NEUROCRINE BIOSCIENCES INC
Form 10-Q
November 05, 2018

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, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number 0-22705

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	33-0525145 (IRS Employer Identification No.)
12780 El Camino Real, San Diego, California (Address of principal executive office)	92130 (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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

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

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

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 90,682,182 as of October 30, 2018.

NEUROCRINE BIOSCIENCES, INC.

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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, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 195,734	$254,712
Short-term investments, available for sale	439,609	261,217
Accounts receivable	54,097	31,127
Inventory	6,054	1,024
Other current assets	18,900	6,839
Total current assets	714,394	554,919
Property and equipment, net	28,618	10,811
Long-term investments, available for sale	185,257	247,361
Restricted cash	5,477	4,500
Total assets	$ 933,746	$817,591
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 72,022	$53,520
Current portion of convertible senior notes	383,647	—
Other current liabilities	731	906
Total current liabilities	456,400	54,426
Deferred gain on sale of real estate	7,495	8,043
Deferred revenue	10,231	10,231
Deferred rent	12,107	3,135
Convertible senior notes	—	369,618
Total liabilities	486,233	445,453
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 90,673,214 as of September 30, 2018 and 88,793,903 as of December 31, 2017	91	89
Additional paid-in capital	1,645,311	1,572,765

Accumulated other comprehensive loss	(2,056)	(1,850)
Accumulated deficit	(1,195,833)	(1,198,866)
Total stockholders' equity	447,513	372,138
Total liabilities and stockholders' equity	$933,746	$817,591

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

AND COMPREHENSIVE INCOME (LOSS)

(in thousands, except per share data)

(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$111,291	$45,774	$279,282	$52,109
Collaboration revenue	40,466	15,000	40,466	15,000
Total revenues	151,757	60,774	319,748	67,109
Operating expenses:				
Cost of sales	1,551	433	3,355	494
Research and development	35,482	22,463	121,417	96,213
Sales, general and administrative	60,401	43,873	179,952	113,597
Total operating expenses	97,434	66,769	304,724	210,304
Income (loss) from operations	54,323	(5,995)	15,024	(143,195)
Other (expense) income:				
Interest expense	(7,672)	(7,337)	(22,767)	(12,104)
Investment income and other, net	4,113	2,207	10,776	5,863
Total other expense, net	(3,559)	(5,130)	(11,991)	(6,241)
Net income (loss)	$50,764	$(11,125)	$3,033	$(149,436)
Net income (loss) per common share:				
Basic	$0.56	$(0.13)	$0.03	$(1.70)
Diluted	$0.52	$(0.13)	$0.03	$(1.70)
Shares used in the calculation of net income (loss) per common share:				
Basic	90,555	88,325	90,064	87,894
Diluted	96,798	88,325	95,272	87,894
Other comprehensive income (loss):				
Net income (loss)	$50,764	$(11,125)	$3,033	$(149,436)
Net unrealized gain (loss) on available-for-sale securities	753	179	(206)	(216)
Comprehensive income (loss)	$51,517	$(10,946)	$2,827	$(149,652)

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	For the Nine Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	$3,033	$(149,436)
Reconciliation of net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,749	1,694
Amortization of debt discount	13,040	6,755
Amortization of debt issuance costs	989	526
Amortization of premiums on investments	1,436	1,202
Non-cash share-based compensation expense	44,800	29,070
Other	(482)	(1,261)
Change in operating assets and liabilities:		
Accounts receivable	(22,970)	(29,818)
Inventory	(3,907)	(242)
Reimbursements for tenant improvements	3,657	—
Other current assets	(6,837)	(4,315)
Accounts payable and accrued liabilities	15,577	11,107
Other current liabilities	(175)	(188)
Net cash provided by (used in) operating activities	50,910	(134,906)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(329,289)	(444,538)
Sales and maturities of investments	211,402	257,235
Purchases of property and equipment	(18,802)	(4,563)
Proceeds from sales of property and equipment	30	7
Net cash used in investing activities	(136,659)	(191,859)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	27,748	8,265
Proceeds from issuance of convertible senior notes, net	—	502,781
Net cash provided by financing activities	27,748	511,046
Net (decrease) increase in cash, cash equivalents and restricted cash	(58,001)	184,281
Cash, cash equivalents and restricted cash at beginning of the period	259,212	88,150
Cash, cash equivalents and restricted cash at end of the period	$201,211	$272,431

SUPPLEMENTAL DISCLOSURE		
Cash paid for interest	$5,822	$—
Non-cash capital expenditures	$1,802	$—

See accompanying notes to the condensed consolidated financial statements.

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, develops and commercializes innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through its novel research and development (R&D) platform, focused on neurological and endocrine related disorders. The Company discovered, developed and markets INGREZZA® (valbenazine), the first United States Food and Drug Administration (FDA)-approved product indicated for the treatment of adults with tardive dyskinesia (TD), a movement disorder. Discovered and developed through Phase II clinical trials by Neurocrine, ORILISSA™ (elagolix), the first FDA-approved oral medication for the management of endometriosis associated with moderate to severe pain in over a decade, is marketed by AbbVie Inc. (AbbVie) as part of a collaboration to develop and commercialize elagolix for women’s health. Neurocrine’s clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in Parkinson's disease patients, elagolix for uterine fibroids with AbbVie, valbenazine for the treatment of Tourette syndrome, NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH), a vesicular monoamine transporter 2 (VMAT2) inhibitor and first-in-class central nervous system (CNS) compound with potential use in the treatment of neurologic and psychiatric disorders.

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, 2017 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, 2017, 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.

Reclassifications. Certain amounts in prior year periods have been reclassified to conform with the presentation adopted in current year periods.

Impact of Recently Issued Accounting Standards. In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, “Revenue from Contracts with Customers (Topic 606)”, which supersedes all existing revenue recognition requirements, including most industry-specific guidance. This new standard amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The FASB subsequently issued additional, clarifying standards to address issues arising from implementation of the new revenue recognition standard. The Company adopted this new standard as of January 1, 2018, using the modified retrospective method. The adoption of the new revenue standard did not change the Company’s revenue recognition. As the Company did not identify any accounting changes that impacted the amount of reported revenues

with respect to product revenues, or revenue from collaboration and license agreements, no adjustment to retained earnings was required upon adoption. See below for discussion of the Company's revenue recognition policy.

In February 2016, the FASB issued 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. As of September 30, 2018, the Company was in the process of analyzing its lease contracts and the potential impact the standard may have on its condensed consolidated financial statements and related disclosures. The Company is also in the process of evaluating potential changes to its controls to support lease accounting and the related disclosures under the new standard. Based on management's preliminary analysis, the Company anticipates the adoption of this guidance will have a material impact on the Company's Condensed Consolidated Balance Sheets due to the requirement to recognize lease right-of-use (ROU) assets and corresponding liabilities, primarily relating to leases of office space.

