at June 30, 2021	94.6	$ 0.1	$ 1,929.4	$ 0.7	$ (651.0)	$ 1,279.2
Balance at December 31, 2019	92.3	$ 0.1	$ 1,768.1	$ 1.4	$ (1,132.7)	$ 636.9
Net income	—	—	—	—	117.0	117.0
Unrealized gain on debt securities available-for-sale, net of tax	—	—	—	3.2	—	3.2
Share-based compensation expense	—	—	52.3	—	—	52.3
Issuances of common stock under stock plans	0.9	—	21.8	—	—	21.8
Balance at June 30, 2020	93.2	$ 0.1	$ 1,842.2	$ 4.6	$ (1,015.7)	$ 831.2

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

(in millions)	Six Months Ended June 30, 2021	2020
Cash Flows from Operating Activities:		
Net income	$ 74.4	$ 117.0
Reconciliation of net income to net cash provided by operating activities:		
Share-based compensation expense	61.5	52.3
Depreciation	5.1	4.2
Amortization of debt discount	7.9	10.0
Amortization of debt issuance costs	0.6	0.7
Change in fair value of equity security investments	(0.7)	5.2
Deferred income taxes	3.3	—
Other	5.6	0.7
Change in operating assets and liabilities:		
Accounts receivable	(1.4)	(21.8)
Inventories	(0.3)	(4.7)
Accounts payable and accrued liabilities	29.0	(5.1)
Other assets and liabilities, net	5.5	(4.1)
Net cash provided by operating activities	190.5	154.4
Cash Flows from Investing Activities:		
Purchases of debt securities available-for-sale	(383.1)	(288.6)
Sales and maturities of debt securities available-for-sale	364.2	421.2
Purchases of property and equipment	(8.8)	(6.0)
Net cash (used in) provided by investing activities	(27.7)	126.6
Cash Flows from Financing Activities:		
Issuances of common stock under benefit plans	18.2	21.8
Partial repurchase of convertible senior notes	(0.1)	—
Net cash provided by financing activities	18.1	21.8
Change in cash, cash equivalents and restricted cash	180.9	302.8
Cash, cash equivalents and restricted cash at beginning of period	190.3	115.5
Cash, cash equivalents and restricted cash at end of period	$ 371.2	$ 418.3
Supplemental Disclosure:		
Non-cash capital expenditures	$ 2.2	$ 0.9
Right-of-use assets acquired through operating leases	$ 21.6	$ —
Cash paid for interest	$ 4.3	$ 5.8
Cash paid for income taxes	$ 1.6	$ —

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

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

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2020, included in our Annual Report on Form 10-K, or the 2020 Form 10-K, filed with the SEC. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or the full year. The condensed consolidated balance sheet as of December 31, 2020, 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 2020 Form 10-K.

Recently Adopted Accounting Pronouncements.

ASU 2019-12. On January 1, 2021, we adopted Accounting Standards Update, or ASU, 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, using the modified retrospective transition method. ASU 2019-12 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. The adoption of ASU 2019-12 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. The impact of the adoption is expected to be immaterial to our financial position, results of operations, and cash flows on an ongoing basis.

Recently Issued Accounting Pronouncements.

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. We plan to adopt ASU 2020-06 effective January 1, 2022 using the modified retrospective transition method. We are currently evaluating the effect ASU 2020-06 will have on our consolidated financial statements and related disclosures.

2. Significant Collaboration and Licensing Agreements

Takeda Pharmaceutical Company Limited. We entered into an exclusive license agreement with Takeda Pharmaceutical Company Limited, or Takeda, which became effective in July 2020, to develop and commercialize certain compounds in Takeda's early to mid-stage psychiatry pipeline. Specifically, Takeda granted us an exclusive license to (i) luvadaxistat (NBI-1065844/TAK-831) which we are studying in cognitive impairment associated with schizophrenia, (ii) NBI-1065845 (TAK-653) which we are studying in inadequate response to treatment in major depressive disorder, (iii) NBI-1065846 (TAK-041) which we are studying in anhedonia in depression and (iv) four non-clinical stage assets.

With respect to luvadaxistat, Takeda declined to opt-in to a profit-sharing arrangement and instead will be entitled to receive royalties on the future net sales of such asset (in lieu of equally sharing in the operating profits and losses).

With respect to NBI-1065845 and NBI-1065846, Takeda will retain the rights to opt-out of the profit-sharing arrangements pursuant to which Takeda would be entitled to receive royalties on the future net sales of such asset (in lieu of equally sharing in the operating profits and losses). Takeda may elect to exercise such opt-out rights immediately following the completion of the associated second Phase II clinical study or, under certain circumstances related to the development and commercialization activities to be performed by us, before the initiation of a Phase III clinical study for such asset.

Under the terms of the agreement, Takeda may be entitled to receive payments of up to $1.9 billion upon the achievement of certain milestones associated with luvadaxistat and the four non-clinical stage assets, as well as receive royalties on the future net sales of such assets. We and Takeda will equally share in the operating profits and losses associated with NBI-1065845 and NBI-1065846.

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

Under the terms of the agreement, Idorsia may be entitled to receive payments of up to $1.7 billion upon the achievement of certain milestones as well as receive royalties on the future net sales of any collaboration product.

Xenon Pharmaceuticals, Inc. In December 2019, we entered into a license and collaboration agreement with Xenon Pharmaceuticals Inc., or Xenon, to identify, research, and develop sodium channel inhibitors, including clinical candidate NBI-921352 (XEN901) and three preclinical candidates.

Under the terms of the agreement, Xenon may be entitled to receive payments of up to $1.7 billion upon the achievement of certain milestones as well as receive royalties on the future net sales of any collaboration product.

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

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

Under the terms of the agreement, Voyager may be entitled to receive payments of up to $1.3 billion upon the achievement of certain milestones, as well as receive royalties on the future net sales of any collaboration product.

BIAL – Portela & Ca, S.A. We acquired the United States, or US, and Canada rights to ONGENTYS® (opicapone) from BIAL in the first quarter of 2017. We launched ONGENTYS in the US in September 2020, after receiving FDA approval for ONGENTYS as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in adult Parkinson's disease patients in April 2020. ONGENTYS net product sales were $2.0 million and $3.4 million for the three and six months ended June 30, 2021, respectively.

