NEUROCRINE BIOSCIENCES INC
Form 10-Q
November 01, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

OR

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

For the transition period from _____ to _____

Commission File Number: 0-22705

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0525145**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
12780 El Camino Real, San Diego, California	**92130**
(Address of principal executive offices)	**(Zip Code)**

(858) 617-7600

(Registrant s telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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	(Do not check if a smaller reporting company)	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 88,493,045 as of October 27, 2017.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share information)

(unaudited)

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 267,818	$ 83,267
Short-term investments, available-for-sale	243,200	224,083
Accounts receivable	29,818	
Inventory	242	
Other current assets	7,407	3,092
Total current assets	548,485	310,442
Property and equipment, net	9,140	6,271
Long-term investments, available-for-sale	210,258	43,490
Restricted cash	4,613	4,883
Total assets	$ 772,496	$ 365,086
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 37,289	$ 26,182
Current portion of cease-use liability	121	236
Current portion of deferred rent		470
Current portion of deferred gain on sale of real estate	731	3,526
Total current liabilities	38,141	30,414
Deferred gain on sale of real estate	8,226	7,372
Deferred revenue	10,231	10,231
Deferred rent	3,163	1,462
Convertible senior notes	365,110	
Cease-use liability		617
Other liabilities	113	113
Total liabilities	424,984	50,209

Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, $0.001 par value; 220,000,000 shares authorized; issued and outstanding shares were 88,462,002 as of September 30, 2017 and 86,883,300 as of December 31, 2016	88	87
Additional paid-in capital	1,553,718	1,371,432
Accumulated other comprehensive loss	(534)	(318)
Accumulated deficit	(1,205,760)	(1,056,324)
Total stockholders equity	347,512	314,877
Total liabilities and stockholders equity	$ 772,496	$ 365,086

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product sales, net	$ 45,774	$	$ 52,109	$
License fees and milestones	15,000		15,000	15,000
Total revenues	60,774		67,109	15,000
Operating expenses:				
Cost of product sales	433		494	
Research and development	22,463	20,942	96,213	71,708
Sales, general and administrative	43,873	17,494	113,597	44,413
Total operating expenses	66,769	38,436	210,304	116,121
Loss from operations	(5,995)	(38,436)	(143,195)	(101,121)
Other (expense) income, net:				
Gain/(loss) on sale/disposal of assets	5	(9)	7	8
Deferred gain on real estate	183	853	1,941	2,560
Interest expense	(7,337)		(12,104)	
Investment income, net	2,019	705	3,915	2,122
Total other (expense) income	(5,130)	1,549	(6,241)	4,690
Net loss	$ (11,125)	$ (36,887)	$ (149,436)	$ (96,431)
Net loss per common share:				
Basic and diluted	$ (0.13)	$ (0.43)	$ (1.70)	$ (1.11)
Shares used in the calculation of net loss per common share:				
Basic and diluted	88,325	86,784	87,894	86,659
Other comprehensive loss:				
Net loss	$ (11,125)	$ (36,887)	$ (149,436)	$ (96,431)
Net unrealized gains/(losses) on available-for-sale securities	179	(148)	(216)	790
Comprehensive loss	$ (10,946)	$ (37,035)	$ (149,652)	$ (95,641)

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (149,436)	$ (96,431)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,694	1,008
Gain on sale of assets	(1,948)	(2,568)
Deferred rent	1,231	(208)
Cease-use expense	(544)	(584)
Amortization of debt issuance costs	526	
Amortization of debt discount	6,755	
Amortization of premiums on investments	1,202	3,151
Non-cash share-based compensation expense	29,070	20,511
Change in operating assets and liabilities:		
Accounts receivable	(29,818)	
Inventory	(242)	
Other current assets	(4,315)	34
Accounts payable and accrued liabilities	11,107	878
Cease-use liability	(188)	(239)
Other non-current liabilities		(108)
Net cash used in operating activities	(134,906)	(74,556)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(444,538)	(217,141)
Sales and maturities of investments	257,235	318,776
Proceeds from sales of property and equipment	7	13
Deposits and restricted cash	270	(92)
Purchases of property and equipment	(4,563)	(3,761)
Net cash (used in) provided by investing activities	(191,589)	97,795
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	8,265	2,327
Proceeds from issuance of senior convertible notes, net	502,781	
Net cash provided by financing activities	511,046	2,327
Net increase in cash and cash equivalents	184,551	25,566

Cash and cash equivalents at beginning of the period	83,267	74,195
Cash and cash equivalents at end of the period	$ 267,818	$ 99,761
Supplemental Cash Flow Information		
Cash paid for interest during the period	$	$

See accompanying notes to the condensed consolidated financial statements.

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NEUROCRINE BIOSCIENCES, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Description of Business. Neurocrine Biosciences, Inc. (the Company or Neurocrine) was incorporated in California in 1992 and reincorporated in Delaware in 1996. The Company discovers and develops innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs through its novel research and development (R&D) platform focused on neurological, psychological, and endocrine based diseases and disorders. In April 2017, the Company received approval from the United States Food and Drug Administration (FDA) for INGREZZA® (valbenazine), a vesicular monoamine transporter 2 (VMAT2) inhibitor for the treatment of tardive dyskinesia. The Company s three lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone (GnRH) antagonist for women s health that is partnered with AbbVie Inc. (AbbVie), INGREZZA for Tourette syndrome and opicapone, a highly-selective catechol-O-methyltransferase inhibitor for the treatment of Parkinson s disease.

Basis of Presentation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions of the Securities and Exchange Commission (SEC) on Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of the Company s 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 the Company and its wholly owned subsidiaries.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2016 included in the Company s Annual Report on 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 for the full year. The balance sheet at December 31, 2016 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

Impact of Recently Issued Accounting Standards. In May 2014, the Financial Accounting Standards Board (FASB) amended the existing accounting standards for revenue recognition, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. The amended guidance defines a five-step approach for recognizing revenue, which may require us to use more judgment and make more estimates than under the current guidance. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. The amended guidance as currently issued will be effective for public companies in 2018, however early adoption is permitted.

The Company does not anticipate the new standard having a material impact on currently reported net product sales. The Company is also currently evaluating the impact of the new standard on historical revenue recorded for its two

collaboration agreements. This ongoing evaluation is dependent upon the resolution of certain questions relating to the application of, and transition to, the new revenue recognition guidance for collaboration agreements which will ultimately determine the adoption method and the ultimate impact the adoption of this standard will have on the Company s consolidated financial statements. Based on the Company s current assessment of the effect of the new standard on historical revenue under its collaboration agreements that is related to contingent payments, which are not dependent on its performance, the Company believes revenue could potentially be recognized earlier than historically recorded if information is available to allow the Company to record the payments without the risk of a future reversal.

In February 2016, the FASB issued Accounting Standards Update (ASU) 2016-02 Leases. This update amends the current accounting guidance for lease transactions. Under the new guidance, a lessee will be required to recognize both assets and liabilities for any leases in excess of twelve months. Additionally, certain qualitative and quantitative disclosures will also be required in the financial statements. The Company is required to adopt this new guidance beginning in 2019 and early adoption is permitted. The Company s lease for its corporate headquarters is subject to this new guidance and the process of determining the impact of the adoption of this update will have on its consolidated financial statements is ongoing.

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In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash , which clarifies the presentation of restricted cash and restricted cash equivalents in the statements of cash flows. Under this ASU, restricted cash and restricted cash equivalents are included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts presented on the statements of cash flows. This ASU is intended to reduce diversity in practice in the classification and presentation of changes in restricted cash on the statement of cash flows. This ASU requires that the statement of cash flows explain the change in total cash and equivalents and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. This ASU also requires a reconciliation between the total of cash and equivalents and restricted cash presented on the statement of cash flows and the cash and equivalents balance presented on the balance sheet. This ASU is effective for the Company on January 1, 2018, with early adoption permitted. The Company does not expect the adoption of this ASU to have a material effect on its results of operations, financial condition or cash flows.

Use of Estimates. The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

2. PRODUCT SALES, NET

Revenue Recognition Policy. The Company s net product sales consist of U.S. sales of INGREZZA and are recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title to the product and associated risk of loss has passed to the customer, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured.

INGREZZA was approved by the FDA on April 11, 2017 and the Company commenced shipments of INGREZZA to select pharmacies (SPs) and a select distributor (SD) in late April 2017. The SPs dispense product to a patient based on the fulfillment of a prescription and the SD sells product to government facilities, long-term care pharmacies or in-patient hospital pharmacies. The Company s agreements with SPs and SDs provide for transfer of title to the product at the time the product is delivered to the SP or SD. In addition, except for limited circumstances, the SPs and SDs have no right of product return to the Company.

The Company has determined it can reasonably estimate its allowances for rebates and chargebacks at the time title and risk of loss transfers to the SP or SD. Therefore, the Company records revenue when the product is delivered to the SPs or SD, which is an approach frequently referred to as the sell-in revenue recognition model.

The Company recognizes revenue from product sales net of the following allowances:

Distribution Fees: Distribution fees include fees paid to the SPs and SD for data and prompt payment discounts. Distribution fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Rebates: Rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. The Company s expected utilization of rebates is based on data received from the SPs and SD.

Chargebacks: Chargebacks are discounts that relate to contracts with government and other entities purchasing from the SD at a discounted price. The SD charges back to the Company the difference between the price initially paid by the SD and the discounted price paid to the SD by these entities. The Company allowance for chargebacks is based on known SD sales to contracted entities.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is recorded as an offset to gross revenue at the time revenue from the product sale is recognized based on expected and actual program participation.

Product Returns: The Company offers the SPs and SD limited product return rights for damages and shipment errors provided it is within a very limited period after the original shipping date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient or for drug expiration. The Company receives real-time shipping reports and inventory reports from the SPs and SD and has the ability to control the amount of product that is sold to the SPs and SD. It is also able to make a reasonable estimate of potential product returns due to the limited time-frame allowed for the SPs and SD to process returns due to shipment error or damaged product.

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3. REVENUE RECOGNITION FOR SIGNIFICANT COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Revenue Recognition Policy. The Company recognizes revenue for the performance of services when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) services are rendered or products are delivered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

Since 2011, the Company has followed the Accounting Standards Codification (ASC) for Revenue Recognition Multiple-Element Arrangements, if applicable, to determine the recognition of revenue under license and collaboration agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses to the Company s intellectual property, (ii) materials and technology, (iii) pharmaceutical supply, (iv) participation on joint development or joint steering committees, and (v) development services. The payments the Company receives under these arrangements typically include one or more of the following: up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; manufacturing and royalties on future product sales.

The ASC provides guidance relating to the separation of deliverables included in an arrangement into different units of accounting and the allocation of consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. The selling prices of deliverables under an arrangement may be derived using vendor specific objective evidence (VSOE), third-party evidence, or a best estimate of selling price (BESP), if VSOE or third-party evidence is not available. For most pharmaceutical licensing and collaboration agreements, BESP is utilized. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the agreement was sold on a standalone basis. Establishing BESP involves management s judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the agreement. In validating the BESP, management considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as unearned revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

The Company typically receives up-front payments when licensing its intellectual property, which often occurs in conjunction with an R&D agreement. The Company recognizes revenue attributed to the license upon delivery, provided that the license has stand-alone value.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, the Company recognizes the portion of the payment allocable to delivered items as revenue when the specific milestone is achieved, and the contingency is removed.

