NEUROCRINE BIOSCIENCES INC
Form 10-Q
July 31, 2012
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2012

OR

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

For the transition period from to

Commission file number 0-22705

NEUROCRINE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, was 66,325,246 as of July 24, 2012.

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

FORM 10-Q INDEX

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, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,018	$ 50,107
Short-term investments, available for sale	135,522	78,996
Receivables under collaboration agreements	1,539	1,903
Other current assets	2,179	1,470
Total current assets	181,258	132,476
Property and equipment, net	1,861	1,586
Long-term investments	14,634	
Restricted cash	4,334	4,306
Total assets	$ 202,087	$ 138,368
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,420	$ 1,111
Accrued liabilities	6,937	8,451
Current portion of deferred revenues	17,435	34,242
Current portion of cease-use liability	273	264
Current portion of deferred gain on sale of real estate	3,087	3,042
Total current liabilities	29,152	47,110
Deferred revenues	1,460	2,919
Deferred gain on sale of real estate	22,442	24,005
Deferred rent	1,959	1,800
Cease-use liability	2,190	2,328
Other liabilities	151	125
Total liabilities	57,354	78,287
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; 110,000,000 shares authorized; issued and outstanding shares were 66,320,225 as of June 30, 2012 and 55,262,734 as of December 31, 2011	66	55
Additional paid-in capital	870,895	784,811
Accumulated other comprehensive loss	(143)	(87)
Accumulated deficit	(726,085)	(724,698)

Total stockholders equity	144,733	60,081
Total liabilities and stockholders equity	$ 202,087	$ 138,368

See accompanying notes to the condensed consolidated financial statements.

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(in thousands, except per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenues:				
Sponsored research and development	$ 1,540	$ 2,919	$ 3,569	$ 6,193
Milestones and license fees	9,029	9,238	18,267	18,476
Total revenues	10,569	12,157	21,836	24,669
Operating expenses:				
Research and development	8,818	8,176	18,206	15,493
General and administrative	3,131	2,809	6,802	5,965
Cease-use expense		76		176
Total operating expenses	11,949	11,061	25,008	21,634
(Loss) income from operations	(1,380)	1,096	(3,172)	3,035
Other income:				
Gain on sale/disposal of assets		18	25	98
Deferred gain on real estate	759	737	1,517	1,473
Investment income, net	115	120	236	239
Other income, net	5	5	7	13
Total other income	879	880	1,785	1,823
Net (loss) income	$ (501)	$ 1,976	$ (1,387)	$ 4,858
Net (loss) income per common share:				
Basic	$ (0.01)	$ 0.04	$ (0.02)	$ 0.09
Diluted	$ (0.01)	$ 0.04	$ (0.02)	$ 0.09
Shares used in the calculation of net (loss) income per common share:				
Basic	66,309	55,209	64,857	55,097
Diluted	66,309	56,434	64,857	56,276
Other comprehensive (loss) income:				
Net (loss) income	$ (501)	$ 1,976	$ (1,387)	$ 4,858
Net unrealized (losses) gains on available-for-sale securities	(16)	31	(56)	29
Comprehensive (loss) income	$ (517)	$ 2,007	$ (1,443)	$ 4,887

See accompanying notes to the condensed consolidated financial statements.

4

Table of Contents

NEUROCRINE BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2012	**2011**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (loss) income	$ (1,387)	$ 4,858
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	318	414
Gain on sale of assets	(1,542)	(1,571)
Cease-use expense		176
Deferred revenues	(18,266)	(18,550)
Deferred rent	159	215
Amortization of premiums on investments	1,490	1,153
Non-cash share-based compensation expense	2,799	1,107
Change in operating assets and liabilities:		
Receivables under collaboration agreements and other assets	(345)	1,308
Accounts payable and accrued liabilities	(1,205)	(1,167)
Cease-use liability	(129)	(2,433)
Other liabilities	26	
Net cash used in operating activities	(18,082)	(14,490)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(123,161)	(75,879)
Sales and maturities of investments	50,455	54,986
Deposits and restricted cash	(28)	(2)
Proceeds from sales of property and equipment	25	101
Purchases of property and equipment	(594)	(148)
Net cash used in investing activities	(73,303)	(20,942)
CASH FLOWS FROM FINANCING ACTIVITIES		
Issuance of common stock	83,296	219
Net cash provided by financing activities	83,296	219
Net decrease in cash and cash equivalents	(8,089)	(35,213)
Cash and cash equivalents at beginning of the period	50,107	54,051
Cash and cash equivalents at end of the period	$ 42,018	$ 18,838