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 amended guidance was retrospectively adopted on January 1, 2018 and required that cash, cash equivalents and restricted cash reported on the Condensed Consolidated Statements of Cash Flows now includes restricted cash of $5.5 million and $4.6 million as of September 30, 2018 and 2017, respectively, as well as previously reported cash and cash equivalents.

In June 2018, the FASB issued ASU 2018-07, “Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting”, which expands the scope of Topic 718 to include share based payment transactions for acquiring goods and services from nonemployees and applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606. This update is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company is evaluating the effect that this update will have on its condensed consolidated financial statements and related disclosures.

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. Estimates for revenues, cost of sales, inventory, and R&D expenses are evaluated on an ongoing basis and are based on historical experience or other relevant assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Inventory. 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 manufacture were charged to R&D expense in the period incurred. Historically, the Company’s physical inventory included active pharmaceutical product (API) that had been produced prior to FDA approval of INGREZZA and accordingly had no cost basis as the cost associated with producing this material was expensed rather than capitalized in accordance with GAAP. Costs associated with the manufacture of bulk drug product, finished bottling, and other labeling activities that occurred post FDA approval are included in the inventory value at September 30, 2018 and December 31, 2017.

The Company reduces its inventory to net realizable value 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 Sales. Cost of sales includes third-party manufacturing, transportation, freight, and indirect overhead costs associated with the manufacture and distribution of INGREZZA, sales-based license costs on AbbVie net sales of ORILISSA, as defined in the agreement with the party to which the Company pays such costs, and period costs resulting from certain inventory manufacturing services, inventory adjustment charges, and manufacturing variances.

A significant portion of the costs associated with the manufacture of INGREZZA sold to date was expensed as R&D prior to the FDA's approval and is therefore excluded from cost of sales during this period.

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 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.

Research and Development Expenses. 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, development milestones from in-licensed collaboration agreements, 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, in-licenses, and third-party funded research

arrangements. 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.

Revenue Recognition. Effective January 1, 2018, the Company adopted Topic 606, using the modified retrospective method. As the Company did not identify any revenue recognition differences when comparing the revenue recognition criteria under Topic 606 to the requirements under previous criteria with respect to product revenues, or revenue from collaboration and license agreements, no cumulative effect adjustment to retained earnings was necessary upon adoption. See the Company's Annual Report on Form 10-K filed with the SEC for the year ended December 31, 2017, for a detailed description of the Company's accounting policy under Topic 605 which was effective for periods prior to January 1, 2018. Had the Company continued to account for revenue recognition under Topic 605, the Company's revenues for the first three and nine months of 2018 would not have differed by a significant amount from those reported under Topic 606.

Under Topic 606, the Company recognizes revenues when its customers (as defined below) obtain control of its products or services in an amount that reflects the consideration it expects to receive from its customers in exchange for those products or services. To determine revenue recognition, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

If the consideration promised under the contract includes a variable amount, the Company must estimate the consideration it expects to receive for transferring the good or service to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts. Performance milestone payments represent a form of variable consideration.

Product Sales, Net. The Company's product sales consist of U.S. sales of INGREZZA. 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), or collectively, its customers, 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 the SPs and 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 the Company. Product sales are recognized when the customer obtains control of the Company's product, typically upon delivery to the customer.

Revenue from product sales is recorded at the net sales price (transaction price), which includes an estimate of variable consideration for which reserves are established and which results from contractual discounts, returns, chargebacks, rebates, co-pay assistance, and other allowances relating to the Company's sales of its products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes that

are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. The following are the Company's significant categories of sales discounts and allowances:

Trade Discounts and Allowances: The Company generally provides customers with discounts that include prompt payment discounts, discounts for providing sales data, and other off-invoice discounts that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Product Returns: The Company offers customers 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 customers and has the ability to control the amount of product that is sold to the customers. Product returns to date have not been significant and the Company has not considered it necessary to record a reserve for product returns.

Government Rebates: The Company is subject to discount obligations under state Medicaid programs and Medicare prescription drug coverage gap program. The Company estimates its Medicaid and Medicare prescription drug coverage gap rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses on the Condensed Consolidated Balance Sheet. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and the Company generally issues credits for such amounts following the customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period end that the Company expects will be sold to qualified healthcare providers.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Shipping and handling costs related to the Company's product sales are included in selling, general and administrative expenses.

Collaboration and Other Revenue. The Company enters into collaboration and licensing agreements that are within the scope of Topic 606, under which it licenses certain rights to its product candidates to third-parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines,

reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Royalty Revenue: For arrangements that include sales-based royalties, including milestone payments based on the level of sales of licensed products, and where the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Sales-based royalties for ORILISSA are calculated as a percentage of AbbVie net sales as defined in the Company's agreement with AbbVie. Each quarterly period, sales-based royalties are recorded based on estimated quarterly net sales of ORILISSA. Differences between actual results and estimated amounts are adjusted for in the period in which they become known, which typically follows the quarterly period in which the estimate was made.

Licenses of Intellectual Property: If the license to the Company's intellectual property embedded within a collaboration and/or licensing arrangement is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company receives payments from its licensees based on billing schedules established in each agreement. Up-front payments and fees are recorded as deferred revenue upon receipt, or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Milestone Payments: At the inception of each arrangement that includes development, commercialization and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect milestone and license fees revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

2. SIGNIFICANT COLLABORATION AND LICENSING AGREEMENTS

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 INGREZZA for movement disorders in Japan and other select Asian markets. Mitsubishi Tanabe made an up-front license fee of $30 million and has agreed to make payments 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. The Company 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 the terms of the Company's 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 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 INGREZZA product rights for Japan and other select Asian markets would revert to the Company.

The Company assessed this arrangement in accordance with Topic 606 and identified the following material promises under the agreement: (i) INGREZZA technology license and existing know-how; and (ii) development activities to initiate a clinical trial of INGREZZA for Huntington's chorea, at an estimated cost of approximately $12 million, should Mitsubishi Tanabe request. The Company has the option to participate on the joint steering committee, but since participation is at the Company's option it was deemed to not be a material promise. The option for Mitsubishi Tanabe to engage the Company to manufacture and supply pharmaceutical products, not at a discount, was not considered a material right and therefore not a material promise. Based on these assessments, the Company identified the license and the development activities as the only performance obligations at the inception of the agreement, which were both deemed to be distinct.

