

NEUROCRINE BIOSCIENCES INC

Form 10-Q

August 03, 2017

[Table of Contents](#)

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, 2017

OR

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

For the transition period from _____ to _____

Commission File Number: 0-22705

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of	33-0525145 (IRS Employer
incorporation or organization)	Identification No.)
12780 El Camino Real,	
San Diego, California	92130
(Address of principal executive offices)	(Zip Code)
(858) 617-7600	

(Registrant's telephone number, including area code)

Not Applicable

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

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

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

Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 88,221,674 as of July 27, 2017.

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

FORM 10-Q INDEX

	PAGE
PART I. FINANCIAL INFORMATION	
<u>ITEM 1: Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of June 30, 2017 and December 31, 2016</u>	3
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2017 and 2016</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2017 and 2016</u>	5
<u>Notes to the Condensed Consolidated Financial Statements</u>	6
<u>ITEM 2: Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>ITEM 3: Quantitative and Qualitative Disclosures About Market Risk</u>	29
<u>ITEM 4: Controls and Procedures</u>	29
PART II. OTHER INFORMATION	
<u>ITEM 1: Legal Proceedings</u>	30
<u>ITEM 1A: Risk Factors</u>	30
<u>ITEM 5: Other Information</u>	45
<u>ITEM 6: Exhibits</u>	46
<u>Signatures</u>	47

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****NEUROCRINE BIOSCIENCES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS****(in thousands, except share information)****(unaudited)**

	June 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 309,498	\$ 83,267
Short-term investments, available-for-sale	215,522	224,083
Accounts receivable	6,074	
Inventory	128	
Other current assets	5,529	3,092
Total current assets	536,751	310,442
Property and equipment, net	6,954	6,271
Long-term investments, available-for-sale	205,768	43,490
Restricted cash	4,613	4,883
Total assets	\$ 754,086	\$ 365,086
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 26,809	\$ 26,182
Current portion of cease-use liability	181	236
Current portion of deferred rent		470
Current portion of deferred gain on sale of real estate	731	3,526
Total current liabilities	27,721	30,414
Deferred gain on sale of real estate	8,409	7,372
Deferred revenue	10,231	10,231
Deferred rent	1,693	1,462
Convertible senior notes	360,681	
Cease-use liability		617
Other liabilities	113	113
Total liabilities	408,848	50,209

Commitments and contingencies

Stockholders' equity:

Preferred stock, \$0.001 par value; 5,000,000 shares authorized; no shares issued and outstanding

Common stock, \$0.001 par value; 220,000,000 shares authorized; issued and outstanding shares were 88,216,868 as of June 30, 2017 and 86,883,300 as of

December 31, 2016

	88	87
Additional paid-in capital	1,540,498	1,371,432
Accumulated other comprehensive loss	(713)	(318)
Accumulated deficit	(1,194,635)	(1,056,324)
 Total stockholders' equity	 345,238	 314,877
 Total liabilities and stockholders' equity	 \$ 754,086	 \$ 365,086

See accompanying notes to the condensed consolidated financial statements.

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
Product sales, net	\$ 6,335	\$	\$ 6,335	\$
License fees and milestones				15,000
Total revenues	6,335		6,335	15,000
Operating expenses:				
Cost of product sales	61		61	
Research and development	21,868	26,863	73,750	50,766
Sales, general and administrative	41,674	14,965	69,724	26,919
Total operating expenses	63,603	41,828	143,535	77,685
Loss from operations	(57,268)	(41,828)	(137,200)	(62,685)
Other (expense) income, net:				
Gain on sale/disposal of assets	2	14	2	17
Deferred gain on real estate	879	854	1,758	1,707
Interest expense	(4,767)		(4,767)	
Investment income, net	1,169	680	1,896	1,417
Total other (expense) income	(2,717)	1,548	(1,111)	3,141
Net loss	\$ (59,985)	\$ (40,280)	\$ (138,311)	\$ (59,544)
Net loss per common share:				
Basic and diluted	\$ (0.68)	\$ (0.46)	\$ (1.58)	\$ (0.69)
Shares used in the calculation of net loss per common share:				
Basic and diluted	88,063	86,694	87,675	86,595
Other comprehensive loss:				
Net loss	\$ (59,985)	\$ (40,280)	\$ (138,311)	\$ (59,544)
Net unrealized (losses)/gains on available-for-sale securities	(478)	149	(395)	938
Comprehensive loss	\$ (60,463)	\$ (40,131)	\$ (138,706)	\$ (58,606)

See accompanying notes to the condensed consolidated financial statements.

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (138,311)	\$ (59,544)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,078	600
Gain on sale of assets	(1,760)	(1,724)
Deferred rent	(239)	(136)
Cease-use expense	(544)	(584)
Amortization of debt issuance costs	207	
Amortization of debt discount	2,651	
Amortization of premiums on investments	596	2,440
Non-cash share-based compensation expense	18,866	14,192
Change in operating assets and liabilities:		
Accounts receivable	(6,074)	
Inventory	(128)	
Other current assets	(2,437)	315
Accounts payable and accrued liabilities	627	1,184
Cease-use liability	(128)	(181)
Other non-current liabilities		(108)
Net cash used in operating activities	(125,596)	(43,546)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(365,032)	(169,488)
Sales and maturities of investments	210,324	227,150
Proceeds from sales of property and equipment		13
Deposits and restricted cash	270	(92)
Purchases of property and equipment	(1,759)	(2,984)
Net cash (used in) provided by investing activities	(156,197)	54,599
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	5,243	998
Proceeds from issuance of senior convertible notes, net	502,781	
Net cash provided by financing activities	508,024	998
Net increase in cash and cash equivalents	226,231	12,051

Edgar Filing: NEUROCRINE BIOSCIENCES INC - Form 10-Q

Cash and cash equivalents at beginning of the period	83,267	74,195
Cash and cash equivalents at end of the period	\$ 309,498	\$ 86,246

Supplemental Cash Flow Information

Cash paid for interest during the period	\$	\$
--	----	----

See accompanying notes to the condensed consolidated financial statements.

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

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

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

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2016 included in the Company's Annual Report on Form 10-K filed with the SEC. The results of operations for the interim period shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year. The balance sheet at December 31, 2016 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

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

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

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

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

Table of Contents

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

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

2. PRODUCT SALES, NET

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

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

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

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

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

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

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

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

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

Table of Contents

3. REVENUE RECOGNITION FOR SIGNIFICANT COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

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

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

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

To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances.