

BIOMARIN PHARMACEUTICAL INC

Form 10-Q

July 31, 2014

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014

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: 000-26727

BioMarin Pharmaceutical Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

68-0397820
(I.R.S. Employer
Identification No.)

770 Lindero Street, San Rafael, California
(Address of principal executive offices)
(415) 506-6700

94901
(Zip Code)

(Registrant's telephone number including area code)

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 (§ 232.405 of this chapter) 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, 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

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

Applicable only to issuers involved in bankruptcy proceedings during the preceding five years:

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

Applicable only to corporate issuers:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 147,116,873 shares of common stock, par value \$0.001, outstanding as of July 18, 2014.

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BioMarin[®], Naglazyme[®], Kuvan[®] and VIMIZIM[®] are registered trademarks of BioMarin Pharmaceutical Inc., or its affiliates. Aldurazyme[®] is a registered trademark of BioMarin/Genzyme LLC. Firdapse is a trademark of BioMarin Pharmaceutical Inc., or its affiliates.

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BIOMARIN PHARMACEUTICAL INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

June 30, 2014 and December 31, 2013

(In thousands of U.S. dollars, except per share amounts)

	June 30, 2014	December 31, 2013 ⁽¹⁾
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 584,717	\$ 568,781
Short-term investments	251,901	215,942
Accounts receivable, net (allowance for doubtful accounts: \$568 and \$529, respectively)	122,282	117,822
Inventory	193,498	162,605
Current deferred tax assets	30,561	30,561
Other current assets	37,268	41,707
Total current assets	1,220,227	1,137,418
Noncurrent assets:		
Investment in BioMarin/Genzyme LLC	440	816
Long-term investments	244,148	267,700
Property, plant and equipment, net	469,862	319,316
Intangible assets, net	163,045	163,147
Goodwill	54,258	54,258
Long-term deferred tax assets	147,143	145,234
Other assets	46,562	156,171
Total assets	\$ 2,345,685	\$ 2,244,060
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 166,720	\$ 183,271
Total current liabilities	166,720	183,271
Noncurrent liabilities:		
Long-term convertible debt	650,872	655,566
Long-term contingent acquisition consideration payable	40,466	30,790
Other long-term liabilities	25,658	33,392
Total liabilities	883,716	903,019

Stockholders' equity:

Common stock, \$0.001 par value: 250,000,000 shares authorized at June 30, 2014 and December 31, 2013: 147,067,950 and 143,463,668 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively.	147	144
Additional paid-in capital	2,249,445	2,059,101
Company common stock held by Nonqualified Deferred Compensation Plan	(10,146)	(7,421)
Accumulated other comprehensive income	9,941	5,018
Accumulated deficit	(787,418)	(715,801)
Total stockholders' equity	1,461,969	1,341,041
Total liabilities and stockholders' equity	\$ 2,345,685	\$ 2,244,060

(1) December 31, 2013 balances were derived from the audited Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission (the SEC) on February 26, 2014.