Under the terms of the agreement, in order to evaluate the appropriate transaction price, the Company determined that the up-front amount constituted the entirety of the consideration to be included in the transaction price and to be allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. For the license, the stand-alone selling price was calculated using an income approach model and included the following key assumptions: the development timeline, revenue forecast, discount rate and probabilities of technical and regulatory success. The relative selling price of the Company's development activities to initiate a clinical trial of INGREZZA for Huntington's chorea was based on an assessment of costs to perform the study, based upon the peer company analysis for similar studies. The Company believes that a change in the assumptions used to determine its stand-alone selling price for the license most likely would not have a significant effect on the allocation of consideration received (or receivable) to the performance obligations.

At execution, the transaction price included only the $30 million up-front consideration received. None of the development or regulatory milestones has been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Mitsubishi Tanabe and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

To date, the Company has recognized revenue under this agreement of $19.8 million associated with the delivery of a technology license and existing know-how, and $15 million in development event-based payments resulting from Mitsubishi Tanabe's initiation of Phase II/III development of INGREZZA in TD in Asia. 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. No revenue was recognized under the Mitsubishi Tanabe agreement for the three and nine months ended September 30, 2018. During the third quarter of 2017, Mitsubishi Tanabe initiated a pivotal trial of INGREZZA in Asia for the treatment of tardive dyskinesia which generated a $15 million milestone.

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 $115 million has been earned as of September 30, 2018, and up to an additional $50 million in commercial event-based payments.

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.

The Company has evaluated the terms of this agreement under Topic 606 and has determined that there is one performance obligation, the exclusive worldwide license with rights to develop, manufacture and commercialize elagolix. At execution, the transaction price included only the $75 million up-front consideration received. None of the development or regulatory milestones has been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to AbbVie and

therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

On July 24, 2018, AbbVie received approval from the FDA for ORILISSA for the management of moderate to severe endometriosis pain in women, resulting in the achievement of a $40 million event-based milestone, which the Company recognized as revenue in the third quarter of 2018. During 2017, event-based revenue of $30 million was recognized based on AbbVie's NDA submission for elagolix in endometriosis being accepted by the FDA. During 2016, event-based revenue of $15 million was recognized related to AbbVie's initiation of Phase III development of elagolix in uterine fibroids. The Company also recognized sales-based royalties on AbbVie net sales of ORILISSA of $0.5 million in the third quarter of 2018. No revenue was recognized under the AbbVie agreement for the nine months ended September 30, 2017.

BIAL – Portela & CA, S.A. (BIAL). In February 2017, the Company 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, 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, which was expensed in the first quarter of 2017 as in-process research and development. In addition, during the first quarter of 2018, the FDA provided guidance on the regulatory path forward to support an NDA for opicapone for Parkinson's Disease, in which the FDA did not request that the Company conduct an additional Phase III study, resulting in a $10 million event-based milestone payment to BIAL. The Company may also be required to pay up to an additional $105 million in milestone payments associated with the regulatory approval and net sales of products containing opicapone. Prior to FDA approval of opicapone, the Company may be required to pay up to an additional $10 million in milestones based on certain regulatory and clinical results and FDA acceptance of the Company's NDA submission for opicapone. 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 submit 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.

3. INVESTMENTS

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in comprehensive income (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 are included in investment 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 investment 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 investment income.

Investments consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Commercial paper	$ 42,465	$ 75,362
Corporate debt securities	541,694	414,815
Securities of government sponsored entities	40,707	18,401
Total investments	$ 624,866	$ 508,578

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, 2018:					
Classified as current assets:					
Commercial paper	Less than 1	$ 42,514	$ —	$ (49)	$ 42,465
Corporate debt securities	Less than 1	387,627	6	(1,407)	386,226
Securities of government-sponsored entities	Less than 1	11,000	—	(82)	10,918
Total short-term available-for-sale securities		$ 441,141	$ 6	$ (1,538)	$ 439,609
Classified as non-current assets:					
Corporate debt securities	1 to 2	$ 155,935	$ 1	$ (468)	$ 155,468
Securities of government-sponsored entities	1 to 2	29,846	—	(57)	29,789
Total long-term available-for-sale securities		$ 185,781	$ 1	$ (525)	$ 185,257
December 31, 2017:					
Classified as current assets:					
Commercial paper	Less than 1	$ 75,396	$ 1	$ (35)	$ 75,362
Corporate debt securities	Less than 1	178,776	—	(400)	178,376
Securities of government-sponsored entities	Less than 1	7,503	—	(24)	7,479
Total short-term available-for-sale securities		$ 261,675	$ 1	$ (459)	$ 261,217
Classified as non-current assets:					
Corporate debt securities	1 to 2	$ 237,749	$ —	$ (1,310)	$ 236,439
Securities of government-sponsored entities	1 to 2	11,004	—	(82)	10,922
Total long-term available-for-sale securities		$ 248,753	$ —	$ (1,392)	$ 247,361

(1) Unrealized gains and losses are included in other comprehensive income (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, 2018 and December 31, 2017, aggregated by investment category and length of time that individual securities have been in a continuous loss position (in thousands):

	Less Than 12 Months		12 Months or Greater		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
September 30, 2018:						
Commercial paper	$ 32,634	$ (49)	$ —	$ —	$ 32,634	$ (49)
Corporate debt securities	317,733	(931)	188,998	(944)	506,731	(1,875)
Securities of government-sponsored entities	29,789	(57)	10,918	(82)	40,707	(139)
Total	$ 380,156	$ (1,037)	$ 199,916	$ (1,026)	$ 580,072	$ (2,063)

December 31, 2017:						
Commercial paper	$62,602	$ (35)	$—	$ —	$62,602	$ (35)
Corporate debt securities	386,728	(1,660)	28,087	(50)	414,815	(1,710)
Securities of government-sponsored entities	10,922	(82)	7,479	(24)	18,401	(106)
Total	$460,252	$ (1,777)	$35,566	$ (74)	$495,818	$ (1,851)

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.

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, 2018 and December 31, 2017, the Company believed the cost bases for available-for-sale investments were recoverable in all material respects.

4. 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 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 three and nine months ended September 30, 2018.