Prior to the revised multiple element guidance described above, adopted by the Company on January 1, 2011, upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned were classified as deferred revenue and recognized as income over the contract or development period. Revenues from development milestones are accounted for in accordance with the Revenue Recognition Milestone Method Topic of the FASB ASC (Milestone Method). Milestones are recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive. A milestone event is considered to be substantive if its achievability was not reasonably assured at the inception of the agreement and the Company s efforts led to the achievement of the milestone or the milestone was due upon the occurrence of a specific outcome resulting from the Company s performance. The Company assesses whether a milestone is substantive at the inception of each agreement.

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Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe). During 2015, the Company entered into a collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of valbenazine (NBI-98854) for movement disorders in Japan and other select Asian markets. Payments to the Company under this agreement include an up-front license fee of $30 million, up to $85 million in development and commercialization event-based payments, payments for the manufacture of pharmaceutical products, and royalties on product sales in select territories in Asia. Under the terms of the agreement, Mitsubishi Tanabe is responsible for all third-party development, marketing and commercialization costs in Japan and other select Asian markets with the exception of a single Huntington s chorea clinical trial to be performed by the Company, at an estimated cost of approximately $12 million, should Mitsubishi Tanabe request the clinical trial. The Company will be entitled to a percentage of sales of valbenazine in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights.

Under the terms of the Company s agreement with Mitsubishi Tanabe, the collaboration effort between the parties to advance valbenazine towards commercialization in Japan and other select Asian markets is governed by a joint steering committee and joint development committee with representatives from both the Company and Mitsubishi Tanabe. There are no performance, cancellation, termination or refund provisions in the agreement that would have a material financial consequence to the Company. The Company does not directly control when event-based payments will be achieved or when royalty payments will begin. Mitsubishi Tanabe may terminate the agreement at its discretion upon 180 days written notice to the Company. In such event, all valbenazine product rights for Japan and other select Asian markets would revert to the Company.

The Company has identified the following deliverables associated with the Mitsubishi Tanabe agreement: valbenazine technology license and existing know-how, development activities to be performed as part of the collaboration, and the manufacture of pharmaceutical products. The respective standalone value from each of these deliverables has been determined by applying the BESP method and the revenue was allocated based on the relative selling price method with revenue recognition timing to be determined either by delivery or the provision of services.

As discussed above, the BESP method required the use of significant estimates. The Company used an income approach to estimate the selling price for the technology license and an expense approach for estimating development activities and the manufacture of pharmaceutical products. The development activities and the manufacture of pharmaceutical products are expected to be delivered throughout the duration of the agreement. The technology license and existing know-how was delivered on the effective date of the agreement.

During the first quarter of 2015, the Company recognized revenue under this agreement of $19.8 million associated with the delivery of a technology license and existing know-how. In accordance with the Company s continuing performance obligations, $10.2 million of the $30 million up-front payment is being deferred and recognized in future periods. Under the terms of the agreement, there is no general obligation to return the up-front payment for any non-contingent deliverable.

The Company evaluated the event-based payments under the Milestone Method and concluded only one immaterial event-based payment represents a substantive milestone. Event-based payments will be recognized when earned. During the third quarter of 2017, the Company recognized $15 million in development event-based payments resulting from Mitsubishi Tanabe s initiation of Phase II/III development of valbenazine in tardive dyskinesia in Asia.

The Company is eligible to receive from Mitsubishi Tanabe tiered royalty payments based on product sales in Japan and other select Asian markets. Royalties will be recognized as earned in accordance with the terms of the agreement, when product sales are reported by Mitsubishi Tanabe, the amount can be reasonably estimated, and collectability is reasonably assured.

AbbVie Inc. (AbbVie). In June 2010, the Company announced an exclusive worldwide collaboration with AbbVie, to develop and commercialize elagolix and all next-generation GnRH antagonists (collectively, GnRH Compounds) for women s and men s health. AbbVie made an upfront payment of $75 million and has agreed to make additional development and regulatory event-based payments of up to $480 million, of which $45 million has been earned to date, and up to an additional $50 million in commercial event-based payments. The Company has assessed event-based payments under the revised authoritative guidance for research and development milestones and determined that event-based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (1) they are events that can only be achieved in part on the Company s past performance, (2) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (3) they result in additional payments being due to the Company. Development and regulatory event-based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of AbbVie. As of September 30, 2017, approximately $485 million remains outstanding in future event-based payments under the agreement as the performance is based solely on AbbVie. However, none of the remaining event-based payments meet the definition of a milestone in accordance with authoritative accounting guidance.

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Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing and commercialization costs. The Company will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. AbbVie may terminate the collaboration at its discretion upon 180 days written notice to the Company. In such event, the Company would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to the Company. During the first quarter of 2016, the Company recognized $15 million in development event-based payments resulting from AbbVie initiating Phase III development of elagolix in uterine fibroids.

4. INVENTORY AND COST OF PRODUCT SALES

Inventory is stated at the lower of cost or estimated net realizable value. The Company currently uses actual costing to determine the cost basis for its inventory. Inventory is valued on a first-in, first-out basis and consists primarily of third-party manufacturing costs. The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed.

Prior to FDA approval of INGREZZA, all costs related to its manufacturing were charged to research and development expense in the period incurred. At September 30, 2017, the Company s physical inventory included active pharmaceutical product that had been produced prior to FDA approval of INGREZZA and accordingly has no cost basis as the cost associated with producing this material was expensed rather than capitalized in accordance with authoritative guidance. Additionally, manufacturing of bulk drug product, finished bottling and other labeling activities that occurred post FDA approval are included in the inventory value at September 30, 2017.

The Company provides reserves for potential excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. To date, the Company has determined that such reserves are not required.

Cost of product sales consists of third-party manufacturing costs, transportation and freight, and indirect overhead costs associated with the manufacture and distribution of INGREZZA. Cost of product sales may also include period costs related to certain inventory manufacturing services, inventory adjustment charges as well as manufacturing variances. A significant portion of the cost of producing the product sold during the three and nine month periods ended September 30, 2017 was expensed as R&D prior to our New Drug Application (NDA) approval for INGREZZA and therefore is not included in the cost of product sales during this period.

5. ACCOUNTS RECEIVABLE

Accounts receivable are recorded net of customer allowances for prompt payment discounts, chargebacks, and any allowance for doubtful accounts. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. To date, the Company has determined that an allowance for doubtful accounts is not required.

6. INVESTMENTS

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income or expense. The cost of securities sold is based on the specific identification method. Interest and dividends on

securities classified as available-for-sale are included in interest income.

Investments consist of the following (*in thousands*):

	September 30, 2017	December 31, 2016
Certificates of deposit	$ 240	$ 960
Commercial paper	66,735	49,245
Corporate debt securities	363,012	204,436
Securities of government sponsored entities	23,471	12,932
Total investments	$ 453,458	$ 267,573

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The following is a summary of investments classified as available-for-sale securities (*in thousands*):

	Contractual Maturity (in years)	Amortized Cost	Gross Unrealized Gains(1)	Gross Unrealized Losses(1)	Aggregate Estimated Fair Value
September 30, 2017:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 240	$	$	$ 240
Commercial paper	Less than 1	66,759		(24)	66,735
Corporate debt securities	Less than 1	163,870	3	(131)	163,742
Securities of government-sponsored entities	Less than 1	12,503		(21)	12,482
Total short-term available-for-sale securities		$ 243,372	$ 3	$ (176)	$ 243,199
Classified as non-current assets:					
Corporate debt securities	1 to 2	$ 199,615	$	$ (345)	$ 199,270
Securities of government-sponsored entities	1 to 2	11,005		(16)	10,989
Total long-term available-for-sale securities		$ 210,620	$	$ (361)	$ 210,259
December 31, 2016:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 960	$	$	$ 960
Commercial paper	Less than 1	49,280	3	(38)	49,245
Corporate debt securities	Less than 1	168,548	3	(117)	168,434
Securities of government-sponsored entities	Less than 1	5,448		(4)	5,444
Total short-term available-for-sale securities		$ 224,236	$ 6	$ (159)	$ 224,083
Classified as non-current assets:					
Corporate debt securities	1 to 2	$ 36,149	$	$ (147)	$ 36,002
Securities of government-sponsored entities	1 to 2	7,506		(18)	7,488
Total long-term available-for-sale securities		$ 43,655	$	$ (165)	$ 43,490

(1) Unrealized gains and losses are included in other comprehensive loss.

The following table presents gross unrealized losses and fair value for those available-for-sale investments that were in an unrealized loss position as of September 30, 2017 and December 31, 2016, aggregated by investment category and length of time that individual securities have been in a continuous loss position (*in thousands*):

						Total	

	Less Than 12 Months		12 Months or Greater		Estimated	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
September 30, 2017:						
Commercial paper	$ 66,735	$ (24)	$	$	$ 66,735	$ (24)
Corporate debt securities	325,223	(463)	14,298	(13)	339,521	(476)
Securities of government-sponsored entities	15,988	(17)	7,483	(20)	23,471	(37)
Total	$ 407,946	$ (504)	$ 21,781	$ (33)	$ 429,727	$ (537)
December 31, 2016:						
Commercial paper	$ 43,781	$ (38)	$	$	$ 43,781	$ (38)
Corporate debt securities	185,243	(261)	9,144	(3)	194,387	(264)
Securities of government-sponsored entities	12,932	(22)			12,932	(22)
Total	$ 241,956	$ (321)	$ 9,144	$ (3)	$ 251,100	$ (324)

The primary objective of the Company s investment portfolio is to enhance overall returns in an efficient manner while maintaining safety of principal, prudent levels of liquidity and acceptable levels of risk. The Company s investment policy limits interest-bearing security investments to certain types of instruments issued by institutions with primarily investment grade credit ratings and places restrictions on maturities and concentration by asset class and issuer.

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The Company reviews the available-for-sale investments for other-than-temporary declines in fair value below cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. This evaluation is based on a number of factors, including the length of time and the extent to which the fair value has been below the cost basis and adverse conditions related specifically to the security, including any changes to the credit rating of the security, and the intent to sell, or whether the Company will more likely than not be required to sell the security before recovery of its amortized cost basis. The assessment of whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security. As of September 30, 2017 and December 31, 2016, the Company believed the cost bases for available-for-sale investments were recoverable in all material respects.

7. FAIR VALUE MEASUREMENTS

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;
Level 2: Inputs include quoted prices for similar instruments in active markets and/or quoted prices for identical or similar instruments in markets that are not active near the measurement date; and
Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company classifies its cash equivalents and available-for-sale investments within Level 1 or Level 2. The fair value of the Company s high quality investment grade corporate debt securities is determined using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or prices for similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company did not reclassify any investments between levels in the fair value hierarchy during the nine months ended September 30, 2017.

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The Company s assets which were measured at fair value on a recurring basis as of September 30, 2017 and December 31, 2016 were determined using the inputs described above and are as follows (*in millions*):

	Carrying Value	Fair Value Measurements Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
September 30, 2017:				
Classified as current assets:				
Cash and money market funds	$ 269.4	$ 269.4	$	$
Certificates of deposit	0.2	0.2		
Commercial paper	66.7		66.7	
Securities of government-sponsored entities	12.5		12.5	
Corporate debt securities	163.7		163.7	
Subtotal	512.5	269.6	242.9	
Classified as long-term assets:				
Certificates of deposit	3.0	3.0		
Securities of government-sponsored entities	11.0		11.0	
Corporate debt securities	199.3		199.3	
Total	725.8	272.6	453.2	
Less cash, cash equivalents and restricted cash	(272.4)	(272.4)		
Total investments	$ 453.4	$ 0.2	$ 453.2	$
December 31, 2016:				
Classified as current assets:				
Cash and money market funds	$ 73.6	$ 73.6	$	$
Certificates of deposit	1.0	1.0		
Commercial paper	49.2		49.2	
Securities of government-sponsored entities	5.4		5.4	
Corporate debt securities	178.1		178.1	
Subtotal	307.3	74.6	232.7	
Classified as long-term assets:				
Certificates of deposit	4.9	4.9		
Securities of government-sponsored entities	7.5		7.5	
Corporate debt securities	36.0		36.0	
Total	355.7	79.5	276.2	
Less cash, cash equivalents and restricted cash	(88.1)	(78.5)	(9.6)	

Total investments	$ 267.6	$ 1.0	$ 266.6	$

The carrying amounts of the Company s receivables and payables approximate their fair value due to their short maturities.