Under the terms of the agreement, BIAL may be entitled to receive payments of up to $75.0 million upon the achievement of certain milestones.

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® (valbenazine) for movement disorders in Japan and other select Asian markets.

In April 2021, MTPC submitted a marketing authorization application, or MAA, with the Ministry of Health and Welfare in Japan for valbenazine for the treatment of tardive dyskinesia. The MTPC submission of valbenazine triggered a milestone payment of $15.0 million, which we recognized as collaboration revenue in the second quarter of 2021.

We are currently conducting the KINECT-HD study, a placebo-controlled Phase III study of valbenazine in adult Huntington's disease patients with chorea. In connection with the ongoing study, we recognized collaboration revenue of $1.3 million and $2.4 million for the three and six months ended June 30, 2021, respectively, and $1.3 million for the six months ended June 30, 2020. At June 30, 2021, $4.4 million of revenue is being deferred in connection with our continuing performance obligations under the collaboration and will be recognized as collaboration revenue over the remaining study period using an input method according to costs incurred to-date relative to estimated total costs associated with the study.

Under the terms of the agreement, we are entitled to receive royalties on the future worldwide net sales of any collaboration product in select territories in Asia and may also be entitled to receive potential future payments of up to $55.0 million upon the achievement of certain milestones.

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

AbbVie launched ORILISSA® (elagolix tablets) in the US and Canada in August and November 2018, respectively, after receiving FDA and Health Canada approval for ORILISSA for endometriosis in July and October 2018, respectively. In June 2020, AbbVie launched ORIAHNN® (elagolix, estradiol and norethindrone acetate capsules and elagolix capsules) in the US after receiving FDA approval for ORIAHNN for uterine fibroids in May 2020. We recognized sales-based royalties on AbbVie net sales of ORILISSA and ORIAHNN of $5.9 million and $10.4 million for the three and six months ended June 30, 2021, respectively, and $4.8 million and $9.5 million for the three and six months ended June 30, 2020, respectively.

Under the terms of the agreement, we are entitled to receive royalties on the future worldwide net sales of any collaboration product and may also be entitled to receive potential future payments of up to $366.0 million upon the achievement of certain milestones.

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 June 30, 2021, 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	$ 168.6	$ —	$ —	$ —	$ 168.6
Corporate debt securities	Within 1 year	212.0	0.5	—	—	212.5
Securities of government-sponsored entities	Within 1 year	135.7	0.1	—	—	135.8
		$ 516.3	$ 0.6	$ —	$ —	$ 516.9
Corporate debt securities	1 to 2 years	$ 230.3	$ 0.1	$ (0.2)	$ —	$ 230.2
Securities of government-sponsored entities	1 to 2 years	107.6	0.1	(0.1)	—	107.6
		$ 337.9	$ 0.2	$ (0.3)	$ —	$ 337.8

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

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

The following table summarizes debt securities available-for-sale in an unrealized loss position for which an allowance for credit losses has not been recorded at June 30, 2021 and December 31, 2020, aggregated by major security type and length of time in a continuous unrealized loss position:

	Less Than 12 Months		12 Months or Longer		Total	
(in millions)	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
June 30, 2021:						
Corporate Debt Securities	$ 211.0	$ (0.2)	$ —	$ —	$ 211.0	$ (0.2)
Securities of government-sponsored entities	34.5	(0.1)	—	—	34.5	(0.1)
	$ 245.5	$ (0.3)	$ —	$ —	$ 245.5	$ (0.3)
December 31, 2020:						
Securities of government-sponsored entities	$ 95.0	$ (0.1)	$ —	$ —	$ 95.0	$ (0.1)

At June 30, 2021, our security portfolio consisted of 142 securities related to investments in debt securities available-for-sale, of which 56 securities were in an unrealized loss position.

Our investments in corporate debt securities in an unrealized loss position at June 30, 2021 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.

Accrued interest receivables on debt securities available-for-sale totaled $2.7 million and $3.7 million at June 30, 2021 and December 31, 2020, respectively. 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 six months ended June 30, 2021 or 2020.

4. Fair Value Measurements

We record cash equivalents and investments in 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.

Investments at June 30, 2021, 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	$ 368.0	$ 368.0	$ —	$ —
Total cash and cash equivalents	368.0	368.0	—	—
Restricted cash:				
Certificates of deposit	3.2	3.2	—	—
Total restricted cash	3.2	3.2	—	—
Debt securities available-for-sale:				
Commercial paper	168.6	—	168.6	—
Corporate debt securities	442.7	—	442.7	—
Securities of government-sponsored entities	243.4	—	243.4	—
Total debt securities available-for-sale	854.7	—	854.7	—
Equity securities:				
Equity securities–biotechnology industry	38.9	—	—	38.9
Total equity securities	38.9	—	—	38.9
Total recurring fair value measurements	$ 1,264.8	$ 371.2	$ 854.7	$ 38.9

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

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

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 June 30,		Six Months Ended June 30,	
(in millions)	2021	2020	2021	2020
Balance at beginning of period	$ 38.9	$ 39.4	$ 38.2	$ 55.9
Unrealized gain (loss) included in earnings	—	11.3	0.7	(5.2)
Balance at end of period	$ 38.9	$ 50.7	$ 38.9	$ 50.7

At June 30, 2021, the discount for lack of marketability used in the valuation analysis of equity security investments ranged from 9.0% to 13.0% (weighted average of 10.5%). 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 security investments are included in other income (expense), net.

5. Inventories

Inventories consisted of the following:

(in millions)	June 30, 2021	December 31, 2020
Raw materials	$ 14.2	$ 16.6
Work in process	2.6	2.4
Finished goods	11.5	9.0
Total inventories	$ 28.3	$ 28.0

6. Cash, Cash Equivalents and Restricted Cash

The following table presents a reconciliation of cash, cash equivalents and restricted cash to amounts shown in the condensed consolidated statements of cash flows.