The Company's assets which were measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017, 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, 2018:				
Classified as current assets:				
Cash and money market funds	$ 195.7	$ 195.7	$ —	$ —
Commercial paper	42.5	—	42.5	—
Securities of government-sponsored entities	10.9	—	10.9	—
Corporate debt securities	386.2	—	386.2	—
Subtotal	635.3	195.7	439.6	—
Classified as long-term assets:				
Cash and money market funds	1.5	1.5	—	—
Certificates of deposit	4.0	4.0	—	—
Securities of government-sponsored entities	29.8	—	29.8	—
Corporate debt securities	155.5	—	155.5	—
Total	826.1	201.2	624.9	—
Less cash, cash equivalents and restricted cash	(201.2)	(201.2)	—	—
Total investments	$ 624.9	$—	$ 624.9	$ —
December 31, 2017:				
Classified as current assets:				
Cash and money market funds	$ 170.2	$ 170.2	$ —	$ —
Commercial paper	159.9	—	159.9	—
Securities of government-sponsored entities	7.5	—	7.5	—
Corporate debt securities	178.4	—	178.4	—
Subtotal	516.0	170.2	345.8	—
Classified as long-term assets:				
Cash and money market funds	1.5	1.5	—	—
Certificates of deposit	3.0	3.0	—	—
Securities of government-sponsored entities	10.9	—	10.9	—
Corporate debt securities	236.4	—	236.4	—
Total	767.8	174.7	593.1	—
Less cash, cash equivalents and restricted cash	(259.2)	(174.6)	(84.6)	—
Total investments	$ 508.6	$0.1	$ 508.5	$ —

5. INVENTORY

Inventory at September 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 4,773	$ —
Work in process	270	491
Finished goods	1,011	533
Total inventory	$ 6,054	$ 1,024

6. 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.

As the conditional conversion feature described under (i) above had been triggered as of September 30, 2018, holders of the 2024 Notes may convert the 2024 Notes at any time during the period beginning on October 1, 2018 and ending at the close of business on December 31, 2018. Accordingly, the 2024 Notes have been classified as a current liability on the Company's Condensed Consolidated Balance Sheet as of September 30, 2018. The future conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of the Company's common stock during the prescribed measurement periods.

Upon conversion, holders will receive the principal amount of their 2024 Notes and any excess conversion value, calculated based on the per share volume-weighted average price for each of the 30 consecutive trading days during the observation period (as more fully described in the 2024 Indenture). For both the principal and excess conversion value, holders may receive cash, shares of 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. At the initial conversion rate, settlement of the 2024 Notes for shares of the Company's common stock would approximate 6.8 million shares. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. The initial conversion price of the 2024 Notes represented a premium of approximately 42.5% to the closing sale price of $53.28 per share of 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.

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, 2018, the fair value approximated 171% of the face principal amount of the 2024 Notes.

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, 2018 and December 31, 2017, consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Principal	$ 517,500	$517,500
Deferred financing costs	(8,663)	(9,652)
Debt discount, net	(125,190)	(138,230)
Net carrying amount	$ 383,647	$369,618

7. NET INCOME (LOSS) PER SHARE

Basic net income per share is computed using the weighted average number of common shares outstanding during the period. Diluted net income per share is computed using the weighted average number of common and potentially dilutive shares outstanding during the period, including the potentially dilutive shares resulting from the conversion of the 2024 Notes, and excluding the effect of stock options and restricted stock outstanding for periods when their effect is anti-dilutive, using the treasury stock method.

Convertible debt instruments that may be settled entirely or partly in cash (such as the 2024 Notes) may, in certain circumstances where the borrower has the ability and intent to settle in cash, be accounted for under the treasury stock method. The Company issued the 2024 Notes with a combination settlement feature, which it has the ability and intent to use upon conversion of the notes, to settle the principal amount of debt for cash and the excess of the principal portion in shares of the Company's common stock. As a result, of the approximately 6.8 million shares underlying the 2024 Notes, only the shares required to settle the excess of the principal portion would be considered dilutive under the treasury stock method. Further, approximately 0.3 million restricted stock units (RSUs) with performance-based vesting requirements (PRSUs) have been excluded from the calculation of diluted net income per share as the performance condition has not been achieved. In loss periods, basic net loss per share and diluted net loss per share are identical because the otherwise dilutive potential common shares become anti-dilutive and are therefore excluded.

Net income (loss) per share was calculated as follows (in thousands, except per share data):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net income (loss) - basic and diluted	$50,764	$(11,125)	$3,033	$(149,436)
Weighted-average common shares outstanding:				
Basic	90,555	88,325	90,064	87,894
Effect of dilutive securities:				
Employee stock purchase program	7	—	2	—
Stock options	3,352	—	3,322	—
Restricted stock	629	—	558	—
2024 Notes	2,255	—	1,326	—
Diluted	96,798	88,325	95,272	87,894
Net income (loss) per share:				
Basic	$0.56	$(0.13)	$0.03	$(1.70)
Diluted	$0.52	$(0.13)	$0.03	$(1.70)

Shares which have been excluded from diluted per share amounts because their effect would have been anti-dilutive include the following (in thousands):

	Three Months Ended	Nine Months Ended

	September 30, 2018	2017	September 30, 2018	2017
Stock options and restricted stock	882	7,862	823	7,898

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 Income (Loss) as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
General and administrative	$8,371	$6,531	$23,199	$18,234
Research and development	4,699	3,672	21,601	10,836
Total share-based compensation expense	$13,070	$10,203	$44,800	$29,070

The fair value of equity instruments that vest based on continued employee service is recognized and amortized on a straight-line basis over the requisite service period. No expense is recognized for PRSUs until the performance condition is probable of being achieved. During the nine months ended September 30, 2018, the Company recorded a non-recurring share-based compensation charge of $7.7 million related to the modification of certain options and RSUs.

As of September 30, 2018, 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 $60.7 million and $57.3 million, respectively, which is expected to be recognized over a weighted average period of approximately 2.5 and 2.2 years, respectively. Additionally, the Company has approximately 0.3 million PRSUs outstanding. As of September 30, 2018, total unrecognized estimated compensation cost related to these PRSUs was $19.7 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, 2018 and 2017, stock options to purchase approximately 1.5 million and 1.0 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, 2018 and 2017 was approximately $27.7 million and $8.3 million, respectively. The Company also issued approximately 0.4 million and 0.3 million shares of common stock pursuant to the vesting of RSUs during each of the nine months ended September 30, 2018 and 2017.

Stock Option Assumptions

The Company granted stock options to purchase approximately 1.0 million and 1.6 million shares of the Company's common stock during the nine months ended September 30, 2018 and 2017, 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, 2018 and 2017 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		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Risk-free interest rate	2.8%	1.8%	2.5%	2.0%
Expected volatility of common stock	53.7%	59.6%	59.9%	58.2%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected option term	4.5 years	5.0 years	4.8 years	5.7 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, 2018 and 2017, share-based compensation expense related to stock options was $28.2 million and $18.7 million, respectively.

Restricted Stock Units

During the nine months ended September 30, 2018 and 2017, the Company granted approximately 0.5 million and 0.6 million RSUs, respectively, which vest annually over a four-year period. Additionally, the Company granted approximately 0.2 million PRSUs during the nine months ended September 30, 2018, which vest based on the

achievement of pre-defined Company-specific performance criteria and expire approximately four to five years from the grant date. Expense recognition for PRSUs commences when attainment of the performance-based criteria is 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, 2018 and 2017, the aggregate share-based compensation expense related to RSUs and PRSUs was $16.5 million and $10.4 million, respectively.