8. SHARE-BASED COMPENSATION

The compensation expense related to the Company s share-based compensation arrangements has been included in the condensed consolidated statements of comprehensive loss as follows (*in millions*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Sales, general and administrative	$ 6.5	$ 3.5	$ 18.2	$ 11.8
Research and development	3.7	2.8	$ 10.9	$ 8.7
Total share-based compensation expense	$ 10.2	$ 6.3	$ 29.1	$ 20.5

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The fair value of equity instruments that vest based on continued employee service, net of estimated forfeitures, is recognized and amortized on a straight-line basis over the requisite service period. For restricted stock units (RSUs) with performance-based vesting requirements (PRSUs), no expense is recorded until the performance condition is probable of being achieved. The Company estimates forfeiture rates for equity awards based on past behavior for similar equity awards with further consideration given to the class of employees to whom the equity awards were granted.

As of September 30, 2017, total unrecognized estimated compensation cost related to non-vested stock options and non-vested RSUs, that vest over a given service period, granted prior to that date was $50.9 million and $32.7 million, respectively, which is expected to be recognized over a weighted average period of approximately 2.8 years and 2.9 years, respectively. Additionally, the Company has approximately 0.2 million PRSUs outstanding. The total unrecognized estimated compensation cost related to these PRSUs is $7.5 million and will be recognized over the expected performance period once the achievement of performance conditions becomes probable.

During the nine months ended September 30, 2017 and 2016, stock options to purchase approximately 1.0 million and 0.3 million shares of the Company s common stock were exercised, respectively. The cash received by the Company from stock option exercises during the nine months ended September 30, 2017 and 2016 was approximately $8.3 million and $2.3 million, respectively. The Company also issued approximately 0.3 million shares of common stock pursuant to the vesting of RSUs during each of the nine months ended September 30, 2017 and 2016, and 0.2 million shares of common stock pursuant to the vesting of PRSUs during the second quarter of 2017.

Stock Option Assumptions

The Company granted stock options to purchase approximately 1.6 million and 1.0 million shares of the Company s common stock during the nine months ended September 30, 2017 and 2016, respectively. These stock options generally vest monthly over a four-year period. The exercise price of all stock options granted during the nine months ended September 30, 2017 and 2016 was equal to the closing price of the Company s common stock on the date of grant. The estimated fair value of each stock option granted was determined on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions for the stock option grants:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Risk-free interest rate	1.8%	1.1%	2.0%	1.4%
Expected volatility of common stock	59.6%	59.3%	58.2%	60.0%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option term	5 years	5 years	5.7 years	5.6 years

The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and interest rates. The expected volatility is based on the historical volatility of the Company s common stock over the most recent period commensurate with the estimated expected term of the Company s stock options. The expected option term is estimated based on historical experience as well as the status of the employee. For example, directors and officers have a longer expected option term than all other employees. The risk-free rate for periods within the contractual life of the option is based upon observed interest rates appropriate for the expected term of the Company s employee stock options. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future. For the nine months ended September 30, 2017 and 2016, share-based compensation expense related to stock options was $18.7 million and $13.1 million, respectively.

Restricted Stock Units

During the nine months ended September 30, 2017 and 2016, the Company granted approximately 0.6 million and 0.3 million RSUs, respectively, that generally vest annually over a four-year period. Additionally, during the nine months ended September 30, 2016, the Company granted approximately 0.2 million PRSUs. These PRSUs vest based on the achievement of pre-defined Company-specific performance criteria and expire four years from the grant date. Expense recognition for PRSUs commences when attainment of the performance based criteria is determined to be probable. The fair value of RSUs and PRSUs is estimated based on the closing sale price of the Company s common stock on the date of grant. For the nine months ended September 30, 2017 and 2016, share-based compensation expense related to RSUs and PRSUs was $10.4 million and $7.4 million, respectively.

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9. STOCKHOLDERS EQUITY

Equity Financing

In February 2017, the Company filed an automatic shelf registration statement which immediately became effective by rule of the SEC. For so long as the Company continues to satisfy the requirements to be deemed a well-known seasoned issuer, this shelf registration statement allows the Company to issue an unlimited number of securities from time to time. As of September 30, 2017, the Company had not sold any securities under this shelf registration statement.

The specific terms of future offerings, if any, under the shelf registration statement would be established at the time of such offerings.

10. REAL ESTATE

In December 2007, the Company closed the sale of its facility and associated real property for a purchase price of $109 million. Concurrent with the sale, the Company retired the entire $47.7 million in mortgage debt previously outstanding with respect to the facility and associated real property, and received cash of $61.0 million net of transaction costs and debt retirement.

Upon the closing of the sale of the facility and associated real property, the Company entered into a lease agreement (Lease) whereby it leased back for an initial term of 12 years its corporate headquarters comprised of two buildings located at 12790 El Camino Real (Front Building) and 12780 El Camino Real (Rear Building) in San Diego, California. The Company also entered into a series of lease amendments (Amendments), beginning in late 2008 through 2011, through which it was able to vacate the Front Building, but continue to occupy the Rear Building. The ultimate result of this real estate sale was a net gain of $39.1 million which was deferred in accordance with authoritative guidance. The Company recognized $0.2 million and $0.9 million of the deferred gain during the three month periods ending September 30, 2017 and 2016, respectively. The Company recognized $2.0 million and $2.6 million of the deferred gain during the nine month periods ending September 30, 2017 and 2016, respectively, and will recognize the remaining $9.0 million of the deferred gain on a straight-line basis over the amended Lease term which will expire at the end of 2029.

During 2017, the Company entered into an amendment to extend the current term of the Lease through December 31, 2029 (Term Amendment). Under the Term Amendment, the Company reduced its base rental rate by approximately 8% and will continue to pay base annual rent (subject to an annual fixed percentage increase), plus a 3.5% annual management fee, property taxes and other normal and necessary expenses associated with the Lease such as utilities, repairs and maintenance. Certain incentives were included in the Term Amendment, including approximately $13.1 million in various tenant improvement allowances, three months of rent abatement, and a reduction in the required security deposit amount from $4.7 million to $3.0 million. In lieu of a cash security deposit, Wells Fargo Bank, N.A. issued on the Company s behalf a letter of credit in the amount of $3.0 million, which is secured by a deposit of equal amount with the same bank. The Company also has the right to extend the Lease for two consecutive ten-year terms as well as a right of first offer for future rental of adjacent office space owned by the landlord.

As of September 30, 2017, the Company had one sublease agreement for approximately 16,000 square feet of the Rear Building. This sublease is expected to result in approximately $0.6 million of rental income in 2017 with this sublease rental income being recorded as an offset to rent expense. The income generated under this sublease is lower than the Company s financial obligation under the Lease for the Rear Building, as determined on a per square foot basis. Consequently, at the inception of a sublease, or in association with an amendment to a sublease, the Company is

required to record a cease-use liability for the net present value of the estimated difference between the expected income to be generated under the sublease and future subleases and the Lease obligation over the remaining term of the Lease for the space that is occupied by the subtenant. As a result of the recent FDA approval for INGREZZA and the Term Amendment, the Company has determined that it will reoccupy the space at the conclusion of the sole remaining sublease in March 2018. Additionally, during the first quarter of 2016, the Company terminated another previously existing sublease and began to reoccupy the related space to allow for expansion. These two sublease terminations resulted in reversal of cease use expense of approximately $0.5 million and $0.8 million during the second quarter of 2017 and the first quarter of 2016, respectively.

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The following table sets forth changes to the accrued cease-use liability during the three and nine months ended September 30, 2017 and 2016 (*in thousands*):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Beginning balance	$ 181	$ 972	$ 853	$ 1,983
Change in estimate			(544)	(830)
Payments	(60)	(58)	(188)	(239)
Ending balance	$ 121	$ 914	$ 121	$ 914

11. CONVERTIBLE SENIOR NOTES

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

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 commencing after the calendar quarter ending on September 30, 2017 (and only during such calendar quarter), if the last reported sale price of the Company s common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than 130% of the conversion price on each applicable trading day;

(ii) during the five business-day period immediately after any five consecutive trading-day period (the measurement period) in which the trading price (as defined in the 2024 Indenture) per $1,000 principal amount of the 2024 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company s 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 the Company s assets; or

(iv) if the Company calls 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 the Company s common stock or a combination of cash and shares of the Company s common stock, at the Company s option.

It is the Company s 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 indenture for the notes. 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 (VWAP) of the Company s 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 the Company s common stock. 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 represents a premium of approximately 42.5% to the closing sale price of $53.28 per share of the Company s common stock on the NASDAQ Global Select Market on April 26, 2017, the date that the Company priced the private offering of the 2024 Notes.

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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, the Company would be required to repay the $517.5 million in principal value and any conversion premium in any combination of cash and shares of its common stock (at the Company s option).

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

If the Company undergoes a fundamental change, as defined in the 2024 Indenture, subject to certain conditions, holders of the 2024 Notes may require the Company 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, the Company 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 the Company s general unsecured obligations that rank senior in right of payment to all of its indebtedness that is expressly subordinated in right of payment to the 2024 Notes, and equal in right of payment to the Company s unsecured indebtedness.

The fair value of the 2024 Notes is estimated utilizing market quotations from an over-the-counter trading market. As of September 30, 2017, the fair value approximated 113.75 percent of the face principal amount of the 2024 Notes.

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While the 2024 Notes are currently classified on the Company s consolidated balance sheet at September 30, 2017 as long-term, the future convertibility and resulting balance sheet classification of this liability will be monitored at each quarterly reporting date and will be analyzed dependent upon market prices of the Company s common stock during the prescribed measurement periods. In the event that 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.

Under current accounting guidance, an entity must separately account for the liability and equity components of convertible debt instruments (such as the 2024 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer s 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 is 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.

The Company 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 the Company. 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.

Debt, net of discounts and deferred financing costs at September 30, 2017, consisted of the following:

Principal	$ 517,500
Deferred financing costs	(9,975)
Debt discount, net	(142,415)
Net carrying amount	$ 365,110

12. LOSS PER COMMON SHARE

The Company computes basic net loss per share using the weighted average number of common shares outstanding during the period. In computing the diluted net loss, potentially dilutive securities, composed of incremental common shares issuable upon the exercise of stock options and warrants and the vesting of RSUs and PRSUs as well as the conversion of the excess conversion value on the 2024 Notes, are excluded from the diluted loss per share calculation because of their anti-dilutive effect. Since it is the Company s intent to settle the principal amount of its convertible senior notes in cash, the potentially dilutive effect of such notes on net income (loss) per share is computed under the

treasury stock method.

Basic net income (loss) per share is calculated by dividing the net income (loss) attributable to common shares by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is calculated by dividing the net income (loss) attributable to common shares by the weighted average number of common shares outstanding plus dilutive potential common stock outstanding during the period. Potential common shares outstanding include the shares of common stock issuable upon the exercise of outstanding stock options and the vesting of RSUs, calculated using the treasury stock method. In addition, since it is the Company s intent to settle the principal amount of its 2024 Notes in cash, the potentially dilutive effect of these notes is also calculated under the treasury stock method.