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

Table of Contents**BIOMARIN PHARMACEUTICAL INC.****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS****Three and Six Months Ended June 30, 2014 and 2013****(In thousands of U.S. dollars, except per share amounts)****(Unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
REVENUES:				
Net product revenues	\$ 188,244	\$ 132,400	\$ 337,248	\$ 259,744
Collaborative agreement revenues	506	889	921	1,024
Royalty, license and other revenues	3,037	3,521	5,170	3,970
Total revenues	191,787	136,810	343,339	264,738
OPERATING EXPENSES:				
Cost of sales (excludes amortization of certain acquired intangible assets)	31,210	22,567	54,026	43,067
Research and development	107,702	85,661	193,868	169,404
Selling, general and administrative	68,089	50,656	128,158	101,706
Intangible asset amortization and contingent consideration	3,668	(2,022)	12,625	3,534
Total operating expenses	210,669	156,862	388,677	317,711
LOSS FROM OPERATIONS	(18,882)	(20,052)	(45,338)	(52,973)
Equity in the loss of BioMarin/Genzyme LLC	(539)	(163)	(877)	(564)
Interest income	1,735	650	2,858	1,368
Interest expense	(9,221)	(603)	(18,327)	(2,328)
Debt conversion expense	(674)	0	(674)	(10,420)
Other income (expense)	(147)	(123)	6	105
LOSS BEFORE INCOME TAXES	(27,728)	(20,291)	(62,352)	(64,812)
Provision for (benefit from) income taxes	5,774	1,242	9,265	(3,469)
NET LOSS	\$ (33,502)	\$ (21,533)	\$ (71,617)	\$ (61,343)
NET LOSS PER SHARE, BASIC	\$ (0.23)	\$ (0.15)	\$ (0.49)	\$ (0.46)
NET LOSS PER SHARE, DILUTED	\$ (0.23)	\$ (0.16)	\$ (0.50)	\$ (0.46)
Weighted average common shares outstanding, basic	146,120	139,400	145,066	133,716

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Weighted average common shares outstanding, diluted	146,351	139,596	145,297	133,716
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COMPREHENSIVE LOSS	\$ (30,836)	\$ (20,247)	\$ (66,694)	\$ (58,700)
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The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

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BIOMARIN PHARMACEUTICAL INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Six Months Ended June 30, 2014 and 2013

(In thousands of U.S. dollars)

(Unaudited)

	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (71,617)	\$ (61,343)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	25,701	24,216
Non-cash interest expense	13,465	289
Accretion of discount on investments	3,741	2,829
Equity in the loss of BioMarin/Genzyme LLC	877	564
Stock-based compensation	34,788	25,848
Gain on termination of lease	(9,265)	0
Deferred income taxes	(4,722)	(9,722)
Excess tax benefit from stock option exercises	(331)	(453)
Unrealized foreign exchange (gain) loss on forward contracts	2,606	(1,397)
Non-cash changes in the fair value of contingent acquisition consideration payable	9,371	984
Debt conversion expense	674	10,420
Other non-cash movements	325	939
Changes in operating assets and liabilities:		
Accounts receivable, net	(4,460)	(5,997)
Inventory	(30,893)	(13,601)
Other current assets	3,140	(6,359)
Other assets	(4,675)	(385)
Accounts payable and accrued liabilities	(5,948)	(7,695)
Other long-term liabilities	(1,183)	2,017
Net cash used in operating activities	(38,406)	(38,846)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(64,709)	(22,238)
Maturities and sales of investments	119,666	155,099
Purchase of available-for-sale investments	(132,920)	(118,181)
Business acquisitions, net of cash acquired	0	(9,875)
Investment in BioMarin/Genzyme LLC	(500)	(485)
Other	(1,000)	0
Net cash (used in) provided by investing activities	(79,463)	4,320

CASH FLOWS FROM FINANCING ACTIVITIES:

Proceeds from exercises of stock options	28,102	45,782
Taxes paid related to net share settlement of equity awards	(6,694)	(5,987)
Proceeds from public offering of common stock, net	117,463	0
Excess tax benefit from stock option exercises	331	453
Payments for debt conversion	(674)	(10,420)
Payment of contingent acquisition consideration payable	(4,691)	0
Other	(32)	(384)

Net cash provided by financing activities	133,805	29,444
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NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS 15,936 (5,082)

Cash and cash equivalents:

Beginning of period	\$ 568,781	\$ 180,527
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End of period	\$ 584,717	\$ 175,445
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SUPPLEMENTAL CASH FLOW DISCLOSURES:

Cash paid for interest, net of interest capitalized into fixed assets	\$ 4,855	\$ 3,033
Cash paid for income taxes	13,091	11,388
Stock-based compensation capitalized into inventory	3,909	2,390
Depreciation capitalized into inventory	5,348	5,391

SUPPLEMENTAL CASH FLOW DISCLOSURES FROM INVESTING AND FINANCING ACTIVITIES:

Decrease in accounts payable and accrued liabilities related to fixed assets	\$ (5,978)	\$ (7,125)
Conversion of convertible debt	16,482	238,304
Deferred offering costs reclassified into additional paid-in-capital as a result of conversion of convertible debt	126	2,315
Release of escrow balance for purchase of San Rafael Corporate Center	116,500	0

The accompanying notes are an integral part of these Condensed Consolidated Financial Statements.