9. REAL ESTATE

In connection with the sale-leaseback transaction of the Company's facility in 2007, the Company recognized a net gain of $39.1 million which was deferred in accordance with authoritative guidance. The Company recognized $0.5 million and $1.9 million of the deferred gain during the nine months ended September 30, 2018 and 2017, respectively, and will recognize the remaining $8.2 million of the deferred gain on a straight-line basis over the remaining 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 for its current headquarters 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. (Wells Fargo) 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 and is included in restricted cash on the Company's Condensed Consolidated Balance Sheet. 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.

In April 2018, the Company entered into a commercial lease agreement for the lease of 44,718 square feet of office space located directly behind the Company's current headquarters. The term of such lease is 130 months (commenced on July 1, 2018). In lieu of a cash security deposit, the Company issued an approximately $1.0 million letter of credit at lease execution, which is secured by a deposit of equal amount and is included in restricted cash on the Company's Condensed Consolidated Balance Sheet as of September 30, 2018. The Company is entitled to twelve months of base rent abatement and, as such, the base rent payments will commence in August 2019.

10. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. 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 (Mount Sinai Case). In the complaint, Mount Sinai alleged that the Company breached a license agreement with Mount Sinai dated August 27, 1999. In the third quarter of 2018, Mount Sinai and the Company reached agreement to dismiss the Mount Sinai Case in its entirety.

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.

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, 2017 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, 2017, and our Quarterly Report on Form 10-Q for the three and six months ended June 30, 2018.

OVERVIEW

We are a company focused on discovering, developing and commercializing innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through our novel research and development (R&D) platform, focused on neurological and endocrine related 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 occurred on May 1, 2017.

On July 24, 2018, we were notified by AbbVie Inc. (AbbVie) that FDA approval was granted for ORILISSA™ (elagolix) for the management of moderate to severe endometriosis pain in women. Discovered and developed through Phase II clinical trials by us, ORILISSA, the first FDA-approved oral medication for the management of endometriosis with associated moderate to severe pain in over a decade, began to be marketed by AbbVie in August 2018 as part of a collaboration to develop and commercialize elagolix for women's health.

Our clinical development programs include opicapone as an adjunctive therapy to levodopa/DOPA decarboxylase inhibitors in Parkinson's disease patients, elagolix for uterine fibroids with AbbVie, valbenazine for the treatment of Tourette syndrome, NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH), a vesicular monoamine transporter 2 (VMAT2) inhibitor and first-in-class central nervous system (CNS) compound with potential use in the treatment of neurologic and psychiatric disorders.

We currently have three major collaborations. Two of these collaborations involve out-licensing 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). 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. The third collaboration agreement, which was entered into in February 2018, is one in which we in-licensed technology from 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.

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 collaborations to meet our funding requirements. While we were profitable for the three and

nine months ended September 30, 2018, we expect our future operating results and profitability to fluctuate from period to period as product candidates are advanced through the various stages of clinical development and as we proceed with the commercial launch of INGREZZA and other potential future pipeline products. As of December 31, 2017, we had an accumulated deficit of approximately $1.2 billion.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States. 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 revenue recognition, clinical trial accruals (R&D expense), convertible debt, and share-based compensation. 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. Historically, revisions to our estimates have not resulted in a material change to the financial statements. The items in our financial statements requiring significant estimates and judgments are as follows:

Revenue Recognition

Effective January 1, 2018, we adopted Topic 606, using the modified retrospective method. Under Topic 606, we recognize revenues when our customers (as defined below) obtain control of our products or services in an amount that reflects the consideration we expect to receive from our customers in exchange for those products or services. To determine revenue recognition, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract to determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

If the consideration promised under the contract includes a variable amount, we must estimate the consideration we expect to receive for transferring the good or service to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and; (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts. Performance milestone payments represent a form of variable consideration.

Product Sales, Net. Our product sales consist of U.S. sales of INGREZZA. INGREZZA was approved by the FDA on April 11, 2017 and we commenced shipments of INGREZZA to select pharmacies (SPs) and a select distributor (SD), or collectively, our customers, 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. Our agreements with the SPs and 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. Product sales are recognized when the customer obtains control of our product, typically upon delivery to the customer.

Revenue from product sales are recorded at the net sales price (transaction price), which includes an estimate of variable consideration for which reserves are established and which results from contractual discounts, returns, chargebacks, rebates, co-pay assistance and other allowances relating to sales of our products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will

adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. The following are our significant categories of sales discounts and allowances:

Trade Discounts and Allowances: We generally provide customers with discounts that include prompt payment discounts, discounts for providing sales data, and other off-invoice discounts that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized.

Product Returns: We offer customers 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. We do not allow product returns for product that has been dispensed to a patient or for drug expiration. We receive real-time shipping reports and inventory reports from the customers and have the ability to control the amount of product that is sold to the customers. Product returns to date have not been significant and we have not considered it necessary to record a reserve for product returns.

Government Rebates: We are subject to discount obligations under state Medicaid programs and Medicare prescription drug coverage gap program. We estimate our Medicaid and Medicare prescription drug coverage gap rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued expenses on the Condensed Consolidated Balance Sheet. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and we generally issue credits for such amounts following the customer's notification to us of the resale. Reserves for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to qualified healthcare providers.

Co-Payment Assistance: We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period.

Shipping and handling costs related to our product sales are included in selling, general and administrative expenses.

Collaboration and Other Revenue. We enter into collaboration and licensing agreements that are within the scope of Topic 606, under which we license certain rights to our product candidates to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services; and royalties on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Royalty Revenue: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Sales-based royalties for ORILISSA are calculated as a percentage of AbbVie net sales as defined in our agreement with AbbVie. Each quarterly period, sales-based royalties are recorded based on estimated quarterly net sales of ORILISSA. Differences between actual results and

estimated amounts are adjusted for in the period in which they become known, which typically follows the quarterly period in which the estimate was made.

Licenses of Intellectual Property: If the license to our intellectual property embedded within a collaboration and/or licensing arrangement is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

We receive payments from our licensees based on billing schedules established in each agreement. Up-front payments and fees are recorded as deferred revenue upon receipt, or when due, and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional.

Milestone Payments: At the inception of each arrangement that includes development, commercialization and regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or that of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect milestone and license fees revenues and earnings in the period of adjustment.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee’s discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations.