Potential common shares are excluded from the diluted net loss per share computation to the extent they would be antidilutive. Because the Company reported a net loss for the three and nine months ended September 30, 2017 and 2016, no potentially dilutive securities have been included in the computation of diluted net loss per share for those periods.

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For the three and nine months ended September 30, 2017, the Company realized a net loss of $11.1 million and $149.4 million, respectively. Options to purchase approximately 0.2 million and 0.4 million shares of common stock were outstanding during the three and nine months ended September 30, 2017, respectively, with an exercise price greater than the average market price of the underlying common shares.

For the three and nine months ended September 30, 2016, the Company realized a net loss of $36.9 million and $96.4 million, respectively. Options to purchase approximately 0.1 million and 0.4 million shares of common stock were outstanding during each of the three and nine months ended September 30, 2016, with an exercise price greater than the average market price of the underlying common shares.

13. RESEARCH AND DEVELOPMENT

R&D expenses consist primarily of salaries, payroll taxes, employee benefits, and share-based compensation charges, for those individuals involved in ongoing R&D efforts; as well as scientific contractor fees, preclinical and clinical trial costs, R&D facilities costs, laboratory supply costs, and depreciation of scientific equipment. All such costs are charged to R&D expense as incurred. These expenses result from the Company s independent R&D efforts as well as efforts associated with collaborations and in-licensing arrangements. In addition, the Company funds R&D at other companies and research institutions under agreements, which are generally cancelable. The Company reviews and accrues clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of patient studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical costs are subject to revisions as trials progress. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

14. BIAL AGREEMENT

In February 2017, the Company entered into an exclusive license agreement with BIAL Portela & CA, S.A. (BIAL) for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson s disease, in the United States and Canada. Under the terms of the agreement, the Company is responsible for the management and cost of all opicapone development and commercialization activities in the United States and Canada.

Under the terms of the agreement, the Company paid BIAL an upfront license fee of $30 million, and may also be required to pay up to an additional $115 million in milestone payments associated with the regulatory approval and net sales of products containing opicapone. The initial upfront license fee was expensed in the first quarter of 2017 as in-process research and development. Upon commercialization of opicapone, the Company has agreed to determine certain annual sales forecasts. In the event that the Company fails to meet the minimum sales requirements for a particular year, the Company will be required to pay BIAL an amount corresponding to the difference between the actual net sales and the minimum sales requirements for such year, and if the Company fails to meet the minimum sales requirements for any two years, BIAL may terminate the agreement.

The agreement, unless terminated earlier, will continue on a licensed product-by-licensed product and country-by-country basis until a generic product in respect of such licensed product under the agreement is sold in a country and sales of such generic product are greater than a specified percentage of total sales of such licensed product in such country. Upon the Company s written request prior to the estimated expiration of the term in respect of a licensed product, the parties shall negotiate a good faith continuation of BIAL s supply of such licensed product after the term. After the term, and if BIAL is not supplying a certain licensed product, the Company shall pay BIAL a trademark royalty based on the net sales of such licensed product. Either party may terminate the agreement earlier if

the other party materially breaches the agreement and does not cure the breach within a specified notice period, or upon the other party s insolvency. BIAL may terminate the agreement if the Company fails to use commercially reasonable efforts or fails to file an NDA for a licensed product by a specified date or under certain circumstances involving a change of control of the Company. In certain circumstances where BIAL elects to terminate the agreement in connection with the Company s change of control, BIAL shall pay the Company a termination fee. The Company may terminate the agreement at any time for any reason upon six months written notice to BIAL if prior to the first NDA approval in the United States, and upon nine months written notice to BIAL if such notice is given after the first NDA approval in the United States. If the Company s termination request occurs prior to the first NDA approval in the United States, the Company will have to pay BIAL a termination fee except under certain conditions specified in the agreement.

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15. COMMITMENTS AND CONTINGENCIES

On December 1, 2015, Icahn School of Medicine at Mount Sinai (Mount Sinai) filed a complaint against the Company in the United States District Court for the Southern District of New York: Icahn School of Medicine at Mount Sinai v. Neurocrine Biosciences, Inc., Case No. 1:15-cv-09414. In the complaint, Mount Sinai alleges that the Company, by entering into an exclusive worldwide collaboration with AbbVie to develop and commercialize next-generation GnRH antagonists, breached a license agreement with Mount Sinai dated August 27, 1999 (Mount Sinai License). Mount Sinai is seeking unspecified monetary damages, future sublicensing fees and attorney s fees. In January 2016, the Company filed a motion to dismiss this complaint in its entirety. In June 2016, the Court denied the motion in part and granted the motion in part, ruling that while Mount Sinai could continue its lawsuit against the Company, there was no requirement by the Company to obtain Mount Sinai s consent prior to licensing the next-generation GnRH antagonists to AbbVie. In July 2016, the Company filed its answer denying Mount Sinai s allegations, and filed counterclaims against Mount Sinai. Mount Sinai filed a motion to dismiss the Company s counterclaims and affirmative defenses, which the Court granted. A trial is anticipated to occur in the first half of 2018.The Company believes that it has meritorious defenses to the claims made in the complaint and intends to vigorously defend against such claims, but is not able to predict the ultimate outcome of this action, or estimate any potential loss.

The Company is not aware of any other proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

16. CONCENTRATION RISK

The Company does not currently have any of its own manufacturing facilities, and therefore it depends on an outsourced manufacturing strategy for the production of INGREZZA for commercial use and for the production of its product candidates for clinical trials. The Company has contracts in place with one third-party manufacturer that is approved for the commercial production of INGREZZA s capsules and one third-party manufacturer that is approved for the production of INGREZZA s active pharmaceutical ingredient. Although there are potential sources of supply other than the Company s existing suppliers, any new supplier would be required to qualify under applicable regulatory requirements.

The Company has entered into distribution agreements with a limited number of SPs and SDs, and all of the Company s product sales are to these customers. The Company s three largest customers represented all of the Company s product revenue for the quarter ended September 30, 2017 and all of the Company s accounts receivable balance at September 30, 2017.

17. SUBSEQUENT EVENTS

During October 2017, the Company was notified by AbbVie that the NDA submission for elagolix was accepted as filed by the FDA. This filing generated a $30 million event-based payment to the Company during the fourth quarter of 2017, which is payable by AbbVie within 30 days of the event.

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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 below 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, 2016 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, 2016 and our Quarterly Report on Form 10-Q for the three and six months ended June 30, 2017.

OVERVIEW

We discover and develop innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through our novel research and development (R&D) platform, focused on neurological, psychological and endocrine based diseases and disorders. Utilizing a portfolio approach to drug discovery, we have multiple small molecule drug candidates at various stages of pharmaceutical development. We develop proprietary pharmaceuticals for our pipeline, as well as collaborate with other pharmaceutical companies on our discoveries.

On April 11, 2017, the U.S. Food and Drug Administration (FDA) approved INGREZZA® (valbenazine) capsules for the treatment of adults with tardive dyskinesia (TD). We market INGREZZA for TD in the United States through our specialty sales force focused primarily on physicians who treat TD patients, including psychiatrists and neurologists. The commercial launch of INGREZZA, with our field-based sales team of approximately 160 personnel, occurred on May 1, 2017.

Our three lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone (GnRH) antagonist that is partnered with AbbVie Inc. (AbbVie). AbbVie has filed for marketing approval with the FDA for endometriosis and which is currently in Phase III development for uterine fibroids, opicapone, a highly-selective catechol-O-methyltransferase inhibitor (COMT inhibitor) that is an adjunct therapy to preparations of levodopa/DOPA decarboxylase inhibitors for adult patients with Parkinson s disease and was inlicensed from BIAL Portela & CA, S.A. (BIAL), and our vesicular monoamine transporter 2 (VMAT2) inhibitor, INGREZZA, is currently in Phase II development for Tourette syndrome.

We have funded our operations primarily through private and public offerings of our common stock, debt securities and payments received under collaboration agreements. While we independently develop many of our product candidates, we have entered into collaborations for several of our programs, and intend to rely on our product revenues and existing and future collaborators to meet funding requirements. We expect to generate future operating cash flow losses as product candidates are advanced through the various stages of clinical development and as we proceed with the commercial launch of INGREZZA. As of December 31, 2016, we had an accumulated deficit of approximately $1.1 billion and expect to incur operating cash flow losses for the foreseeable future, which may be greater than losses in prior years.

We currently have three major collaborations. Two of these collaborations involve outlicensing of our proprietary technology to pharmaceutical partners. In June 2010, we announced an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation GnRH antagonists (collectively, GnRH Compounds) and in March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe Pharma Corporation (Mitsubishi Tanabe) for the development and commercialization of INGREZZA for movement

disorders in Japan and other select Asian markets. These two agreements are discussed below under the heading Critical Accounting Policies and Estimates. The third collaboration agreement is one in which we inlicensed technology from BIAL.

In February 2017, we entered into an exclusive license agreement with BIAL for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson s disease, in the United States and Canada. Under the terms of the agreement, we are responsible for the management and cost of all opicapone development and commercialization activities in the United States and Canada.

Under the terms of the agreement, we paid BIAL an upfront license fee of $30 million, and we may also be required to pay up to an additional $115 million in milestone payments associated with the regulatory approval and net sales of products containing opicapone. The initial upfront license fee was expensed in the first quarter of 2017 as in process research and development. Upon commercialization of opicapone, we have agreed to determine certain annual sales forecasts. In the event that we fail to meet the minimum sales requirements for a particular year, we will be required to pay BIAL an amount corresponding to the difference between the actual net sales and the minimum sales requirements for such year, and if we fail to meet the minimum sales requirements for any two years, BIAL may terminate the agreement.

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The agreement, unless terminated earlier, will continue on a licensed product-by-licensed product and country-by-country basis until a generic product in respect of such licensed product under the agreement is sold in a country and sales of such generic product are greater than a specified percentage of total sales of such licensed product in such country. Upon our written request prior to the estimated expiration of the term in respect of a licensed product, the parties shall negotiate a good faith continuation of BIAL s supply of such licensed product after the term. After the term, and if BIAL is not supplying a certain licensed product, we shall pay BIAL a trademark royalty based on the net sales of such licensed product. Either party may terminate the agreement earlier if the other party materially breaches the agreement and does not cure the breach within a specified notice period, or upon the other party s insolvency. BIAL may terminate the agreement if we fail to use commercially reasonable efforts or fail to file a New Drug Application (NDA) for a licensed product by a specified date or under certain circumstances involving our change of control. In certain circumstances where BIAL elects to terminate the agreement in connection with our change of control, BIAL shall pay us a termination fee. We may terminate the agreement at any time for any reason upon six months written notice to BIAL if prior to the first NDA approval in the United States, and upon nine months written notice to BIAL if such notice is given after the first NDA approval in the United States. If our termination request occurs prior to the first NDA approval in the United States, we will have to pay BIAL a termination fee except under certain conditions specified in the agreement.

In May 2017, we issued $517.5 million aggregate principal amount of 2.25% Convertible Senior Notes due May 2024 (2024 Notes). Debt issuance costs of approximately $14.7 million were primarily comprised of initial purchasers discounts and commissions, legal, accounting, and other professional fees, a portion of which was capitalized and are recorded as a reduction to long-term debt and is being amortized as interest expense using the effective interest method over the seven-year term of the notes. The remaining debt issuance costs were allocated as a component of equity in additional paid-in capital.