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, develops and intends to commercialize drugs for the treatment of neurological and endocrine-related diseases and disorders. The Company s product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, stress-related disorders, pain, tardive dyskinesia, uterine fibroids, diabetes, insomnia, and other neurological and endocrine-related diseases and disorders. While the Company independently develops many of its product candidates, it has entered into collaborations for six of its programs. The Company s lead clinical development program, elagolix, is a drug candidate for the treatment of endometriosis and uterine fibroids that is partnered with Abbott International Luxembourg S.à r.l. (Abbott).

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 subsidiary.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2011 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, 2011 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 December 2011, the Financial Accounting Standards Board (FASB) issued accounting guidance requiring an entity to disclose information about offsetting arrangements and the impact of these arrangements on the Company s financial position. This guidance is effective for interim and annual periods beginning on or after January 1, 2013. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

In May 2011, the FASB issued updated accounting guidance that clarifies existing fair value measurements and disclosures, and eliminates differences between GAAP and International Financial Reporting Standards to make convergence guidance more understandable. This guidance is effective for interim and annual periods beginning after December 15, 2011. The adoption of this guidance did not have a material impact on the Company s condensed consolidated financial statements.

Effective January 1, 2012, the Company adopted guidance issued by the FASB concerning presentation and disclosure only for the presentation of comprehensive (loss) income. The adoption of this guidance did not have a material impact on the Company s condensed consolidated financial position or results of operations, other than its impact on the presentation of comprehensive (loss) income.

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. REVENUE RECOGNITION AND SIGNIFICANT COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

Revenue Recognition Policy. Revenues under collaborative agreements and grants are recognized as research costs are incurred over the period specified in the related agreement or as the services are performed. These agreements are on a best-efforts basis, do not require scientific achievement as a performance obligation and provide for payment to be made when costs are incurred or the services are performed. All fees are nonrefundable to the collaborators. Prior to the revised multiple element guidance adopted by the Company on January 1, 2011, upfront, nonrefundable payments for license fees, grants, and advance payments for sponsored research revenues received in excess of amounts earned were classified as deferred revenue and recognized as income over the contract or development period. Estimating the duration of the

development period includes continual assessment of development stages and regulatory requirements. If and when the Company enters into a new collaboration agreement or materially modifies an existing collaboration agreement, the Company will be required to apply the new multiple element guidance. Milestone payments are recognized as revenue upon achievement of pre-defined scientific events, which require substantive effort, and for which achievement of the milestone was not readily assured at the inception of the agreement.

Table of Contents

Abbott International Luxembourg S.à r.l. In June 2010, the Company announced an exclusive worldwide collaboration with Abbott to develop and commercialize elagolix and all next-generation gonadotropin-releasing hormone (GnRH) antagonists (collectively, GnRH Compounds) for women s and men s health. Under the terms of the Company s agreement with Abbott, the Company and Abbott will work jointly to advance GnRH Compounds towards commercialization. Abbott made an upfront payment of $75 million and agreed to make additional development and regulatory event based payments of up to $480 million and up to an additional $50 million in commercial event based payments. The Company has assessed event based payments under the revised authoritative guidance for research and development milestones and determined that event based payments prior to commencement of a Phase III clinical study, as defined in the agreement, meet the definition of a milestone in accordance with authoritative guidance as (1) they are events that can only be achieved in part on the Company s past performance, (2) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (3) they result in additional payments being due to the Company. Development and regulatory event based payments subsequent to the commencement of a Phase III clinical study, however, currently do not meet these criteria as their achievement is based on the performance of Abbott. As of June 30, 2012, there are no further event based payments that meet the definition of a milestone in accordance with authoritative guidance.