Research and Development Expense

R&D expense consists primarily of salaries, payroll taxes, employee benefits, and share-based compensation charges, for those individuals involved in ongoing research and development efforts; as well as scientific contractor fees, preclinical and clinical trial costs, research and development 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 our independent R&D efforts as well as efforts associated with collaborations, in-licenses, and third-party funded research arrangements. We review and accrue clinical trials expense based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies and other events. We follow 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. Historically, revisions have not resulted in material changes to R&D expense; however, a modification in the protocol of a clinical trial or cancellation of a trial could result in a charge to our results of operations.

Share-based Compensation

We grant stock options to purchase our common stock to our employees and directors under our 2011 Equity Incentive Plan (the 2011 Plan) and grant stock options to certain employees pursuant to Employment Commencement Nonstatutory Stock Option Agreements (inducement grants). We also grant certain employees restricted stock units (RSUs) and performance-based restricted stock units (PRSUs) under the 2011 Plan and grant certain employees stock options and RSUs under the Neurocrine Biosciences, Inc. Inducement Plan (Inducement Plan). Share-based compensation expense was $13.1 million and $44.8 million for the third quarter and first nine months of 2018, respectively, compared to $10.2 million and $29.1 million for the third quarter and first nine months of 2017, respectively. Share-based compensation expense for the first nine months of 2018 included a non-recurring charge of $7.7 million related to the modification of certain options and RSUs.

Stock option awards and RSUs generally vest over a three to four-year period and expense is ratably recognized over those same time periods. For PRSUs, no expense is recorded until the performance condition is probable of being achieved; upon which expense is then recognized ratably over the expected performance period.

For purposes of calculating share-based compensation, we estimate the fair value of share-based compensation 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. For example, an increase in the underlying stock price results in a significant increase in the Black-Scholes option-pricing.

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 results of operations in the period such changes are made. For actual forfeitures, we recognize the adjustment to compensation expense in the period the 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 (the 2024 Notes). 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.

Debt acquisition costs related to the 2024 Notes were $14.7 million. In addition, we allocated $149.2 million to the equity component of the convertible debt instrument. We are amortizing the debt acquisition costs and the equity component over the life of the 2024 Notes as additional non-cash interest expense utilizing the effective interest method.

Results of Operations for the Three and Nine Months Ended September 30, 2018 and 2017

Revenues

The following table presents our revenues by category during the periods presented (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	$ Change	2018	2017	$ Change
Revenues:						
INGREZZA product sales, net	$111,291	$45,774	$65,517	$279,282	$52,109	$227,173
Collaboration revenue	40,466	15,000	25,466	40,466	15,000	25,466
Total revenues	$151,757	$60,774	$90,983	$319,748	$67,109	$252,639

Product Sales, Net

In April 2017, the FDA approved INGREZZA for the treatment of TD. INGREZZA became available for prescription in late April 2017. Net product sales were $111.3 million and $279.3 million for the third quarter and first nine months of 2018, respectively, compared to $45.8 million and $52.1 million for the third quarter and first nine months of 2017, respectively.

Collaboration Revenue

On July 24, 2018, we were notified by AbbVie that FDA approval was granted for ORILISSA for the management of moderate to severe endometriosis pain in women, resulting in the achievement of a $40.0 million event-based milestone, which we recognized as revenue in the third quarter of 2018. We also recognized sales-based royalties, payable to us by our partner AbbVie on quarterly net sales of ORILISSA, of $0.5 million for both the third quarter and first nine months of 2018. During the third quarter of 2017, Mitsubishi Tanabe initiated a pivotal trial of INGREZZA in Asia for the treatment of tardive dyskinesia which generated a $15 million milestone.

Operating Expenses

Cost of Sales

Cost of sales was $1.6 million for the third quarter of 2018, compared to $0.4 million for the third quarter of 2017. For the first nine months of 2018, cost of sales was $3.4 million, compared to $0.5 million for the first nine months of 2017. The increase in cost of sales for the third quarter and first nine months of 2018 is primarily due to increased INGREZZA net product sales. Product sold to date included active pharmaceutical ingredients (API) that was previously charged to R&D expense prior to FDA approval of INGREZZA for TD. This minimal cost API had a positive impact on our cost of sales and related product gross margins. Beginning in the fourth quarter of 2018, we expect to have a higher cost of sales that includes the cost of INGREZZA API produced following FDA approval.

Research and Development

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	$ Change	2018	2017	$ Change
External development expense:						
VMAT2	$9.1	$4.8	$ 4.3	$28.0	$13.7	$ 14.3
CRF	2.6	0.8	1.8	6.6	2.7	3.9
Other	1.0	1.1	(0.1)	5.0	2.8	2.2
Total external development expense	12.7	6.7	6.0	39.6	19.2	20.4
In-process R&D	—	—	—	10.0	30.0	(20.0)
R&D personnel expense	14.6	10.2	4.4	49.7	30.8	18.9
R&D facility and depreciation expense	2.3	1.6	0.7	5.9	4.3	1.6
Other R&D expense	5.9	4.0	1.9	16.2	11.9	4.3
Total R&D expense	$35.5	$22.5	$ 13.0	$121.4	$96.2	$ 25.2

R&D expense increased $13.0 million and $25.2 million for the third quarter and first nine months of 2018, respectively, compared to the same periods last year. The increase in R&D expense is primarily due to the ongoing progression of our product candidate pipeline and increase in personnel expenses on higher headcount, including $1.0 million and $10.8 million of non-cash share-based compensation increases for the third quarter and first nine months of 2018, respectively. Personnel expense for the first nine months of 2018 includes a non-recurring share-based compensation charge of $7.7 million related to the modification of certain options and RSUs. In-process R&D expense for the first nine months of 2017 includes a $30 million payment to BIAL to in-license opicapone, partially offset by a $10 million event-based payment to BIAL in the first quarter of 2018 as a result of guidance received from the FDA in which the FDA did not request an additional Phase III clinical trial to support an NDA submission for opicapone. Excluding the $20 million decrease in BIAL payments, R&D expense for the first nine months of 2018 increased $45.2 million compared to the same period last year.

Sales, General and Administrative

Sales, general and administrative (SG&A) expense increased to $60.4 million and $180.0 million for the third quarter and first nine months of 2018, respectively, compared to $43.9 million and $113.6 million for the third quarter and first nine months of 2017, respectively. The increase in SG&A expense for the third quarter and first nine months of 2018 is primarily due to our commercial launch for INGREZZA in April 2017 and the subsequent sales force expansion in the third quarter of 2018, which included higher personnel related costs of $9.9 million and $31.2 million for the third quarter and first nine months of 2018, respectively, including non-cash share-based compensation increases of $1.8 million and $5.0 million for the third quarter and first nine months of 2018, respectively.