The 2024 Notes will be convertible into cash, shares of common stock, or a combination of cash and shares of common stock based on an initial conversion rate, subject to adjustment, of 13.1711 shares per $1,000 principal amount of the 2024 Notes (which represents an initial conversion price of approximately $75.92 per share). The 2024 Notes will mature on May 15, 2024, unless earlier converted, redeemed or repurchased. Prior to the close of business on the business day immediately preceding January 15, 2024, the 2024 Notes will be convertible at the option of the holders only upon satisfaction of certain circumstances. Thereafter, the 2024 Notes will be convertible at the option of the holders at any time up until the close of business on the scheduled trading day immediately preceding May 15, 2024. We may not redeem the 2024 Notes prior to May 15, 2021. On or after this date, at our election, we may redeem all, or any portion, of the 2024 Notes for cash if the last reported sales price of our common stock, for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day immediately preceding the date which we send the related redemption notice, is more than 130% of the conversion price of the 2024 Notes in effect on each applicable trading day.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to product revenue, cost of product sales, revenues under collaborative research agreements, clinical trial accruals (R&D expense), share-based compensation, lease related activities, investments, accounts receivable, inventories and fixed assets. Estimates are based on historical experience, information received from third parties and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not

readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The items in our financial statements requiring significant estimates and judgments are as follows:

Product Revenue Recognition. Our net product sales consist of U.S. sales of INGREZZA and are recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title to the product and associated risk of loss has passed to the customer, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured. INGREZZA was approved by the FDA on April 11, 2017 and we commenced shipments of INGREZZA to select pharmacies (SPs) and a select distributors (SD) in late April 2017. SPs dispense product to a patient based on the fulfillment of a prescription and SDs sell product to government facilities, long-term care pharmacies or in-patient hospital pharmacies. Our agreements with SPs and the SD provide for transfer of title to the product at the time the product is delivered to the SP or SD. In addition, except for limited circumstances, the SPs and SD have no right of product return to us. This limited right of return results in the SP or SD using a just-in-time inventory model and which results in frequent product deliveries from our central distribution center. Our agreements with our SPs and SD provide data related to prescription fulfillment including the insurance coverage, copay amounts, deductibles and other data necessary to determine net product sales.

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We record revenue when the product is delivered to our SPs or SD, which is an approach frequently referred to as the sell-in revenue recognition model. We recognize revenue from product sales net of allowances for distribution fees, rebates, chargebacks, and co-payment assistance.

Collaboration Agreement Revenue Recognition. We recognize revenue for the performance of services when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) services are rendered or products are delivered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

Since 2011, we have followed the Accounting Standards Codification (ASC) for Revenue Recognition Multiple-Element Arrangements, if applicable, to determine the recognition of revenue under license and collaboration agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) licenses to our intellectual property, (ii) materials and technology, (iii) pharmaceutical supply, (iv) participation on joint development or joint steering committees, and (v) development services. The payments we receive under these arrangements typically include one or more of the following: up-front license fees; funding of research and/or development efforts; amounts due upon the achievement of specified milestones; manufacturing and royalties on future product sales.

The ASC provides guidance relating to the separation of deliverables included in an arrangement into different units of accounting and the allocation of consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables, (ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

To determine the units of accounting under a multiple-element arrangement, we evaluate certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. The selling prices of deliverables under an arrangement may be derived using vendor specific objective evidence (VSOE), third-party evidence, or a best estimate of selling price (BESP), if VSOE or third-party evidence is not available. For most pharmaceutical licensing and collaboration agreements, BESP is utilized. The objective of BESP is to determine the price at which we would transact a sale if the element within the agreement was sold on a standalone basis. Establishing BESP involves our judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the agreement. In validating the BESP, we consider whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

We typically receive up-front payments when licensing our intellectual property, which often occurs in conjunction with a research and development agreement. We recognize revenue attributed to the license upon delivery, provided that the license has stand-alone value.

Revenues from development milestones are accounted for in accordance with the Revenue Recognition Milestone Method Topic of the Financial Accounting Standards Board (FASB) ASC (Milestone Method). Milestones are recognized when earned, as evidenced by written acknowledgment from the collaborator or other persuasive evidence that the milestone has been achieved, provided that the milestone event is substantive. A milestone event is considered to be substantive if its achievability was not reasonably assured at the inception of the agreement and our efforts led to the achievement of the milestone or the milestone was due upon the occurrence of a specific outcome resulting from our performance. We assess whether a milestone is substantive at the inception of each agreement. For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, we recognize the portion of the payment allocable to delivered items as revenue when the specific milestone is achieved, and the contingency is removed.

Prior to the revised multiple element guidance described above, adopted by us on January 1, 2011, upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned were classified as deferred revenue and recognized as income over the contract or development period.

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Mitsubishi Tanabe Pharma Corporation. In 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe for the development and commercialization of INGREZZA (valbenazine) for movement disorders in Japan and other select Asian markets. Payments to us under this agreement include an up-front license fee of $30 million, up to $85 million in development and commercialization event-based payments, payments for the manufacture of pharmaceutical products, and royalties on product sales in select territories in Asia. Under the terms of the agreement, Mitsubishi Tanabe is responsible for all third-party development, marketing and commercialization costs in Japan and other select Asian markets with the exception of a single Huntington s chorea clinical trial to be performed by us, at an estimated cost of approximately $12 million, should Mitsubishi Tanabe request the clinical trial. We will be entitled to a percentage of sales of INGREZZA in Japan and other select Asian markets for the longer of ten years or the life of the related patent rights.

Under our agreement with Mitsubishi Tanabe, the collaboration effort between the parties to advance INGREZZA towards commercialization in Japan and other select Asian markets is governed by a joint steering committee and joint development committee with representatives from both us and Mitsubishi Tanabe. There are no performance, cancellation, termination or refund provisions in the agreement that would have a material financial consequence to us. We do not directly control when event-based payments will be achieved or when royalty payments will begin. Mitsubishi Tanabe may terminate the agreement at its discretion upon 180 days written notice to us. In such event, all INGREZZA product rights for Japan and other select Asian markets would revert to us.

We have identified the following deliverables associated with the Mitsubishi Tanabe agreement: INGREZZA technology license and existing know-how, development activities to be performed as part of the collaboration, and the manufacture of pharmaceutical products. The respective standalone value from each of these deliverables has been determined by applying the BESP method and the revenue was allocated based on the relative selling price method with revenue recognition timing to be determined either by delivery or the provision of services.

As discussed above, the BESP method required the use of significant estimates. We used an income approach to estimate the selling price for the technology license and an expense approach for estimating development activities and the manufacture of pharmaceutical products. The development activities and the manufacture of pharmaceutical products are expected to be delivered throughout the duration of the agreement. The technology license and existing know-how was delivered on the effective date of the agreement.

For the year ended December 31, 2015, we recognized revenue under this agreement of $19.8 million associated with the delivery of a technology license and existing know-how. In accordance with our continuing performance obligations, $10.2 million of the $30 million up-front payment is being deferred and recognized in future periods. Under the terms of the agreement, there is no general obligation to return the up-front payment for any non-contingent deliverable. We also evaluated the event-based payments under the Milestone Method and concluded only one immaterial event-based payment represents a substantive milestone. Event-based payments will be recognized when earned. During the third quarter of 2017, we recognized $15 million in development event-based payments resulting from Mitsubishi Tanabe s initiation of Phase II/III development of valbenazine in tardive dyskinesia in Asia. No revenue was recognized under the Mitsubishi Tanabe agreement during 2016. As of September 30, 2017, $70 million remains outstanding in potential future event-based payments under the agreement.

We are eligible to receive tiered royalty payments based on product sales in Japan and other select Asian markets. Royalties will be recognized as earned in accordance with the terms of the agreement, when product sales are reported by Mitsubishi Tanabe, the amount can be reasonably estimated, and collectability is reasonably assured.

AbbVie Inc. In June 2010, we announced an exclusive worldwide collaboration with AbbVie to develop and commercialize elagolix and all next-generation GnRH antagonists (collectively, GnRH Compounds) for women s and

men s health. AbbVie made an upfront payment of $75 million and agreed to make additional development and regulatory event-based payments of up to $480 million and up to an additional $50 million in commercial event-based payments. We assessed event-based payments under the revised authoritative guidance for research and development milestones and determined that event-based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (i) they are events that can only be achieved in part on our past performance, (ii) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (iii) they result in additional payments being due to us. Development and regulatory event-based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of AbbVie. As of September 30, 2017, $485 million remains outstanding in future event-based payments under the agreement. However, none of the remaining event-based payments meet the definition of a milestone in accordance with authoritative accounting guidance and will be recognized when earned.

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Under the terms of the agreement, AbbVie is responsible for all third-party development, marketing and commercialization costs. We will be entitled to a percentage of worldwide sales of GnRH Compounds for the longer of ten years or the life of the related patent rights. AbbVie may terminate the collaboration at its discretion upon 180 days written notice to us. In such event, we would be entitled to specified payments for ongoing clinical development and related activities and all GnRH Compound product rights would revert to us. During the first quarter of 2016, event-based revenue of $15 million was recognized related to AbbVie s initiation of Phase III development of elagolix in uterine fibroids. No revenue has been recognized during 2017 under this collaboration agreement.

Cost of Product Sales. Cost of product sales primarily consists of third-party manufacturing costs, storage, freight and other costs associated with sales of INGREZZA. Cost of product sales may also include period costs related to certain inventory manufacturing services, inventory adjustment charges, and manufacturing variances.

Accounts Receivable. Accounts receivable are recorded net of customer allowances for prompt payment discounts, chargebacks, and any allowance for doubtful accounts. We estimate the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. To date, we have determined that an allowance for doubtful accounts is not required.

Inventory. Inventory is stated at the lower of cost or estimated net realizable value. We currently use actual costing methodologies to determine the cost basis for our inventories. Inventory is valued on a first-in, first-out basis and consists primarily of third-party manufacturing costs. We capitalize inventory costs associated with our products upon regulatory approval when, based on our judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. Prior to FDA approval of INGREZZA, all costs related to its manufacturing were charged to research and development expense in the period incurred. At September 30, 2017, our physical inventory consisted primarily of active pharmaceutical product that had been produced prior to FDA approval of INGREZZA with no cost basis as the cost associated with producing this material was expensed rather than capitalized in accordance with accounting guidance. Additionally, bulk drug production, finished bottling and other activities that occurred post FDA approval are included in inventory at September 30, 2017. We provide reserves for potential excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. To date, we have determined that such reserves are not required

Research and Development Expense. Our R&D expenditures include costs related to preclinical and clinical trials, scientific personnel, equipment, consultants, sponsored research, inlicensed programs, share-based compensation and allocated facility costs. We do not track fully burdened R&D costs separately for each of our drug candidates. We review our R&D expenses by focusing on four categories: external development, personnel, facility and depreciation, and other. External development expenses consist of costs associated with our external preclinical and clinical trials, including pharmaceutical development and manufacturing. Personnel expenses include salaries and wages, share-based compensation, payroll taxes and benefits for those individuals involved in ongoing R&D efforts. Other R&D expenses mainly represent laboratory supply expenses, scientific consulting expenses and other expenses. During the first quarter of 2017, we inlicensed opicapone from BIAL for $30 million, which was expensed as in-process research and development in accordance with authoritative accounting guidance.

Share-based Compensation. We grant stock options to purchase our common stock to our employees and directors under our 2011 Equity Incentive Plan, as amended (the 2011 Plan), and grant stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements. We also grant certain employees stock bonuses and restricted stock units (RSUs) under the 2011 Plan. Additionally, we have outstanding stock options that were granted under previous option plans from which we no longer make grants. Share-based compensation expense recognized in accordance with authoritative guidance for the three months ended September 30, 2017 and

2016 was $10.2 million and $6.3 million, respectively. For the nine months ended September 30, 2017 and 2016, we recognized share-based compensation expense of $29.1 million and $20.5 million, respectively.