(in millions)	June 30, 2021	June 30, 2020
Cash and cash equivalents	$ 368.0	$ 415.1
Restricted cash included in other assets	3.2	3.2
Total cash, cash equivalents and restricted cash	$ 371.2	$ 418.3

7. Leases

We have operating leases for our office and laboratory facilities, including our corporate headquarters, with terms that expire from 2024 through 2031. Certain of these lease agreements contain clauses for renewal at our option. As we were not reasonably certain to exercise any of these renewal options at commencement of the associated leases, no such options were recognized as part of our operating lease right-of-use, or ROU, assets or operating lease liabilities. In connection with our operating leases, in lieu of a cash security deposits, Wells Fargo Bank, N.A., issued letters of credit on our behalf, which are secured by deposits totaling $3.2 million.

The following table presents supplemental operating lease information.

	Six Months Ended June 30,	
(in millions, except weighted average data)	2021	2020
Operating lease cost	$ 7.3	$ 5.0
Cash paid for amounts included in the measurement of operating lease liabilities	$ 5.5	$ 4.3

	June 30, 2021	June 30, 2020
Weighted average remaining lease term	9.2 years	11.0 years
Weighted average discount rate	5.3 %	5.8 %

The following table presents approximate future minimum lease payments under operating leases.

(in millions)	June 30, 2021
Year ending December 31, 2021 (6 months remaining)	$ 7.1
Year ending December 31, 2022	16.8
Year ending December 31, 2023	17.5
Year ending December 31, 2024	17.0
Year ending December 31, 2025	15.5
Thereafter	85.4
Total operating lease payments	159.3
Less accreted interest	35.3
Total operating lease liabilities	124.0
Less current operating lease liabilities included in other current liabilities	15.0
Noncurrent operating lease liabilities	$ 109.0

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 May 15, 2024, or the 2024 Notes, and entered into an indenture agreement, or the 2024 Indenture, with respect to the 2024 Notes. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. At June 30, 2021, $381.2 million aggregate principal amount of the 2024 Notes remained outstanding. Interest on the 2024 Notes is due semi-annually on May 15 and November 15 of each year.

Pursuant to the terms of the 2024 notes, we could 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 (equal to $98.70 as of June 30, 2021) for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending on, and including, the trading day immediately before the date which we provide notice of redemption.

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

(i) during any calendar quarter (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than 130% of the conversion price (equal to $98.70 as of June 30, 2021) 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.

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

In the event of conversion, holders would forgo all future interest payments, any unpaid accrued interest and the possibility of further stock price appreciation. Upon the receipt of conversion requests, the settlement of the 2024 Notes will be paid pursuant to the terms of the 2024 Indenture. In the event that all of the 2024 Notes are converted, we would be required to repay the $381.2 million in principal value and any conversion premium in any combination of cash and shares of our common stock, at our option.

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.

While the 2024 Notes are currently classified as a long-term liability, the future convertibility and associated balance sheet classification will be monitored at each quarterly reporting date and analyzed dependent upon market prices of our common stock during the prescribed measurement periods. In the event that we have the election to redeem the 2024 Notes or the holders of the 2024 Notes have the election to convert the 2024 Notes at any time during the prescribed measurement period, the 2024 Notes would then be considered a current obligation and classified as such.

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 June 30, 2021, the remaining period over which the discount on the liability component will be amortized was approximately 2.9 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)	June 30, 2021	December 31, 2020
Principal	$ 381.2	$ 381.3
Deferred financing costs	(3.4)	(4.0)
Debt discount, net	(51.5)	(59.4)
Net carrying amount	$ 326.3	$ 317.9

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 $506.6 million at June 30, 2021 and $514.3 million at December 31, 2020.

9. Net Income Per Share

Net income per share was calculated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions, except per share data)	2021	2020	2021	2020
Net income - basic and diluted	$ 42.3	$ 79.6	$ 74.4	$ 117.0
Weighted-average common shares outstanding:				
Basic	94.6	93.0	94.4	92.8
Effect of dilutive securities:				
Stock options	1.8	2.6	1.9	2.5
Restricted stock	0.2	0.5	0.4	0.5
2024 Notes	1.0	2.1	1.2	1.8
Diluted	97.7	98.2	98.0	97.6
Net income per share:				
Basic	$ 0.45	$ 0.86	$ 0.79	$ 1.26
Diluted	$ 0.43	$ 0.81	$ 0.76	$ 1.20
Shares excluded from diluted per share amounts because their effect would have been anti-dilutive	4.7	2.2	3.7	1.4

Convertible debt instruments that may be settled entirely or partly in cash (such as the 2024 Notes) may, in certain circumstances where the borrower has the ability and intent to settle in cash, be accounted for under the treasury stock method. We issued the 2024 Notes with a combination settlement feature, which we have the ability and intent to use upon conversion of the 2024 Notes, to settle the principal amount of debt for cash and the excess of the principal portion in shares of our common stock. As a result, of the approximately 5.0 million shares underlying the 2024 Notes, only the shares required to settle the excess of the principal portion are considered under the treasury stock method.

10. Legal Proceedings

In the second quarter of 2021, we received notices from (i) Teva Pharmaceuticals Development, Inc., (ii) Lupin Limited, (iii) Crystal Pharmaceutical (Suzhou) Co. Ltd., and (iv) Zydus Pharmaceuticals (USA) Inc. (each an “ANDA Filer”) that each company had filed an abbreviated new drug application, or ANDA, with the FDA seeking approval of a generic version of INGREZZA. The ANDAs each contained a Paragraph IV Patent Certification alleging that certain of our patents covering INGREZZA are invalid and/or will not be infringed by each ANDA Filer’s manufacture, use or sale of the medicine for which the ANDA was submitted. We filed suit in the U.S. District Court for the District of Delaware in July 2021 against (i) Teva Pharmaceuticals, Inc. and its affiliates Teva Pharmaceuticals Development, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., (ii) Lupin Limited and its affiliates Lupin Pharmaceuticals, Inc., and Lupin Atlantis Holdings S.A., (iii) Crystal Pharmaceutical (Suzhou) Co., Ltd., and its affiliate Crystal Pharmatech Co., Ltd., and (iv) Zydus Pharmaceuticals (USA) Inc. and its affiliates Zydus Worldwide DMCC, Cadila Healthcare Limited d/b/a Zydus Cadila and Zydus Healthcare (USA) LLC. We also filed suit in the U.S. District Court for the District of New Jersey in July 2021 against

Zydus Pharmaceuticals (USA) Inc. and its affiliates Zydus Worldwide DMCC, Cadila Healthcare Limited d/b/a Zydus Cadila and Zydus Healthcare (USA) LLC seeking to prevent any ANDA Filer from selling a generic version of INGREZZA.