Net Income (Loss)

Net income for the third quarter of 2018 was $50.8 million, or $0.52 diluted net income per share, compared to a net loss of $11.1 million, or a $0.13 net loss per share, for the third quarter of 2017. Net income for the first nine months of 2018 was $3.0 million, or $0.03 diluted net income per share, compared to a net loss of $149.4 million, or a $1.70 net loss per share, for the first nine months of 2017. The decrease in our net loss was primarily the result of increased

INGREZZA net product sales and the achievement of the $40.0 million event-based milestone related to the FDA's approval of ORILISSA, offset by ongoing support for the commercial launch of INGREZZA and progression of our clinical pipeline.

LIQUIDITY AND CAPITAL RESOURCES

Net cash provided by operating activities in the first nine months of 2018 was $50.9 million compared to $134.9 million net cash used in operating activities in the same period in 2017. The significant change to positive cash flow generated from operations was primarily due to an increase in total revenues driven by higher INGREZZA net product sales and the achievement of the $40.0 million event-based milestone related to the FDA’s approval of ORILISSA.

Net cash used in investing activities in the first nine months of 2018 was $136.7 million compared to $191.9 million in the same period in 2017. The fluctuation in net cash used in investing activities resulted primarily from the timing differences in investment purchases, sales and maturities of investments, the fluctuation of our portfolio mix between cash equivalents and short-term and long-term investment holdings, and an increase in additions to our property, plant and equipment, which consisted predominantly of tenant improvements to our corporate facilities.

Net cash provided by financing activities in the first nine months of 2018 was $27.7 million compared to $511.0 million in the same period in 2017. The change in cash provided by financing activities was primarily due to net proceeds of approximately $502.8 million from our offering of the 2024 Notes in May 2017.

At September 30, 2018, our cash and cash equivalents, restricted cash, and investments totaled $826.1 million compared with $767.8 million at December 31, 2017.

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, 2018, 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 efforts and 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 and other potential future pipeline products, to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, and the cost of product in-licensing and any possible acquisitions. In addition, we may require additional funding to establish manufacturing and marketing capabilities in the future. We 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 pursuant to the 2024 Notes 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 achieve profitability on a sustained basis.

OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2018, 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, 2018, 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

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

FORWARD-LOOKING STATEMENTS

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

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

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

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

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes to our internal control over financial reporting that occurred during our last fiscal quarter and that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Our evaluation did not identify significant changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the quarter ended September 30, 2018, 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 10 “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, 2017, 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, we may face difficulties related to managing the rapid growth of our personnel and infrastructure, and there can be no guarantee that we will be able to 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.

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 United States, state and non-United States 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 United States 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.

*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 allow 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 studies as a condition of the initiation of Phase I clinical studies, or additional clinical studies for progression from Phase I to Phase II, or Phase II to Phase III, or for NDA approval;
- the product candidate may not prove to be effective or as effective as other competing product candidates;
- we may discover that a product candidate may cause harmful side effects or results of required toxicology studies may not be acceptable to the FDA;
- the results may not replicate the results of earlier, smaller trials;
- the FDA or similar foreign regulatory authorities may require use of new or experimental endpoints that may prove insensitive to treatment effects;
-

we or the FDA or similar foreign regulatory authorities may suspend the trials;

- the results may not be statistically significant;
- patient recruitment may be slower than expected;
- patients may drop out of the trials; and
- regulatory requirements may change.

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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. Likewise, any of the clinical, regulatory or operational events described above could change our planned clinical and regulatory activities for the opicapone program in Parkinson's disease. With respect to our gonadotropin-releasing hormone (GnRH) program with AbbVie, any of these events could delay timelines for the completion of the Phase III uterine fibroids program. 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 products and 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 ORILISSA is dependent upon maintaining our current collaboration agreement with AbbVie. This collaboration agreement provides for significant future payments should certain development, regulatory and commercial milestones be achieved, and royalties on future sales of elagolix. Under this agreement, AbbVie is responsible for, among other things, conducting clinical trials and obtaining required regulatory approvals for elagolix; as well as manufacturing and commercialization of ORILISSA.

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

- does not successfully commercialize ORILISSA for endometriosis;
- fails to gain regulatory approval of elagolix for uterine fibroids, and if applicable, successfully launch and commercialize elagolix for that indication;
- does not conduct its collaborative activities in a timely manner;
- does not devote sufficient time and resources to our partnered program;
- terminates its agreement with us;
- develops, either alone or with others, products that may compete with elagolix;
- disputes our respective allocations of rights to any products or technology developed during our collaboration; or
- merges with a third party that wants to terminate our agreement.

In 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 products and product candidates we licensed to AbbVie.

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

*We are subject to ongoing obligations and continued regulatory review for INGREZZA, 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 the 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 (especially for a product, such as INGREZZA, which has been administered in only a limited patient population to date), 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 on a sustained basis.

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 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, or our sales and marketing efforts are not effective, we may not generate sufficient revenue.

The commercial success of INGREZZA or any of our other products, 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. We may face difficulties related to managing the growth of our sales and marketing organization, and it is possible that the rapid expansion in our sales and marketing team may have a short-term negative effect on our external sales and marketing efforts given the need to devote significant time to the training and integration of these

personnel. If our sales and marketing efforts are not effective and 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 exceptions of INGREZZA, which has been approved by the FDA for TD, and ORILISSA (partnered with AbbVie), which has been approved by the FDA for the management of moderate to severe endometriosis pain in women. Only a small number of research and development programs ultimately result in commercially successful drugs. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. These reasons include the possibilities that the potential products may:

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

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

Our 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 liquidity.

As of September 30, 2018, the conditional conversion feature of the 2024 Notes had been triggered, allowing holders of 2024 Notes to convert their 2024 Notes at any time during the period beginning on October 1, 2018 and ending at the close of business on December 31, 2018. The future conditional convertibility of the 2024 Notes will be monitored at each quarterly reporting date and analyzed dependent upon market prices of the Company’s common stock during the prescribed measurement periods, and as a result, it is possible that holders of 2024 Notes will

continue to be entitled to convert their 2024 Notes at any time during specified periods at their option. If one or more of the holders of the 2024 Notes elects to convert their 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.

*We have a history of losses and expect to increase our expenses 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 $1.2 billion as of December 31, 2017.

In April 2017, we received FDA approval of INGREZZA for TD, and in July 2018, our partner AbbVie received FDA approval for ORILISSA for management of moderate to severe endometriosis pain in women. However, we have not yet obtained regulatory approvals for any other product candidates. Even if we succeed in commercializing INGREZZA or developing and commercializing any of our other product candidates, we may not be profitable. We also expect to continue to incur significant operating and capital expenditures as we:

- commercialize INGREZZA for TD;
- seek regulatory approvals for our product candidates;
- develop, formulate, manufacture and commercialize our product candidates;
- in-license or acquire new product development opportunities;
- implement additional internal systems and infrastructure; and
- hire additional clinical, scientific, sales and marketing personnel.