For purposes of calculating share-based compensation, we estimate the fair value of stock option awards using a Black-Scholes option-pricing model. The determination of the fair value of share-based compensation awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including but not limited to expected stock price volatility over the term of the awards and the expected term of stock options. Our stock options have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates. The fair value of RSUs is estimated based on the closing sale price of our common stock on the date of issuance.

Stock option awards and RSUs generally vest over a three to four year period and the corresponding expense is ratably recognized over those same time periods. For RSUs with performance-based vesting requirements (PRSUs), no expense is recorded until the performance condition is probable of being achieved.

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If factors change and we employ different assumptions, share-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining share-based compensation expense and the actual factors which become known over time, we may change the input factors used in determining share-based compensation expense for future grants. These changes, if any, may materially impact our future results of operations. In addition, share-based compensation expense related to PRSUs, may increase significantly in any period once the performance condition becomes probable of achievement. Additionally, forfeitures of share-based grants are recognized in the period of forfeiture and may result in a significant decrease in share-based compensation expense in any period that forfeitures occur.

Convertible Debt. We account for convertible debt instruments that may be settled in cash upon conversion by separating the liability and equity components of the instruments in a manner that reflects our nonconvertible debt borrowing rate. In May 2017, we issued $517.5 million aggregate principal amount of 2.25% Convertible Senior Notes due 2024. We determined the carrying amount of the liability component of the 2024 Notes by using assumptions that market participants would use in pricing a debt instrument, including market interest rates, credit standing, yield curves and volatilities. Determining the fair value of the debt component requires the use of accounting estimates and assumptions. These estimates and assumptions are judgmental in nature and could have a significant impact on the determination of the debt component, and the associated non-cash interest expense.

The difference between the face value of the 2024 Notes and the fair value of the debt component results in us recording the debt at a discount. We are amortizing this debt discount over the life of the 2024 Notes as additional non-cash interest expense utilizing the effective interest method.

THREE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016

Product Sales, net

In April 2017, the FDA approved INGREZZA for the treatment of tardive dyskinesia. INGREZZA became available for prescription in late April 2017. Net product sales were $45.8 million for the three months ended September 30, 2017 with no similar net product sales during the three months ended September 30, 2016.

License Fees and Milestone Revenues

During the third quarter of 2017, we recognized $15 million in development event-based payments resulting from Mitsubishi Tanabe s initiation of Phase II/III development of valbenazine in tardive dyskinesia in Asia. There was no license fee or milestone revenue recognized during the third quarter of 2016.

Cost of Product Sales

Cost of product sales was $0.4 million for the three months ended September 30, 2017. Product sold during the three months ended September 30, 2017 included drug product that was previously charged to research and development expense prior to FDA approval of INGREZZA. This minimal cost drug product had a positive impact on our cost of product sales and related product gross margins for the three months ended September 30, 2017. We will continue to have a lower cost of product sales that excludes the cost of the active pharmaceutical ingredient (API) that was produced prior to FDA approval until we manufacture API and sell INGREZZA that includes this newly manufactured API. We expect that this will be the case for the near-term and as a result, our cost of product sales will be less than we anticipate it will be in future periods. No similar cost of product sales was recognized during the three months ended September 30, 2016.

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Other Operating Expenses

Research and Development

The following table presents our total R&D expenses by category during the periods presented:

	Three Months Ended September 30,	
	2017	2016
	(In millions)	
External development expense:		
VMAT2	$ 4.8	$ 6.2
Corticotropin-Releasing Factor (CRF)	0.8	0.8
Other	1.1	0.1
Total external development expense	6.7	7.1
R&D personnel expense	10.2	8.5
R&D facility and depreciation expense	1.6	1.7
Other R&D expense	4.0	3.6
Total R&D expense	$ 22.5	$ 20.9

R&D expense increased by $1.6 million; from $20.9 million in the third quarter of 2016 to $22.5 million in the third quarter of 2017. A $1.7 million increase in R&D personnel related expense was primarily due to higher headcount and increased share-based compensation expense. External development expense decreased quarter over quarter primarily due to a decrease in INGREZZA tardive dyskinesia R&D efforts during 2017.

Sales, general and Administrative

Sales, general and administrative expense increased to $43.9 million in the third quarter of 2017 compared to $17.5 million during the same period in 2016. The $26.4 million increase in sales, general and administrative expense is primarily due to the launch of our commercial efforts for INGREZZA in April 2017. This led to overall higher personnel related costs (increased by $13.4 million), with share-based compensation costs accounting for $3.0 million of this increase in personnel costs. Additionally, external costs related to market research, patient support, commercial launch activities and other professional services were $12.5 million higher for the third quarter of 2017 when compared to the same period in 2016.

Net Loss

Our net loss for the third quarter of 2017 was $11.1 million, or a net loss of $0.13 per share, compared to a net loss of $36.9 million, or a net loss of $0.43 per share, during the same period in 2016. The decrease in our net loss from 2016 to 2017 was primarily a result of the above mentioned higher revenues.

NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016

Product Sales, net

In April 2017, the FDA approved INGREZZA for the treatment of tardive dyskinesia. INGREZZA became available for prescription in late April 2017. Net product sales were $52.1 million for the nine months ended September 30, 2017 with no similar net product sales during the nine months ended September 30, 2016.

License Fees and Milestone Revenues

During 2017, we recognized $15 million in development event-based payments resulting from Mitsubishi Tanabe s initiation of Phase II/III development of valbenazine in tardive dyskinesia in Asia. During the first quarter of 2016, AbbVie initiated Phase III development of elagolix in uterine fibroids, which triggered a $15 million milestone event payment to us.

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Cost of Product Sales

Cost of product sales was $0.5 million for the nine months ended September 30, 2017. Product sold during the nine months ended September 30, 2017 included drug product that was previously charged to research and development expense prior to FDA approval of INGREZZA. This minimal cost drug product had a positive impact on our cost of product sales and related product gross margins for the nine months ended September 30, 2017. We will continue to have a lower cost of product sales that excludes the cost of the API that was produced prior to FDA approval until we manufacture API and sell INGREZZA that includes this newly manufactured API. We expect that this will be the case for the near-term and as a result, our cost of product sales will be less than we anticipate it will be in future periods. No similar cost of product sales was recognized during the nine months ended September 30, 2016.

Other Operating Expenses

Research and Development

The following table presents our total R&D expenses by category during the periods presented:

	Nine Months Ended September 30,	
	2017	2016
	(In millions)	
External development expense:		
VMAT2	$ 13.7	$ 24.8
CRF	2.7	1.7
Other	2.8	0.3
Total external development expense	19.2	26.8
R&D personnel expense	30.8	25.8
R&D facility and depreciation expense	4.3	4.7
Other R&D expense	41.9	14.4
Total R&D expense	$ 96.2	$ 71.7

R&D expense increased by $24.5 million, from $71.7 million in the first nine months of 2016 to $96.2 million in the first nine months of 2017. This increase in R&D expense was primarily driven by the $30 million paid to BIAL to inlicense opicapone as discussed above. Approximately $5.0 million of the increase in R&D expense was due to higher R&D personnel related expense, offset by a decrease in VMAT2 spending due to the wind down of the Phase III clinical program and NDA preparation activities related to INGREZZA for tardive dyskinesia during 2016.

Sales, General and Administrative

Sales, general and administrative expense increased to $113.6 million in the first nine months of 2017 compared with $44.4 million during the same period in 2016. The $69.2 million increase in sales, general and administrative expense is primarily due to the launch of our commercial efforts for INGREZZA in April 2017 and is primarily due to higher personnel related costs (increased by $33.7 million), with share-based compensation costs accounting for $6.4 million of this increase in personnel costs. Additionally, external costs related to market research, patient support, commercial

launch activities and other professional services were $32.9 million higher for the first nine months of 2017 when compared to the same period in 2016.

Net Loss

Our net loss for the first nine months of 2017 was $149.4 million, or a net loss of $1.70 per share, compared to a net loss of $96.4 million, or a net loss of $1.11 per share, during the same period in 2016. Operating expenses increased by $94.2 million from the first nine months of 2016 to the first nine months of 2017 primarily due to the inlicensing of opicapone and the commercial launch of INGREZZA for tardive dyskinesia. This increase in operating expenses was offset by a $52.1 million increase in revenue from 2016 to 2017.

LIQUIDITY AND CAPITAL RESOURCES

Net cash used in operating activities during the first nine months of 2017 was $134.9 million compared to $74.6 million during the same period in 2016. The $60.3 million change in cash flows from operating activities is primarily due an increase in net loss of approximately $53.0 million, however approximately $8.6 million of this increase in expenses consisted of an increase in non-cash share-based compensation expense.

Net cash used in investing activities during the first nine months of 2017 was $191.6 million compared to net cash provided by investing activities of $97.8 million during the same period in 2016. The fluctuation in net cash used in investing activities resulted primarily from the timing differences in investment purchases, sales and maturities of investments, and the fluctuation of our portfolio mix between cash equivalents and short-term and long-term investment holdings.

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Net cash provided by financing activities during the first nine months of 2017 was $511.0 million compared to $2.3 million during the same period in 2016. The increase in cash provided by financing activities was primarily due to net proceeds of approximately $502.8 million from our offering of senior convertible debt in May 2017. Stock option exercises yielded approximately $8.3 million and $2.3 million in cash proceeds during the first nine months of 2017 and 2016, respectively.

At September 30, 2017, our cash, cash equivalents, and investments totaled $721.3 million compared with $350.8 million at December 31, 2016. In addition, at September 30, 2017 we had $365.1 million in long-term debt on our balance sheet related to our $517.5 million of senior convertible notes due May 2024.

Shelf Registration Statement. In February 2017, we filed an automatic shelf registration statement which immediately became effective by rule of the SEC. For so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, this shelf registration statement allows us to issue an unlimited number of securities from time to time. As of September 30, 2017, we had not sold any securities under this shelf registration statement.

We believe that our existing capital resources, together with interest 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 12 months. However, we cannot guarantee that these capital resources and payments will be sufficient to conduct all of our commercialization plans or R&D programs as planned. The amount and timing of expenditures will vary depending upon a number of factors, including progress of our commercialization efforts and R&D programs.

We may require additional funding to effectively commercialize INGREZZA, to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, the cost of product in-licensing and any possible acquisitions, and we may require additional funding to establish manufacturing and marketing capabilities in the future. We may seek to access the public or private equity markets whenever conditions are favorable. For example, we have an effective shelf registration statement on file with the SEC which allows us to issue an unlimited number of shares of our securities from time to time. In addition, during the second quarter of 2017, we issued $517.5 million of convertible debt and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. We may also seek additional funding through strategic alliances or other financing mechanisms. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt may involve operating covenants that may restrict our business. If adequate funds are not available through these means, we may be required to curtail significantly one or more of our research or development programs or obtain funds through arrangements with collaborators or others. This may require us to relinquish rights to certain of our technologies, products or product candidates. To the extent that we are unable to obtain third-party funding for such expenses, we expect that increased expenses will result in increased cash flow losses from operations. We cannot assure you that we will successfully develop our products under development or that our approved products will generate revenues sufficient to enable us to earn a profit.

OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2017, we did not have any off-balance sheet arrangements.

INTEREST RATE RISK

We are exposed to interest rate risk on our short and long-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 12 months. If a 10% change in interest rates had occurred on September 30, 2017, this change 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 and the nature of our investments, we have concluded that we do not have a material financial market risk exposure.

