NEUROCRINE BIOSCIENCES INC
Form 10-Q
July 31, 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 June 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company		

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

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

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 90,469,361 as of July 25, 2018.

NEUROCRINE BIOSCIENCES, INC.

FORM 10-Q INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share information)

(unaudited)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$166,422	$254,712
Short-term investments, available for sale	342,318	261,217
Accounts receivable	42,646	31,127
Other current assets	16,291	7,863
Total current assets	567,677	554,919
Property and equipment, net	18,775	10,811
Long-term investments, available for sale	249,388	247,361
Restricted cash	5,477	4,500
Total assets	$841,317	$817,591
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$61,031	$53,520
Other current liabilities	731	906
Total current liabilities	61,762	54,426
Deferred gain on sale of real estate	7,677	8,043
Deferred revenue	10,231	10,231
Deferred rent	5,326	3,135
Convertible senior notes	378,885	369,618
Total liabilities	463,881	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 90,403,238 as of June 30, 2018 and 88,793,903 as of December 31, 2017	90	89
Additional paid-in capital	1,626,752	1,572,765
Accumulated other comprehensive loss	(2,809)	(1,850)
Accumulated deficit	(1,246,597)	(1,198,866)

Total stockholders' equity	377,436	372,138
Total liabilities and stockholders' equity	$841,317	$817,591

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)

(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Product sales, net	$96,905	$6,335	$167,991	$6,335
Total revenues	96,905	6,335	167,991	6,335
Operating expenses:				
Cost of product sales	854	61	1,804	61
Research and development	36,988	21,868	85,935	73,750
Sales, general and administrative	60,915	41,674	119,551	69,724
Total operating expenses	98,757	63,603	207,290	143,535
Loss from operations	(1,852)	(57,268)	(39,299)	(137,200)
Other (expense) income:				
Deferred gain on real estate	183	879	366	1,758
Interest expense	(7,591)	(4,767)	(15,095)	(4,767)
Investment income and other, net	3,347	1,171	6,297	1,898
Total other expense, net	(4,061)	(2,717)	(8,432)	(1,111)
Net loss	$(5,913)	$(59,985)	$(47,731)	$(138,311)
Net loss per common share:				
Basic and diluted	$(0.07)	$(0.68)	$(0.53)	$(1.58)
Shares used in the calculation of net loss per common share:				
Basic and diluted	90,100	88,063	89,814	87,675
Other comprehensive loss:				
Net loss	$(5,913)	$(59,985)	$(47,731)	$(138,311)
Net unrealized gain (loss) on available-for-sale securities	888	(478)	(959)	(395)
Comprehensive loss	$(5,025)	$(60,463)	$(48,690)	$(138,706)

See accompanying notes to the condensed consolidated financial statements.

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	For the Six Months Ended June 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(47,731)	$(138,311)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,669	1,078
Gain on sale of assets, net	(348)	(1,760)
Amortization of debt issuance costs	655	207
Amortization of debt discount	8,612	2,651
Deferred rent	(72)	(239)
Cease-use expense	—	(544)
Amortization of premiums on investments	1,064	596
Non-cash share-based compensation expense	31,730	18,866
Change in operating assets and liabilities:		
Accounts receivable	(11,519)	(6,074)
Inventory	(3,271)	(128)
Other current assets	(2,894)	(2,437)
Accounts payable and accrued liabilities	4,273	627
Other current liabilities	(175)	(128)
Net cash used in operating activities	(18,007)	(125,596)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(224,076)	(365,032)
Sales and maturities of investments	138,925	210,324
Proceeds from sales of property and equipment	30	—
Purchases of property and equipment	(6,443)	(1,759)
Net cash used in investing activities	(91,564)	(156,467)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	22,258	5,243
Proceeds from issuance of senior convertible notes, net	—	502,781
Net cash provided by financing activities	22,258	508,024
Net (decrease) increase in cash, cash equivalents and restricted cash	(87,313)	225,961
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	$171,899	$314,111

SUPPLEMENTAL DISCLOSURE		
Cash paid for interest	$5,822	$—
Non-cash capital expenditures	3,238	—

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 with associated 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, and NBI-74788 for the treatment of congenital adrenal hyperplasia (CAH).

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 the 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 standards 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. The Company’s facility leases are subject to this new guidance and the Company is in the process of determining the impact on its condensed consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, “Statement of Cash Flows (Topic 230): Restricted Cash”, which clarifies the presentation of restricted cash and restricted cash equivalents in the statements of cash flows. Under 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 June 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. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606. 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. 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 manufacturing were charged to research and development expense in the period incurred. At June 30, 2018 and December 31, 2017, 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 authoritative guidance. Additionally, manufacturing of bulk drug product, finished bottling and other labeling activities that occurred post FDA approval are included in the inventory value at June 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 Product Sales. Cost of product sales consists of third-party manufacturing costs, transportation and freight, and indirect overhead costs associated with the manufacture and distribution of INGREZZA. Cost of product sales may also include period costs related to certain inventory manufacturing services, inventory adjustment charges as well as manufacturing variances. A significant portion of the cost of producing the product sold to date was expensed as R&D prior to the FDA’s approval of INGREZZA and therefore is not included in the cost of product 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 second quarter and first six 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 Licensing Agreements. 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.

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.

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.

Royalties: 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, 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). To date, the Company has not recognized any royalty revenue resulting from any of its out-licensing arrangements.

The Company receives payments from its licensees based on billing schedules established in each contract. 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.

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 six months ended June 30, 2018 or 2017.

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 $75 million has been earned as of June 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.

During 2017, event-based revenue of $30.0 million was recognized based on AbbVie's NDA submission for elagolix in endometriosis being accepted by the FDA. During 2016, event-based revenue of $15.0 million was recognized related to AbbVie's initiation of Phase III development of elagolix in uterine fibroids. No revenue was recognized under the AbbVie agreement for the six months ended June 30, 2018 or 2017. On July 24, 2018, AbbVie received approval from the FDA for ORILISSA™ (elagolix) for the management of moderate to severe endometriosis pain in women, resulting in the achievement of a $40.0 million event-based milestone, which the Company will recognize as revenue in the third quarter of 2018.

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 loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in 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):

	June 30, 2018	December 31, 2017
Commercial paper	$37,157	$75,362
Corporate debt securities	543,648	414,815
Securities of government sponsored entities	10,901	18,401
Total investments	$591,706	$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
June 30, 2018:					
Classified as current assets:					
Commercial paper	Less than 1	$37,211	$ —	$ (54)	$37,157
Corporate debt securities	Less than 1	300,451	—	(1,243)	299,208
Securities of government-sponsored entities	Less than 1	6,000	—	(47)	5,953
Total short-term available-for-sale securities		$343,662	$ —	$ (1,344)	$342,318
Classified as non-current assets:					

Corporate debt securities	1 to 2	$ 245,850	$ —	$ (1,410)	$ 244,440
Securities of government-sponsored entities	1 to 2	5,003	—	(55)	4,948
Total long-term available-for-sale securities		$ 250,853	$ —	$ (1,465)	$ 249,388
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