Under the terms of the agreement, Abbott is responsible for all third-party development, marketing and commercialization costs. The Company will receive funding for certain internal collaboration expenses which includes reimbursement from Abbott for internal and external expenses related to the GnRH Compounds, which reimbursement includes up to approximately $24 million in personnel funding through the end of 2012. 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. Under the terms of the Company s agreement with Abbott, the collaboration effort between the parties to advance GnRH Compounds towards commercialization is governed by a joint development committee with representatives from both the Company and Abbott; provided, however, that final decision making authority rests with Abbott. Abbott 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 s participation in the joint development committee has been determined to be a substantive deliverable under the contract, and therefore, the upfront payment has been deferred and is being recognized over the estimated term of the joint development committee, which is expected to be through the end of 2012. During the three and six months ended June 30, 2012 and 2011, revenues recognized under the collaboration agreement with Abbott were as follows (*in millions*):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Amortization of up-front license fees	$ 7.3	$ 7.3	$ 14.5	$ 14.5
Sponsored research and development	1.2	$ 2.5	$ 2.6	$ 5.4
Revenues recognized under the Abbott collaboration agreement	$ 8.5	$ 9.8	$ 17.1	$ 19.9

In addition, at June 30, 2012, the Company had $14.5 million of deferred revenue related to the Abbott agreement, which is being amortized over the remaining collaborative development period.

Boehringer Ingelheim International GmbH. In June 2010, the Company announced a worldwide collaboration with Boehringer Ingelheim International GmbH (Boehringer Ingelheim) to research, develop and commercialize small molecule GPR119 agonists for the treatment of Type II diabetes and other indications. Under the terms of the Company s agreement with Boehringer Ingelheim, the Company and Boehringer Ingelheim worked jointly, during a two year collaborative research period which ended in June 2012, to identify and advance GPR119 agonist candidates into preclinical development. Following the collaborative research period, Boehringer Ingelheim is responsible for the global development and commercialization of potential GPR119 agonist products, if any. The Company received a $10 million upfront payment, and received research funding to support discovery efforts. Boehringer Ingelheim agreed to make payments of up to approximately $3 million in additional preclinical milestone payments and payments of up to approximately $223 million in clinical development and commercial event based payments. The Company has assessed milestones under the revised authoritative guidance for research and development milestones and determined that the preclinical milestone payments, as defined in the agreement, meet the definition of a milestone as (1) they are events that can only be achieved in part on the Company s performance or upon the occurrence of a specific outcome resulting from the Company s performance, (2) there is substantive uncertainty at the date the arrangement was entered into that the event will be achieved and (3) they result in additional payments being due to the Company. Clinical development and commercial milestone payments, however, currently do not meet these criteria as their achievement is solely based on the performance of Boehringer Ingelheim. No milestone payments were recognized during the periods presented. The Company will be entitled to a percentage of any future worldwide sales of GPR119 agonists. Under the terms of the agreement, the collaboration effort between the parties to identify and advance GPR119 agonist candidates into preclinical development was initially governed by a steering committee with representatives from both the Company and Boehringer Ingelheim; provided, however, that final decision

making authority rests with Boehringer Ingelheim. The Company s participation in the steering committee was determined to be a substantive deliverable under the contract, and therefore, the upfront payment was deferred and recognized over the two-year term of the steering committee which was completed in June 2012. Boehringer Ingelheim may terminate the agreement at its discretion upon prior written notice to the Company. In such event, the Company may be entitled to specified payments and product rights would revert to the Company.

Table of Contents

During the three and six months ended June 30, 2012 and 2011, revenues recognized under the collaboration agreement with Boehringer Ingelheim were as follows (*in millions*):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Amortization of up-front license fees	$ 1.0	$ 1.3	$ 2.2	$ 2.5
Sponsored research and development	0.4	$ 0.4	$ 1.0	$ 0.8
Revenues recognized under the Boehringer Ingelheim collaboration agreement	$ 1.4	$ 1.7	$ 3.2	$ 3.3

3. INVESTMENTS

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

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

	June 30, 2012	December 31, 2011
Certificates of deposit	$ 10,791	$ 4,552
Commercial paper	4,996	12,467
Corporate debt securities	134,369	61,977
Total investments	$ 150,156	$ 78,996

Table of Contents

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, 2012:					
Classified as current assets:					
Certificates of deposit	Less than 1	$ 10,320	$ 1	$ (9)	$ 10,312
Commercial paper	Less than 1	4,998		(2)	4,996
Corporate debt securities	Less than 1	120,324	3	(113)	120,214
Total short-term available for sale securities		$ 135,642	$ 4	$ (124)	$ 135,522
Classified as long-term assets:					
Certificates of deposit	1-2	480		(1)	479