NEW ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (FASB) amended the existing accounting standards for revenue recognition, which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects

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the expected consideration to be received in exchange for those goods or services. The amended guidance defines a five-step approach for recognizing revenue, which may require us to use more judgment and make more estimates than under the current guidance. The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. The amended guidance as currently issued will be effective for public companies in 2018, however early adoption is permitted.

We do not anticipate the new standard having a material impact on currently reported net product sales. We are also currently evaluating the impact of the new standard on historical revenue recorded for our two collaboration agreements. This ongoing evaluation is dependent upon the resolution of certain questions relating to the application of, and transition to, the new revenue recognition guidance for collaboration agreements which will ultimately determine the adoption method and the ultimate impact the adoption of this standard will have on our consolidated financial statements. Based on our current assessment of the effect of the new standard on historical revenue under our collaboration agreements that are related to contingent payments, which are not dependent on performance by us, we believe revenue could potentially be recognized earlier than historically recorded if information is available to allow us to record the payments without the risk of a future reversal.

In February 2016, the FASB issued Accounting Standards Update 2016-02 Leases. This update amends the current accounting guidance for lease transactions. Under the new guidance, a lessee will be required to recognize both assets and liabilities for any leases in excess of twelve months. Additionally, certain qualitative and quantitative disclosures will also be required in the financial statements. We are required to adopt this new guidance beginning in 2019 and early adoption is permitted. We are in the process of determining the effects the adoption of this update will have on our consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash , which clarifies the presentation of restricted cash and restricted cash equivalents in the statements of cash flows. Under the ASU, restricted cash and restricted cash equivalents are included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts presented on the statements of cash flows. The ASU is intended to reduce diversity in practice in the classification and presentation of changes in restricted cash on the statement of cash flows. The ASU requires that the statement of cash flows explain the change in total cash and equivalents and amounts generally described as restricted cash or restricted cash equivalents when reconciling the beginning-of-period and end-of-period total amounts. The ASU also requires a reconciliation between the total of cash and equivalents and restricted cash presented on the statement of cash flows and the cash and equivalents balance presented on the balance sheet. The ASU is effective for us on January 1, 2018, with early adoption permitted. We do not expect the adoption of the ASU will have a material effect on our results of operations, financial condition or cash flows.

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 antici words (including their use in the negative), or by discussions of future matters such as the development or regulatory

approval 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.

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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.

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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 President, Chief Operating Officer and interim 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 interim Chief Financial Officer, of any changes to our internal control over financial reporting that occurred during our last fiscal quarter and that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Our evaluation did not identify significant changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the quarter ended September 30, 2017, 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

The information set forth under Note 15 Commitments and Contingencies to our condensed consolidated financial statements included in Part I, Item 1 of this report is incorporated herein by reference.

ITEM 1A. RISK FACTORS

The following Risk Factors do not reflect any material changes to the Risk Factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, other than the revisions or additions to the risk factors set forth below with an asterisk (*) next to the title. 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.

Risks Related to Our Company

* ***We have limited marketing experience, and have only recently begun establishing our sales force, distribution and reimbursement capabilities, and we may not be able to successfully commercialize INGREZZA, or any of our product candidates if they are approved in the future.***

Our ability to produce revenues ultimately depends on our ability to sell our products and secure adequate third-party reimbursement if and when they are approved by the FDA. We currently have limited experience in marketing and selling pharmaceutical products. With respect to INGREZZA in particular, we have only recently hired our sales force to sell INGREZZA, and have only recently begun establishing our distribution and reimbursement capabilities, all of which will be necessary to successfully commercialize INGREZZA. While we have recently hired personnel and engaged consultants with experience marketing and selling pharmaceutical products, there can be no guarantee that we will be able to establish or maintain the personnel, systems, arrangements and capabilities necessary to successfully commercialize INGREZZA or any product candidate approved by the FDA in the future. If we fail to establish or maintain successful marketing, sales and reimbursement capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues may suffer.

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* ***We currently depend on a single source supplier for each of the production of INGREZZA and its active pharmaceutical ingredients. The loss of either of these suppliers, or delays or problems in the supply of INGREZZA, could materially and adversely affect our ability to successfully commercialize INGREZZA.***

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 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, including 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, and compliance with strictly enforced U.S., state and non-U.S. regulations. If our third-party suppliers for INGREZZA encounter these or any other manufacturing, quality or compliance difficulties, we may be unable to meet commercial demand for INGREZZA, which could materially and adversely affect our ability to successfully commercialize INGREZZA.

In addition, if our suppliers fail or refuse to supply us with INGREZZA or its active pharmaceutical ingredient 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 active pharmaceutical ingredients 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.

* ***We have no manufacturing capabilities. If third-party manufacturers of INGREZZA 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. Consequently, we depend on, and will continue to depend on, several contract manufacturers for all production of products for development and commercial purposes, including INGREZZA. If we are unable to obtain or retain third-party manufacturers, we will not be able to develop or commercialize our products, including INGREZZA. The manufacture of our products for clinical trials and commercial purposes is subject to specific FDA regulations, including current Good Manufacturing Practice regulations. Our third-party manufacturers might not comply with FDA regulations relating to manufacturing our products for clinical trials and commercial purposes or other regulatory requirements now or in the future. Our reliance on contract manufacturers also exposes us to the following risks:

contract manufacturers may encounter difficulties in achieving volume production, quality control and 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 U.S. Drug Enforcement Administration, and other agencies to ensure strict compliance with current Good Manufacturing Practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers compliance with these regulations and standards.

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

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

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

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

- the FDA or similar foreign regulatory authority may not approve an Investigational New Drug (IND) Application or foreign equivalent filings required to initiate human clinical studies for our drug candidates or the FDA may require additional preclinical or clinical studies as a condition of the initiation of Phase I clinical studies, progression from Phase I to Phase II, or Phase II to Phase III, or for NDA approval;
- the product candidate may not prove to be effective or as effective as other competing product candidates;
- we may discover that a product candidate may cause harmful side effects or results of required toxicology studies may not be acceptable to the FDA;
- the results may not replicate the results of earlier, smaller trials;
- the FDA or similar foreign regulatory authorities may require use of new or experimental endpoints that may prove insensitive to treatment effects;
- we or the FDA or similar foreign regulatory authorities may suspend the trials;
- the results may not be statistically significant;
- patient recruitment may be slower than expected;
- patients may drop out of the trials; and
- regulatory requirements may change.

These risks and uncertainties impact all of our clinical programs. Specifically, our VMAT2 inhibitor program will be impacted if any of the events above lead to delayed timelines for the enrollment in, or completion of, clinical trials of INGREZZA for Tourette syndrome. Similarly, with respect to our gonadotropin-releasing hormone (GnRH) program with AbbVie, any of the clinical, regulatory or operational events described above could delay timelines for the completion of the Phase III endometriosis program or the Phase III uterine fibroids program, or change our planned

clinical and regulatory activities for the opicapone program in Parkinson s disease. 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 our product candidates that we out-license and in-license, and may need to enter into future collaborations to develop and commercialize certain of our product candidates.

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

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Because of our reliance on AbbVie, the development and commercialization of elagolix could be substantially delayed, and our ability to receive future funding could be substantially impaired, if AbbVie:

- failed to gain the requisite regulatory approval of elagolix;
- did not successfully launch and commercialize elagolix;
- did not conduct its collaborative activities in a timely manner;
- did not devote sufficient time and resources to our partnered program;
- terminated its agreement with us;
- developed, either alone or with others, products that may compete with elagolix;
- disputed our respective allocations of rights to any products or technology developed during our collaboration; or
- merged with a third party that wants to terminate our agreement.

In March 2015, we entered into a collaboration and license agreement with Mitsubishi Tanabe to develop and commercialize INGREZZA in Japan and other select Asian markets. We will rely on Mitsubishi Tanabe to achieve certain development, regulatory and commercial milestones which, if achieved, could generate significant future revenue for us. Our collaboration with Mitsubishi Tanabe is subject to risks and uncertainties similar to those described above. In addition, we may need to enter into other out-licensing collaborations to assist in the development and commercialization of other product candidates we are developing now or may develop in the future, and any such future collaborations would be subject to similar risks and uncertainties.

In February 2017, we entered into a license agreement with BIAL for the development and commercialization of opicapone for the treatment of human diseases and conditions, including Parkinson s disease, in the United States and Canada. Under the terms of the agreement, we are responsible for the management of all opicapone development and commercialization activities; however, we will depend on BIAL to supply all drug product and investigation medicinal product for our development and commercialization activities. In addition, pursuant to the license agreement, the parties have established a joint steering committee with overall coordination and strategic oversight over activities under the agreement and to provide a forum for regular exchange of information, and BIAL has the right to co-promote licensed products during certain periods of time and to engage in certain marketing-related activities in cooperation with us. Accordingly, our strategy for developing and commercializing opicapone is dependent upon maintaining our current collaboration with BIAL. Because of our reliance on BIAL for certain aspects related to the development and commercialization of opicapone, any disagreement with BIAL, or BIAL s decision to not devote sufficient time and resources to our collaboration or to not conduct activities in a timely manner, could

substantially delay and/or prohibit our ability to develop and commercialize opicapone.

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

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

We do not and will not have access to all information regarding the products being developed and potentially commercialized by AbbVie, including potentially material information about clinical trial design and execution, safety reports from clinical trials, spontaneous safety reports if a product candidate is later approved and marketed, regulatory affairs, process development, manufacturing, marketing 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 product candidates under our collaboration with AbbVie 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 the clinical development and regulatory approval of our collaboration and product candidates licensed to it, we may make operational and investment decisions that we would not have made had we been fully informed, which may materially and adversely affect our business and operations.

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* ***We have recently received FDA approval for INGREZZA for tardive dyskinesia and that approval subjects us to ongoing obligations and continued regulatory review, which may result in significant additional expense and market withdrawal. Additionally, our other product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

We received FDA regulatory approval for INGREZZA in April 2017. This approval and other regulatory approvals for any of our product candidates may also 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. With respect to FDA s approval of INGREZZA for TD, we are subject to certain post-marketing requirements and commitments. Failure to comply with these post-marketing requirements and commitments could result in withdrawal of our marketing approval for INGREZZA. 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. 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, or failure to comply with regulatory requirements, may result in, among other things:

restrictions on the marketing or manufacturing of the product, 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 FDA s policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any of our product candidates or future indications for currently approved products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

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

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

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

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or

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obtained in the first instance. In addition, communications from government officials regarding health care costs and pharmaceutical pricing could have a negative impact on our stock price, even if such communications do not ultimately impact coverage or reimbursement decisions for our products.

There may also be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize INGREZZA 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.

* ***If physicians and patients do not accept INGREZZA or any of our other products, we may not generate sufficient revenue.***

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

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

- the timing of receipt of marketing approvals for indications;
- the safety and efficacy of the products;
- the pricing of our products;
- the availability of coverage and adequate reimbursement for the products;
- the success of existing products addressing our target markets or the emergence of equivalent or superior products; and
- the cost-effectiveness of the products.

In addition, market acceptance depends on the effectiveness of our marketing strategy and distribution support, and, to date, although we have hired experienced sales and marketing professionals, we have very limited sales and marketing experience. If the medical community and patients do not ultimately accept our products as being safe, effective, superior and/or cost-effective, we may not generate sufficient revenue.

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

All of our product candidates are currently in research or clinical development with the exception of INGREZZA, which has recently been approved by the FDA for tardive dyskinesia. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

be found ineffective or cause harmful side effects during preclinical studies or clinical trials;

fail to receive necessary regulatory approvals on a timely basis or at all;

be precluded from commercialization by proprietary rights of third parties;

be difficult to manufacture on a large scale; or

be uneconomical to commercialize or fail to achieve market acceptance.