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

Item 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, 2020 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, 2020 and our Quarterly Reporting on Form 10-Q for the three months ended March 31, 2021.

Overview

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

We launched INGREZZA® (valbenazine) in the United States, or US, in May 2017 as the first FDA-approved drug for the treatment of tardive dyskinesia. In September 2020, we launched ONGENTYS® (opicapone) for Parkinson's disease in the US, leveraging our existing INGREZZA commercial infrastructure. INGREZZA net product sales represent the significant majority of our total net product sales.

Our partner AbbVie Inc., or AbbVie, launched ORILISSA® (elagolix tablets) in the US and Canada in August and November 2018, respectively. In June 2020, AbbVie launched ORIAHNN® (elagolix, estradiol and norethindrone acetate capsules and elagolix capsules) in the US. We receive royalties at tiered percentage rates on AbbVie net sales of ORILISSA and ORIAHNN.

In addition, we have a rapidly expanding pipeline of potential treatments and gene therapies for diseases such as Huntington's disease, or HD, congenital adrenal hyperplasia, or CAH, epilepsy, schizophrenia and depression.

Pipeline Updates:

INGREZZA:

- In April 2021, Mitsubishi Tanabe Pharma Corporation, or MTPC, submitted a Marketing Authorization Application, or MAA, with the Ministry of Health and Welfare in Japan for valbenazine for the treatment of tardive dyskinesia. The MTPC submission of valbenazine triggered a milestone payment of $15.0 million, which we recognized as collaboration revenue in the second quarter of 2021.

Luvadaxistat (NBI-1065844/TAK-831):

- On March 2, 2021, we announced that investigational drug luvadaxistat did not meet its primary endpoint in the Phase II INTERACT study in adults with negative symptoms of schizophrenia. Luvadaxistat met both secondary endpoints of cognitive assessment. We plan to initiate a Phase II study for the treatment of cognitive impairment associated with schizophrenia, or CIAS, by the end of 2021.

NBIb-1817 (VY-AADC):

- In February 2021, we notified Voyager Therapeutics, Inc., or Voyager, of the termination of our rights to the NBIb-1817 for Parkinson's disease program, which became effective August 2, 2021. The termination does not apply to any other development program other than NBIb-1817 for Parkinson's disease, and our collaboration and license agreement with Voyager will otherwise continue in effect.

COVID-19

The global COVID-19 pandemic 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.

Although the initial impact of the COVID-19 pandemic has subsided, we are uncertain how more transmissible variants may impact our business. We remain committed to (1) prioritizing the safety, health and well-being of patients and their

caregivers, healthcare providers and our employees; (2) ensuring patients with tardive dyskinesia are well supported and have continued uninterrupted access to INGREZZA, for which we currently do not expect any supply disruption; and (3) advancing ongoing clinical studies.

We have developed and implemented plans regarding the partial opening of our sites to enable our employees to return to work in our corporate offices and the field, which plans take into account applicable public health authority and local government guidelines and which are designed to ensure community and employee safety. We continue to evaluate our hybrid work model and the impact of spikes or surges in COVID-19 infection and hospitalization rates.

Most hospitals, community mental health facilities, physicians' offices, pharmacies, and other healthcare facilities have relaxed their policies that limited access of patients and our employees to such facilities and limited the ability of patients, pharmacies, and prescribers to interact with each other. However, we anticipate these policies may change from time to time as communities grapple with local or regional outbreaks. The ultimate impact of the COVID-19 pandemic, including any lasting effects on our revenue and the way we conduct our business, is highly uncertain and subject to continued change. We recognize that this pandemic will continue to present unique challenges for us throughout 2021, and potentially into 2022.

Results of Operations for the Three and Six Months Ended June 30, 2021 and 2020

Revenues

The following table presents revenues by category.

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	**2021**	**2020**	**2021**	**2020**
INGREZZA product sales, net	$ 264.8	$ 267.6	$ 494.4	$ 498.7
ONGENTYS product sales, net	2.0	—	3.4	—
Collaboration revenue	22.1	34.8	27.7	40.8
Total revenues	$ 288.9	$ 302.4	$ 525.5	$ 539.5

Product Sales, Net. Net product sales were $266.8 million and $497.8 million for the three and six months ended June 30, 2021, respectively, compared with $267.6 million and $498.7 million in the comparable periods last year, reflecting a slowdown in INGREZZA sales volume growth, largely attributable to the impact of COVID-19 on our customers.

Collaboration Revenue. Collaboration revenue reflects royalties earned on AbbVie net sales of ORILISSA and ORIAHNN and license fees earned under our collaboration agreements with AbbVie and MTPC. Collaboration revenue was $22.1 million and $27.7 million for the three and six months ended June 30, 2021, respectively, primarily reflecting the achievement of a $15.0 million milestone associated with MTPC's MAA submission for valbenazine for the treatment of tardive dyskinesia in Japan. For the three and six months ended June 30, 2020, collaboration revenue was $34.8 million and $40.8 million, respectively, primarily reflecting the achievement of a $30.0 million 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 $3.1 million and $6.0 million for the three and six months ended June 30, 2021, respectively, compared with $2.4 million and $4.5 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 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. Such costs are not allocated to a specific program or stage.

The following table presents R&D expense by category:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in millions)	2021	2020	2021	2020
Late stage	$ 13.1	$ 13.1	$ 26.1	$ 26.1
Early stage	8.4	5.7	13.9	10.3
Research and discovery	11.7	10.6	21.1	19.8
Milestone expenses	—	20.0	—	20.0
Payroll and benefits	29.1	25.2	64.5	49.1
Facilities and other	12.5	6.3	22.4	13.9
Total R&D expense	$ 74.8	$ 80.9	$ 148.0	$ 139.2

R&D expense was $74.8 million and $148.0 million for the three and six months ended June 30, 2021, respectively, compared with $80.9 million and $139.2 million in the comparable periods last year, primarily reflecting increased investment and headcount to support advancing our expanded clinical portfolio. R&D expense for the six months ended June 30, 2021, also reflects higher personnel expenses driven by a non-cash share-based compensation charge of $6.4 million related to the modification of certain share-based awards.