We expect to increase our expenses and other investments in the coming years as we fund our operations, in-licensing or acquisition opportunities, and capital expenditures. While we were profitable for the three and nine months ended September 30, 2018, we expect our future operating results and profitability to fluctuate from period to period due to the factors described above, and we will need to generate significant revenues to achieve and maintain profitability and positive cash flow on a sustained basis. We may not be able to generate these revenues, and we may never achieve profitability on a sustained basis in the future. Our failure to maintain or increase profitability on a sustained basis could negatively impact the market price of our common stock.

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

As of September 30, 2018, we had approximately 574 employees. Although we have already substantially increased the size of our organization, we may need to add additional qualified personnel and resources, especially now that we have a commercial sales force. Our current infrastructure may be inadequate to support our development and commercialization efforts and expected growth. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as our development and commercialization efforts. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our development and commercialization efforts could be negatively impacted, and we may not be able to implement our business strategy.

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 it is possible that the rapid expansion in our sales and marketing team may have a short-term negative effect on our external sales and marketing efforts given the need to devote significant time to the training and integration of these personnel. In addition, we 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 submit 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. 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 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. We may face particular retention challenges in light of the recent rapid growth in our personnel and infrastructure and the perceived impact of those changes upon our corporate culture. In addition, we rely on a significant number of consultants to assist us in formulating our research and development strategy and our commercialization strategy. Our consultants may have commitments to, or advisory or consulting agreements with, other entities that may limit their availability to us.

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

Certain of the diseases that INGREZZA 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 United States 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 United States 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 United States 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 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, royalties from out-licensed products, the impact of Medicare Part D coverage; our achievement of product development objectives and milestones, clinical trial enrollment and expenses, research and development expenses and the timing and nature of contract manufacturing and contract research payments. In addition, we recently received regulatory approval from the FDA for INGREZZA in TD 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. While we were profitable for the three and nine months ended September 30, 2018, we expect our future operating results and profitability to fluctuate from period to period, and even if we become profitable on a quarterly or annual basis, we may not be able to sustain or increase our profitability. Moreover, as our company and our market capitalization have grown, our financial performance has become increasingly subject to quarterly and annual comparisons with the expectations of securities analysts or investors. The failure of our financial results to meet these expectations, either in a single quarterly or annual period or over a sustained period of time, could cause our stock price to decline.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, new legislation was enacted that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

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

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2017, we had federal and state income tax net operating loss carry forwards of approximately $978.7 million and $535.3 million, respectively. These net operating loss carry forwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carry forwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have determined that no ownership changes have occurred through December 31, 2016 or 2017. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carry forwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

*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, especially as our Company and market capitalization have grown, the price of our common stock has been increasingly affected by quarterly and annual comparisons with the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts’ forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, which is based on assumptions that may be incorrect or that may change from quarter to quarter, the market price of our common stock could decline. Over the course of the last 12 months, the price of our common stock has ranged from approximately $60.00 per share to approximately $127.00 per share. The market price of our common stock may fluctuate in response to many factors, including:

- sales of INGREZZA and/or ORILISSA;
- 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;
- government and third-party payor coverage and reimbursement;
- failure of any of our product candidates, if approved, to achieve commercial success; and
- public concern as to the safety of our drugs.

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

We may require additional funding to effectively commercialize INGREZZA, to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, and the cost of product in-licensing and any possible acquisitions. In addition, we may require additional funding to establish manufacturing and marketing capabilities in the future. We believe that our existing capital resources, together with investment income, and future payments due under our strategic alliances, will be sufficient to satisfy our current and projected funding requirements for at least the next 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 any future litigation;
- the cost of commercialization activities and arrangements, including manufacturing of our product candidates; and
- the cost of product in-licensing and any possible acquisitions.

We intend to seek additional funding through strategic alliances, and may seek additional funding through public or private sales of our securities, including equity securities. 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 the 2024 Notes and we have previously financed capital purchases and may continue to pursue opportunities to obtain additional debt financing in the future. Additional equity or debt financing might not be available on reasonable terms, if at all. 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.

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 provided to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding distribution of the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, notification and purchaser license verification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Additionally, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was signed into law, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our 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% (and 70% commencing January 1, 2019) 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, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA have been put into place. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress

has not passed repeal legislation, the newly enacted federal income tax law includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, a continuing resolution was enacted on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. Moreover, in July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA-qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress may consider other legislation to repeal or replace 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, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 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 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 pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the current presidential administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the current presidential administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has already started the process of soliciting feedback on certain of these measures and, additionally, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019. Although a number of these, and other potential, proposals will require authorization through additional legislation to become effective, Congress and the executive branch have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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, TD, 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 received approval for AUSTEDO® to treat TD.

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.

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 United States and the EU for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs.

In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug. 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 action against our employees, independent contractors, principal investigators, consultants, commercial partners or vendors for violations of these laws could result in significant civil and criminal penalties, fines and imprisonment.

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

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

Such laws include:

- the federal Anti-Kickback Statute which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the 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 their 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 physicians and their immediate family members; and
- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; state and local "drug takeback" laws and regulations; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. 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 $25 million per occurrence and $25 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 $25 million per occurrence and $25 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. Furthermore, regardless of the eventual outcome of a product liability claim, any product liability claim against us may decrease demand for our approved products, including INGREZZA, damage our reputation, result in regulatory investigations that could require costly recalls or product modifications, cause clinical trial participants to withdrawal, result in costs to defend the related litigation, decrease our revenue, and divert management’s attention from managing our business.

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

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

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

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

ITEM 5. Other Information
Not applicable.

ITEM 6. EXHIBITS

Exhibit Number	Description
3.1	Certificate of Incorporation, as amended
3.2	Bylaws, as amended
4.1	Form of Common Stock Certificate (1)
4.2	Indenture, dated as of May 2, 2017, by and between the Company and U.S. Bank National Association, as Trustee (2)
4.3	Form of Note representing the Company's 2.25% Convertible Notes due 2024 (3)
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated under the Securities Exchange Act of 1934
32*	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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 the Company's Registration Statement on Form S-1 (Registration No. 333-03172)
(2) Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K dated May 2, 2017
(3) Incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K dated 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.

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

SIGNATURES

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

NEUROCRINE BIOSCIENCES, INC.(Registrant)

Dated: November 05, 2018 /s/ Matthew C. Abernethy
Matthew C. Abernethy
Chief Financial Officer
(Duly authorized officer and Principal Financial Officer)