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

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

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

increasing our vulnerability to adverse economic and industry conditions;

limiting our ability to obtain additional financing;

requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;

limiting our flexibility to plan for, or react to, changes in our business;

diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the 2024 Notes; and

placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

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

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

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. Furthermore, even if holders of the 2024 Notes did not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the 2024 Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

* ***We have a history of losses and expect to incur negative operating cash flows for the foreseeable future, and we may never achieve sustained profitability.***

Since our inception, we have incurred significant net losses and negative cash flow from operations. As a result of historical operating losses, we had an accumulated deficit of approximately $1.1 billion as of December 31, 2016. We do not expect to be profitable, or generate positive cash flows from operations, for the year ending December 31, 2017.

In April 2017, we received FDA approval of INGREZZA for tardive dyskinesia, however we have not yet obtained regulatory approvals for any other product candidates. Even if we succeed in commercializing INGREZZA or developing and commercializing another of our drugs, we may not be profitable. We also expect to continue to incur significant operating and capital expenditures as we:

commercialize INGREZZA for tardive dyskinesia;

seek regulatory approvals for our product candidates;

develop, formulate, manufacture and commercialize our product candidates;

in-license or acquire new product development opportunities;

implement additional internal systems and infrastructure; and

hire additional clinical, scientific, sales and marketing personnel.

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We expect to experience negative cash flow in the coming years as we fund our operations, in-licensing or acquisition opportunities, and capital expenditures. We will need to generate significant revenues to achieve and maintain profitability and positive cash flow on an annual basis. We may not be able to generate these revenues, and we may never achieve profitability on an annual basis in the future. Our failure to achieve or maintain profitability on an annual basis could negatively impact the market price of our common stock. Even if we become profitable on an annual basis, we cannot assure you that we would be able to sustain or increase profitability on an annual basis.

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

As of September 30, 2017, we employed approximately 400 employees. Although we have already 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 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, 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:

manage our development efforts effectively;

integrate additional management, administrative and manufacturing personnel;

further develop our marketing and sales organization; and

maintain sufficient administrative, accounting and management information systems and controls.

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

We 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 develop and commercialize opicapone, if we fail to use commercially reasonable efforts, fail to file an NDA for a licensed product by a specified date, or otherwise breach the license agreement. In addition, if we were to violate any of the terms of our licenses, we could become subject to damages. For example, on December 1, 2015, The Mount Sinai School of Medicine of the City University of New York (Mount Sinai) filed a complaint against us, seeking unspecified monetary damages, future sublicensing fees and attorney s fees, alleging that we violated the terms of our license with Mount Sinai by inappropriately sublicensing Mount Sinai technology to AbbVie. While we believe that we have meritorious defenses to the claims made in the complaint and intend to vigorously defend ourselves against such claims, we are not able to predict the ultimate outcome of this action. 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 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 (CROs) to conduct our clinical trials under their agreements with us. The investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If our independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, or not in compliance with Good Clinical Practices, it may delay or prevent the approval of our FDA applications and our introduction of new drugs. The CROs we contract with for execution of our clinical trials

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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 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.

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

We are highly dependent on the principal members of our management and scientific staff. The loss of any of these people could impede the achievement of our objectives, including the successful commercialization of INGREZZA 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. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy and our commercialization strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

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

Certain of the diseases that INGREZZA and our 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 and our product candidates may be smaller than we believe they are, our prospects for generating expected revenue may be adversely affected and our business may suffer.

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

A company may not promote off-label uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product s FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician s choice of drug treatment made in the physician s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. 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, 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. A significant number of companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the federal False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. 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 and it is

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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.

* ***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 commercial sales of INGREZZA, 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 and contract research payments. In addition, we recently received regulatory approval from the FDA for INGREZZA in tardive dyskinesia and our revenues will be dependent on our ability to sell INGREZZA and to secure adequate third-party reimbursement. 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. Because of these factors, our financial results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline.

* ***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. Furthermore, the price of our common stock may be dependent upon the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, which is based on assumptions that may be incorrect or that may change from quarter to quarter, the market price of our common stock could decline. Over the course of the last 12 months, the price of our common stock has ranged from approximately $37.00 per share to approximately $64.00 per share. The market price of our common stock may fluctuate in response to many factors, including:

sales of INGREZZA;

the status and cost of our post-marketing commitments for INGREZZA;

the results of our clinical trials;

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;

developments related to on-going litigation;

government regulation;

health care reimbursement;

failure of any of our product candidates, if approved, to achieve commercial success; and

public concern as to the safety of our drugs.

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* ***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 commercialize INGREZZA for tardive dyskinesia, to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses and to pursue regulatory approvals for additional product candidates and indications, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, product in-licensing and any possible acquisitions, establish manufacturing capabilities in the future and we may require additional funding to expand commercial and marketing efforts for other product candidates or indications. 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 12 months. However, these resources might be insufficient to conduct research and development programs, 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;

debt service obligations on the 2024 Notes;

continued scientific progress in our research and development programs;

the magnitude and complexity of our research and development programs;

progress with preclinical testing and clinical trials;

the time and costs involved in obtaining regulatory approvals;

the costs involved in filing and pursuing patent applications, enforcing patent claims, or engaging in interference proceedings or other patent litigation;

competing technological and market developments;

the establishment of additional strategic alliances;

developments related to on-going litigation;

the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and

the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. For example, for so long as we continue to satisfy the requirements to be deemed a well-known seasoned issuer, we can utilize a shelf registration statement currently on file with the Securities and Exchange Commission (SEC), to allow us to issue an unlimited number of securities from time to time. In addition, during the second quarter of 2017, we issued $517.5 million of convertible debt and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Additional equity or debt financing might not be available on reasonable terms, if at all. 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 Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, new SEC regulations and NASDAQ rules, are creating uncertainty for companies such as ours. These laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance and public disclosure. As a result, our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased sales, general and administrative expenses and management time related to compliance activities. If we fail to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

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Risks Related to Our Industry

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

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States, 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 United States 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 recent federal and state legislation imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new legislation, manufacturers are required to provide certain information regarding the drug product 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, the ACA was signed into law, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our potential drug candidates are:

an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

extension of a manufacturer s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby

potentially increasing a manufacturer s Medicaid rebate liability;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% 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.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. For example, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, on October 12, 2017, President Trump signed another Executive Order directing certain federal agencies to propose regulations or guidelines to permit small businesses to form association health plans, expand the availability of short-term, limited duration insurance, and expand the use of health reimbursement arrangements, which may circumvent some of the requirements for health insurance mandated by the ACA. In addition, citing legal guidance from the U.S. Department of Justice and the U.S. Department of Health and Human Services, the Trump administration has concluded that cost-sharing reduction (CSR) payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until such appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA.

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In Congress, the U.S. House of Representatives passed ACA replacement legislation known as the American Health Care Act of 2017 in May 2017, which was not introduced in the Senate. More recently, the Senate Republicans has proposed multiple bills to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress, Congress may consider other legislation to repeal or replace certain elements of 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 will remain in effect through 2025 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, or MACRA, which will be fully implemented in 2019. At this time it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills 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 drug products.

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. 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 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.

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

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

Competition may also arise from, among other things:

other drug development technologies;

methods of preventing or reducing the incidence of disease, including vaccines; and

new small molecule or other classes of therapeutic agents.

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

We are commercializing and performing research on or developing products for the treatment of several disorders including endometriosis, tardive dyskinesia, uterine fibroids, Tourette syndrome, essential tremor, classic congenital adrenal hyperplasia, pain, and other neurological and endocrine-related diseases and disorders, and there are a number of competitors to our products and product candidates. If one or more of our competitors products or programs are successful, the market for our products may be reduced or eliminated. For example, in August 2017, Teva Pharmaceutical Industries, Ltd. received approval for Austedo to treat tardive dyskinesia.

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

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

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

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

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

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

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our commercial collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our commercial collaborators and consultants.

However, if our employees, commercial collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors.

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

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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 U.S. 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 a drug with similar chemical structure 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. Valbenazine has received an orphan drug designation for the treatment of pediatric patients with Tourette syndrome from the FDA. If we seek orphan drug designations for other indications or in other jurisdictions, we may fail to receive such orphan drug designations and, even if we succeed, such orphan drug designations may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position.

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees and independent contractors, such as principal investigators, consultants, commercial partners and vendors, or by employees of our commercial partners could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws, to report financial information or data accurately, to maintain the confidentiality of our trade secrets or the trade secrets of our commercial partners, or to disclose unauthorized activities to us. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. Employee and independent contractor misconduct could also involve the improper use of individually identifiable information, including, without limitation, information

obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation.

Any 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.

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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, including the 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 federal Health Insurance Portability and Accountability Act of 1996 (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 certain types of individuals and entities, 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 and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and

- analogous state 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; 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. 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, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate.

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

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

The use of any of our potential products in clinical trials, and the sale of any approved products, including INGREZZA, may expose us to liability claims. These claims might be made directly by consumers, health care providers, pharmaceutical companies or others selling our products. We have obtained limited product liability insurance coverage for our clinical trials in the amount of $10 million per occurrence and $10 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. Upon FDA approval of INGREZZA we expanded our insurance coverage to include product liability insurance related to the sale of INGREZZA in the amount of $20 million per occurrence and $20 million in the aggregate. However, we may be unable to obtain commercially reasonable product liability insurance for any products approved in the future for marketing. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. 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.

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

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

Cyber security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

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. Despite security measures, however, our information technology and network infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. Any such cyber attack or breach could compromise our networks and data centers and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, delays and impediments to our discovery, development, and commercialization efforts, and damage to our reputation.

ITEM 5: Other Information

Not applicable.

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ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Certificate of Incorporation(1)
3.2	Certificate of Amendment to Certificate of Incorporation(2)
3.3	Bylaws(3)
3.4	Certificate of Amendment to Bylaws(4)
3.5	Certificate of Amendment to Bylaws(5)
3.6	Certificate of Amendment to Bylaws
4.1	Form of Common Stock Certificate(6)
4.2	Indenture, dated as of May 2, 2017, by and between the Company and U.S. Bank National Association, as Trustee. (7)
4.3	Form of Note representing the Company s 2.25% Convertible Notes due 2024. (7)
10.1	Form of Indemnity Agreement entered into with each of the Company s executive officers and directors.
10.2**	Amended and Restated Product Agreement dated June 27, 2017 by and between Patheon UK Limited and the Company
10.3	Second Amendment to Amended and Restated Lease dated October 12, 2017 between Kilroy Realty, L.P. and the Company
31	Certification of Chief Executive Officer and Interim Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Certification of Chief Executive Officer and Interim 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	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Incorporated by reference to Exhibit 3.1 to the Company s Annual Report on Form 10-K filed on February 8, 2013
(2) Incorporated by reference to Exhibit 3.2 to the Company s Annual Report on Form 10-K filed on February 8, 2013
(3) Incorporated by reference to Exhibit 3.3 to the Company s Annual Report on Form 10-K filed on February 8,

2013

(4) Incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed on October 2, 2015

(5) Incorporated by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed on September 23, 2016

(6) Incorporated by reference to the Company s Registration Statement on Form S-1 (Registration No. 333-03172).

(7) Incorporated by reference to Exhibit 4.1 of the Company s Current Report on Form 8-K filed on May 2, 2017

* 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.

** Confidential treatment requested

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.

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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.

(Registrant)

Dated: November 1, 2017

/s/ Kevin C. Gorman
Kevin C. Gorman
Chief Executive Officer and Interim Chief Financial Officer
(Duly authorized officer and Principal Financial Officer)