Acquired In-Process Research and Development. Acquired in-process research and development, or IPR&D, expense was $5.0 million for the three months ended June 30, 2021. In the comparable period last year, IPR&D expense was $46.0 million in connection with the payment of the upfront fee pursuant to our collaboration and license agreement with Idorsia.

Selling, General and Administrative. Selling, general and administrative, or SG&A, expense was $143.2 million and $272.2 million for the three and six months ended June 30, 2021, respectively, compared with $96.5 million and $214.3 million in the comparable periods last year, primarily reflecting increased investment to support our commercial initiatives, including the May 2021 launch of our INGREZZA direct-to-consumer advertising campaign, "TD Spotlight".

Other (Expense) Income, Net

Other expense, net, was $5.3 million and $9.6 million for the three and six months ended June 30, 2021, respectively, compared with other income, net, of $6.6 million for the three months ended June 30, 2020, and other expense, net, of $13.4 million for the six months ended June 30, 2020. 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 $15.2 million and $10.3 million for the three and six months ended June 30, 2021, respectively, compared with $3.6 million and $5.1 million in the comparable periods last year. Our effective tax rate for the three and six months ended June 30, 2021 was lower than federal and state statutory rates primarily due to excess tax benefits related to share-based compensation. On December 31, 2020, we released substantially all of our valuation allowance against our net operating losses and other deferred tax assets. Beginning in the first quarter of 2021, we began recording a provision for income taxes using an effective tax rate approximating federal and state statutory rates. Due to our ability to offset our pre-tax income against previously benefited federal net operating losses, no federal cash tax is expected in 2021.

Net Income

Net income was $42.3 million, or $0.43 diluted earnings per share, and $74.4 million, or $0.76 diluted earnings per share, for the three and six months ended June 30, 2021, compared with $79.6 million, or $0.81 diluted earnings per share, and $117.0 million, or $1.20 diluted earnings per share, in the comparable periods last year, primarily reflecting increased investment to support our commercial initiatives, including the May 2021 launch of our INGREZZA direct-to-consumer advertising campaign, "TD Spotlight", investment in our expanded clinical portfolio and an increase in our provision for income taxes.

Liquidity and Capital Resources

At June 30, 2021, our cash, cash equivalents and debt security investments totaled $1.2 billion compared with $1.0 billion at December 31, 2020.

Net cash provided by operating activities was $190.5 million for the six months ended June 30, 2021, compared with $154.4 million in the comparable period last year, primarily reflecting timing of working capital receipts and payments partially offset by lower net income on increased investment to support our expanded clinical portfolio and commercial initiatives. The six months ended June 30, 2020 includes $46.0 million of upfront fees paid to Idorsia in connection with the execution of our collaboration and license agreement in May 2020.

Net cash used in investing activities was $27.7 million for the six months ended June 30, 2021, compared with net cash provided by investing activities of $126.6 million in the comparable period last year, reflecting timing differences related to purchases, sales, and maturities of debt securities available-for-sale and changes in our portfolio-mix.

Net cash provided by financing activities was $18.1 million for the six months ended June 30, 2021, compared with $21.8 million in the comparable period last year, primarily reflecting proceeds from issuances of our common stock.

Convertible Senior Notes. In May 2017, we completed a private placement of $517.5 million in aggregate principal amount of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. At June 30, 2021, $381.2 million aggregate principal amount of the 2024 Notes remained outstanding. 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 (equal to $98.70 as of June 30, 2021) 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 2024 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by us. There are customary events of default with respect to the 2024 Notes, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the 2024 Notes will automatically become due and payable.

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, 2020.

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 June 30, 2021, 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 June 30, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

In the second quarter of 2021, we received notices from (i) Teva Pharmaceuticals Development, Inc., (ii) Lupin Limited, (iii) Crystal Pharmaceutical (Suzhou) Co. Ltd., and (iv) Zydus Pharmaceuticals (USA) Inc. (each an "ANDA Filer") that each company had filed an abbreviated new drug application, or ANDA, with the FDA seeking approval of a generic version of INGREZZA. The ANDAs each contained a Paragraph IV Patent Certification alleging that certain of our patents covering INGREZZA are invalid and/or will not be infringed by each ANDA Filer's manufacture, use or sale of the medicine for which the ANDA was submitted. We filed suit in the U.S. District Court for the District of Delaware in July 2021 against (i) Teva Pharmaceuticals, Inc. and its affiliates Teva Pharmaceuticals Development, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., (ii) Lupin Limited and its affiliates Lupin Pharmaceuticals, Inc., and Lupin Atlantis Holdings S.A., (iii) Crystal Pharmaceutical (Suzhou) Co., Ltd., and its affiliate Crystal Pharmatech Co., Ltd., and (iv) Zydus Pharmaceuticals (USA) Inc. and its affiliates Zydus Worldwide DMCC, Cadila Healthcare Limited d/b/a Zydus Cadila and Zydus Healthcare (USA) LLC. We also filed suit in the U.S. District Court for the District of New Jersey in July 2021 against Zydus Pharmaceuticals (USA) Inc. and its affiliates Zydus Worldwide DMCC, Cadila Healthcare Limited d/b/a Zydus Cadila and Zydus Healthcare (USA) LLC seeking to prevent any ANDA Filer from selling a generic version of INGREZZA.

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

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations. The risk factors set forth below with an asterisk (*) contain changes to the risk factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Summary Risk Factors

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

- We may not be able to continue to successfully commercialize INGREZZA, ONGENTYS, or any of our product candidates if they are approved in the future.
- If physicians and patients do not continue to accept INGREZZA or do not accept ONGENTYS, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.
- Governmental and third-party payors may impose sales and pharmaceutical pricing controls on our products or limit coverage and/or reimbursement for our products that could limit our product revenues and delay sustained profitability.
- Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic, 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.
- We face intense competition, and if we are unable to compete effectively, the demand for our products may be reduced.
- Because the development of our product candidates is subject to a substantial degree of technological uncertainty, we may not succeed in developing any of our product candidates.
- Our clinical studies may be delayed for safety or other reasons, or fail to demonstrate the safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.

- We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates.
- Use of our approved products or those of our collaborators could be associated with side effects or adverse events.
- We have recently increased the size of our organization and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.
- If we are unable to retain and recruit qualified employees or if any of our key senior executives discontinues his or her employment with us, it may delay our development efforts or impact our commercialization of INGREZZA, ONGENTYS or any product candidate approved by the FDA.
- We currently have no manufacturing capabilities. If third-party manufacturers of INGREZZA, ONGENTYS or any of our product candidates fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed, and our costs may rise.
- We currently depend on a limited number of third-party suppliers. The loss of these suppliers, or delays or problems in the supply of INGREZZA or ONGENTYS, could materially and adversely affect our ability to successfully commercialize INGREZZA or ONGENTYS.
- We license some of our core technologies and drug candidates from third parties. If we default on any of our obligations under those licenses, or violate the terms of these licenses, we could lose our rights to those technologies and drug candidates or be forced to pay damages.
- If we are unable to protect our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.
- Health care reform measures and other recent legislative initiatives could adversely affect our business.
- Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations.
- We have a history of losses and expect to increase our expenses for the foreseeable future, and we may not be able to sustain profitability.
- Our customers are concentrated and therefore the loss of a significant customer may harm our business.
- If we cannot raise additional funding, we may be unable to complete development of our product candidates or establish commercial and manufacturing capabilities in the future.

Risks Related to Our Company

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

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

In addition, our business has been and may continue to be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic. Some 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. However, we anticipate these policies may change from time to time as communities or regions grapple with local or regional outbreaks. In addition, many health care practitioners have adopted telehealth for patient interactions, which may impact the ability of the health care practitioner to diagnose tardive dyskinesia. Further, during the COVID-19 pandemic, the use of physician telehealth services increased, fueled in part by an expansion of coverage and reimbursement from government and other payors. The limitations that telehealth places on the ability to conduct a thorough physical

examination may impact the ability of providers to screen for movement disorders, leading potentially fewer patients to be diagnosed and referred for treatment. The ultimate impact of the COVID-19 pandemic, including any lasting effects on the way we conduct our business, is highly uncertain and subject to change. If we fail to maintain successful marketing, sales and reimbursement capabilities, our product revenues may suffer.

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

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

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

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

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

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

Our ability to continue to commercialize INGREZZA successfully or to successfully commercialize ONGENTYS, will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available. The continuing efforts of government and third-party payors to contain or reduce the costs of health care and the price of prescription drugs through various means may impact our revenues. These payors' efforts could decrease the price that we receive for any products we may develop and sell in the future.

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

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the 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 or indications, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable

coverage policies and reimbursement rates may be implemented in the future. 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. Further, during the early months of the COVID-19 pandemic, the use of physician telehealth services rapidly increased, fueled by an unprecedented expansion of coverage and reimbursement across insurers. The limitations that telehealth places on the ability to conduct a thorough physical examination may impact the ability of providers to screen for movement disorders, leading potentially fewer patients to be diagnosed and referred for treatment.

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

Our business could be adversely affected by the effects of health pandemics or epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. As a result of the ongoing COVID-19 pandemic, we may experience disruptions that could severely impact our supply chain, ongoing and future clinical trials and commercialization of INGREZZA and ONGENTYS. For example, the COVID-19 pandemic has resulted in increased travel restrictions and the shutdown or delay of business activities in various regions. In response the COVID-19 pandemic, we implemented a remote work model in early March 2020 for all employees except certain key essential members involved in business-critical activities. We have implemented plans to enable our employees to return to work in our corporate offices and the field, which plans take into account applicable public health authority and local government guidelines and which are designed to ensure community and employee safety. The effects of our remote work model may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Although the immediate impact of the COVID-19 pandemic has subsided, the effects of the pandemic continue to rapidly evolve and we may face several challenges or disruptions upon a return back to the workplace, including re-integration challenges by our employees and distractions to management related to such transition. These and similar, and perhaps more severe, disruptions in our operations due to the COVID-19 pandemic could negatively impact our business, operating results and financial condition.

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. 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 COVID-19 pandemic, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic 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 COVID-19 pandemic could materially affect our business and the value of our common stock.

The effects of the 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.

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

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

Competition may also arise from, among other things:

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

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

We are commercializing and performing research on or developing products for the treatment of several disorders including endometriosis, tardive dyskinesia, uterine fibroids, essential tremor, classic congenital adrenal hyperplasia, pain, Parkinson's disease, 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, (including the development of generic equivalents) the market for our products may be reduced or eliminated.

- With respect to INGREZZA for tardive dyskinesia, we compete with Teva Pharmaceutical Industries, which received FDA approval for AUSTEDO to treat tardive dyskinesia in August 2017, and several clinical development-stage programs targeting tardive dyskinesia and related movement disorders. Additionally, there are a number of commercially available medicines used to treat tardive dyskinesia off-label, such as Xenazine (tetrabenazine) and generic equivalents, and various antipsychotic medications (e.g., clozapine), anticholinergics, benzodiazepines (off-label), and botulinum toxin.
- In endometriosis, ORILISSA and ORIAHNN each compete with several FDA-approved products for the treatment of endometriosis, uterine fibroids, infertility, and central precocious puberty. Additionally, there is also competition from surgical intervention, including hysterectomies and ablations. Separate from these options, there are many programs in clinical development which serve as potential future competition. Lastly, there are numerous medicines used to treat the symptoms of disease (vs. endometriosis or uterine fibroids directly) which may also serve as competition: oral contraceptives, NSAIDs and other pain medications including opioids.
- With respect to ONGENTYS for Parkinson's disease, there are currently two other FDA-approved COMT inhibitors. ONGENTYS competes directly with these two drugs and their generic equivalents. Additionally, there are a number of alternative adjunctive treatment options (FDA-approved and in clinical development) for Parkinson's patients which compete with ONGENTYS, including various L-dopa preparations, dopamine agonists, MAO-B inhibitors and others. In terms of potential future competition, there are several programs in late-stage clinical development.
- As for CAH, high doses of corticosteroids are the current standard of care to both correct the endogenous cortisol deficiency as well as reduce the excessive ACTH levels. In the US alone, there are more than two dozen companies manufacturing steroid-based products. Additionally, there are several clinical development-stage programs targeting CAH and several companies developing medicinal treatments for CAH.
- Our investigational treatments for potential use in epilepsy may in the future compete with numerous approved anti-seizure medications, or ASMs, and development-stage programs being pursued by several other companies. Commonly used ASMs, among others, include phenytoin, levetiracetam, brivaracetam, cenobamate, carbamazepine, clobazam, lamotrigine, valproate, oxcarbazepine, topiramate, lacosamide, perampanel and cannabidiol. There are currently no FDA-approved treatments specifically indicated for the early infantile epileptic encephalopathies SCN8A-DEE and EE-CSWS; however, a number of different ASMs are currently used in these patient populations.
- The investigational treatment luvadaxistat for the cognitive impairment associated with schizophrenia, or CIAS, may in the future compete with several development-stage programs being pursued by other companies. Currently, there are no FDA approved treatments specifically indicated for CIAS.

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

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

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

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

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

Only a small number of research and development programs ultimately result in commercially successful drugs. In addition, to date the FDA has granted regulatory approval for only a very limited number of gene therapy products and the clinical development of a gene therapy product may result in unforeseen adverse events.

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

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

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

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

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

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

- the FDA or similar foreign regulatory authority may not allow an IND application or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA may require additional preclinical studies as a condition of the initiation of Phase I clinical studies, or additional clinical studies for progression from Phase I to Phase II, or Phase II to Phase III, or for NDA approval;
- the product candidate may not prove to be effective or as effective as other competing product candidates;
- we may discover that a product candidate may cause harmful side effects or results of required toxicology or other studies may not be acceptable to the FDA;
- clinical trial 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;

- clinical site initiation or patient recruitment and enrollment may be slower or more difficult than expected;
- the FDA may not accept the data from any trial or trial site outside of the 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. In addition, due to the impact of the COVID-19 pandemic, clinical site initiation and new patient enrollment has been negatively impacted. Additionally, any of these events described above could result in suspension of a program and/or obviate any filings for necessary regulatory approvals.

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

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

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

We depend on our current collaborators for the development and commercialization of several of our products and product candidates and may need to enter into future collaborations to develop and commercialize certain of our product candidates. For example, we depend on AbbVie for the manufacture and commercialization of ORILISSA and ORIAHNN and for the continued development of elagolix. We collaborate with MTPC for the development and commercialization of INGREZZA for movement disorders in Japan and other select Asian markets. We also rely on BIAL for the commercial supply of ONGENTYS. In addition, we collaborate with Xenon for the development of NBI-921352, Idorsia for the development of NBI-827104 and Takeda for the development of luvadaxistat, NBI-1065845, and NBI-1065846.

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

- strategic collaborators may sell, transfer or divest assets or programs related to our partnered product or product candidates;
- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our products or product candidates;
- we may not be able to influence our strategic collaborator’s decisions regarding the development and collaboration of our partnered product and product candidates, and as a result, our collaboration partners may not pursue or prioritize the development and commercialization of those partnered products and product candidates in a manner that is in our best interest;
- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may not conduct collaborative activities in a timely manner, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;

- disagreements or disputes may arise between us and our strategic collaborators that result in delays or in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and commercialization and may increase the cost of developing and commercializing our products or product candidates; and
- strategic collaborators could develop, either alone or with others, products or product candidates that may compete with ours.

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

We may not be able to successfully commercialize ONGENTYS.

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

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

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

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

At June 30, 2021, we had approximately 884 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.

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

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

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

We have in the past utilized, and intend to continue to utilize, third-party manufacturers to produce the drug compounds we use in our clinical trials and for the commercialization of our products. We have limited experience in manufacturing products for commercial purposes and do not currently have any manufacturing facilities. Establishing internal commercial manufacturing capabilities would require significant time and resources, and we may not be able to timely or successfully establish such capabilities. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes, including INGREZZA and ONGENTYS. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products, including INGREZZA and ONGENTYS. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations, including current Good Manufacturing Practice regulations. Our third-party manufacturers, including BIAL and its suppliers, might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. 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 rely on BIAL and its suppliers to supply all drug product for the commercialization of ONGENTYS. BIAL relies on third-party contract manufacturers to produce ONGENTYS. These contract manufacturers may encounter difficulties in achieving volume production, quality control, or quality assurance. As a result, these contract manufacturers may not be able to adequately produce ONGENTYS in commercial quantities when required, which may impact our ability to deliver ONGENTYS on a timely basis.

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

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

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

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

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

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

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

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

In the event the conditional conversion feature of the 2024 Notes is triggered, holders of 2024 Notes will be entitled to convert their 2024 Notes at any time during specified periods at their option. If one or more of the holders of the 2024 Notes elects to convert their 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. In the event that we have the election to redeem the 2024 Notes or the holders of the 2024 Notes have the election to convert the 2024 Notes at any time during the prescribed measurement period, the 2024 Notes would then be considered a current obligation and classified as such. We are not aware of any events or market conditions that would allow us to redeem the 2024 Notes or the holders of the 2024 Notes to convert the 2024 Notes for the quarterly period ended June 30, 2021, or as of the date of this report.

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

In May 2017, we sold $517.5 million aggregate principal amount of 2.25% convertible senior notes due May 15, 2024, or the 2024 Notes. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. At June 30, 2021, $381.2 million aggregate principal amount of the 2024 Notes remained outstanding. We may also incur additional indebtedness to meet future financing needs. Our indebtedness could have significant negative consequences for our security holders and our business, results of operations and financial condition by, among other things:

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

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

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

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

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

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

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

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.

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

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

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

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

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

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to seasonality and timing of customer purchases and commercial sales of INGREZZA, impact of the commercial launch of ONGENTYS and ORIAHNN, royalties from out-licensed products, the impact of Medicare Part D coverage, our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing, contract research payments, fluctuations in our effective tax rate, and disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic. A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect financial results in a quarter. While we were profitable for the quarter ended June 30, 2021, 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 beginning 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 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 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, 2017, will be subject to a percentage limitation to the extent utilized in tax years beginning after December 31, 2020 and, if we undergo an ownership change (or if we previously underwent such an ownership change), our ability to use all of our pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes may be limited. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California passed legislation imposing limits on the usability of California state NOLs and certain tax credits in tax years beginning after 2019 and before 2023. As a result, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

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

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

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

The price of our common stock is volatile.

The market prices for securities of biotechnology and pharmaceutical companies historically have been highly volatile, and the market for these securities has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The COVID-19 pandemic, for example, has negatively affected the stock market and investor sentiment and has resulted in significant volatility. Furthermore, especially as we and our market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts' forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, which is based on assumptions that may be incorrect or that may change from quarter to quarter, the market price of our common stock could decline. Over the course of the last twelve months, the price of our common stock has ranged from approximately $86 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.

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

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

We have entered into agreements for the distribution of INGREZZA with a limited number of specialty pharmacy providers and a specialty distributor, and all of our product sales of INGREZZA are to these customers. Two of these customers represented approximately 85% of our total product revenue for the six months ended June 30, 2021 and a significant majority of our accounts receivable balance at June 30, 2021. If any of these significant customers becomes subject to bankruptcy, is unable to pay us for our products or is acquired by a company that wants to terminate the relationship with us, or if we otherwise lose any of these significant customers, our revenue, results of operations and cash flows would be adversely affected. Even if we replace the loss of a significant customer, we cannot predict with certainty that such transition would not result in a decline in our revenue, results of operations and cash flows.

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

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

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

- the commercial success of INGREZZA, ONGENTYS, ORILISSA, and/or ORIAHNN;
- debt service obligations on the 2024 Notes;
- continued scientific progress in our R&D and clinical development programs;
- the magnitude and complexity of our research and development programs;
- progress with preclinical testing and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;
- competing technological and market developments;
- developments related to any future litigation;

- the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and
- the cost of any strategic alliances, collaborations, product in-licensing or acquisitions.

We intend to seek additional funding through strategic alliances and may seek additional funding through public or private sales of our securities, including equity securities. In addition, during the second quarter of 2017, we issued the 2024 Notes and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. In November 2020, we entered into separate, privately negotiated transactions with certain holders of the 2024 Notes to repurchase $136.2 million aggregate principal amount of the 2024 Notes for an aggregate repurchase price of $186.9 million in cash. At June 30, 2021, $381.2 million aggregate principal amount of the 2024 Notes remained outstanding. Additional equity or debt financing might not be available on reasonable terms, if at all. In addition, disruptions due to the COVID-19 pandemic could make it more difficult for us to access capital. Any additional equity financings will be dilutive to our stockholders and any additional debt financings may involve operating covenants that restrict our business.

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

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

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

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

Risks Related to Our Industry

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

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

- obtain patent protection for our products;
- preserve our trade secrets;
- prevent third parties from infringing upon our proprietary rights; and
- operate without infringing upon the proprietary rights of others, both in the 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. In addition, potential competitors have in the past and may in the future file an ANDA with the FDA seeking approval to market a generic version of our products before the expiration of the patents covering our products. To prevent infringement or unauthorized use, we have in the past and may in the future need to file infringement claims, which are expensive and time-consuming. For example, we are currently engaged in various intellectual property litigation matters against potential competitors related to INGREZZA. For a more detailed description of these matters, see Note 10 to the condensed consolidated financial statements included in this report. In addition, in an infringement proceeding a court may decide that a patent of ours or a patent of a competitor 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.

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

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

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

- an annual, nondeductible fee on any entity that manufactures, or imports, specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a 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 have been executive 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. The Tax Act includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a 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 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. The US Supreme Court is currently reviewing the constitutionality of the ACA. Although it is unknown when a decision will be made, on January 28, 2021, June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began February 15, 2021 and will remain open through August 15, 2021. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, on February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2030, except for a temporary suspension from May 1, 2020 through December 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review

the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the US Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. The Most Favored Nation regulations mandate participation by identified Medicare Part B providers and will apply in all US states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. On December 28, 2020, the US District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Model interim final rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the federal civil False Claims Act, and Civil Monetary Penalties Laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the Health Insurance Portability and Accountability Act, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates and their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) 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 information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives; and
- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures or drug pricing; state laws that require disclosure of price increases above certain identified thresholds as well as of new commercial launches in the state; state and local laws that require the registration of pharmaceutical sales representatives; state and local "drug take back" laws and regulations; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

In addition, any sales of our product once commercialized outside the 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.

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.

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 business operations may subject us to disputes, claims and lawsuits, which may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.***

From time to time, we may become involved in disputes, claims and lawsuits relating to our business operations. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. Any dispute, claim or lawsuit may divert management’s attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. For example, we are currently engaged in various intellectual property litigation matters against potential competitors related to INGREZZA. For a more detailed description of these matters, see Note 10 to the condensed consolidated financial statements included in this report.

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners and vendors, or by employees of our commercial partners could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately, to maintain the confidentiality of our trade secrets or the trade secrets of our

commercial partners, or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any action against our employees, independent contractors, principal investigators, consultants, commercial partners or vendors for violations of these laws could result in significant civil, criminal, and administrative penalties, fines, and imprisonment.

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

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

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

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

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

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

Additionally, the California Consumer Privacy Act, or CCPA, which went into effect in 2020, created new individual privacy rights for California consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. For example, the CCPA requires covered companies to provide additional disclosures to California consumers, and provides such consumers with new rights, such as the ability to opt out of certain disclosures of personal information. The CCPA provides for civil penalties for violations, as

well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the 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:	Bylaws, as amended
	Reference:	Incorporated by reference to Exhibit 3.2 of the Company's Quarterly Report on Form 10-Q filed on May 5, 2021
4.1	Description:	Form of Common Stock Certificate
	Reference:	Incorporated by reference to the Company's Registration Statement on Form S-1 (Registration No. 333-03172)
4.2	Description:	Indenture, dated as of May 2, 2017, by and between the Company and U.S. Bank National Association, as Trustee
	Reference:	Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed on May 2, 2017
4.3	Description:	Form of Note representing the Company's 2.25% Convertible Notes due 2024
	Reference:	Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K filed on May 2, 2017
31.1	Description:	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Description:	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Description:	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Description:	Inline XBRL Instance Document. – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Description:	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Description:	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Description:	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Description:	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Description:	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Description:	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101)

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

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

SIGNATURES

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

NEUROCRINE BIOSCIENCES, INC.

Dated: August 3, 2021

/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: August 3, 2021

/s/ Kevin C. Gorman

Kevin C. Gorman
Chief Executive Officer

Exhibit 31.2

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

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

1. I have reviewed this 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: August 3, 2021

/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 June 30, 2021 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.

August 3, 2021

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 June 30, 2021 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.

August 3, 2021

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