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

(1) NATURE OF OPERATIONS AND BUSINESS RISKS

BioMarin Pharmaceutical Inc. (the Company or BioMarin), a Delaware corporation, develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. BioMarin selects product candidates for diseases and conditions that represent a significant unmet medical need, have well-understood biology and provide an opportunity to be first-to-market or offer a significant benefit over existing products. The Company's product portfolio is comprised of five approved products and multiple investigational product candidates. The Company's approved products are VIMIZIM (elosulfase alpha), Naglazyme (galsulfase), Kuvan (sapropterin dihydrochloride), Aldurazyme (laronidase) and Firdapse (amifampridine phosphate).

Through June 30, 2014, the Company had accumulated losses of approximately \$787.4 million. The Company expects to continue to finance future cash needs that exceed its operating activities primarily through its current cash, cash equivalents, short-term and long-term investments, and to the extent necessary, through proceeds from equity or debt financings, loans and collaborative agreements with corporate partners. If the Company elects to increase its spending on development programs significantly above current long-term plans or enters into potential licenses and other acquisitions of complementary technologies, products or companies, the Company may need additional capital.

The Company is subject to a number of risks, including: the financial performance of VIMIZIM, Naglazyme, Kuvan, Aldurazyme and Firdapse; the potential need for additional financings; the Company's ability to successfully commercialize its approved product candidates, if approved; the uncertainty of the Company's research and development efforts resulting in future successful commercial products; the Company's ability to successfully obtain regulatory approval for new products; significant competition from larger organizations; reliance on the proprietary technology of others; dependence on key personnel; uncertain patent protection; dependence on corporate partners and collaborators; and possible restrictions on reimbursement from governmental agencies and healthcare organizations, as well as other changes in the health care industry.

(2) BASIS OF PRESENTATION

The accompanying Condensed Consolidated Financial Statements have been prepared pursuant to the rules and regulations of the SEC for Quarterly Reports on Form 10-Q and do not include all of the information and note disclosures required by U.S. generally accepted accounting principles (U.S. GAAP) for complete financial statements. The Condensed Consolidated Financial Statements should therefore be read in conjunction with the Consolidated Financial Statements and Notes thereto for the fiscal year ended December 31, 2013 included in the Company's Annual Report on Form 10-K.

The accompanying Condensed Consolidated Financial Statements have been prepared in accordance with U.S. GAAP, which requires management to make estimates and assumptions that affect amounts reported in the Condensed Consolidated Financial Statements and accompanying disclosures. Although these estimates are based on management's best knowledge of current events and actions that the Company may undertake in the future, actual results may be different from those estimates. The Condensed Consolidated Financial Statements reflect all

adjustments of a normal, recurring nature that are, in the opinion of management, necessary for a fair presentation of results for these interim periods. The results of operations for the three and six months ended June 30, 2014 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2014.

The Company has evaluated events and transactions subsequent to the balance sheet date. Based on this evaluation, the Company is not aware of any events or transactions that occurred subsequent to the balance sheet date but prior to filing this Quarterly Report on Form 10-Q that would require recognition or disclosure in the Condensed Consolidated Financial Statements, except for the transaction disclosed in Note 21.

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BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

(3) SIGNIFICANT ACCOUNTING POLICIES

There have been no material changes to the Company's significant accounting policies during the six months ended June 30, 2014, as compared to the significant accounting policies disclosed in Note 3 of the Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

Reclassifications

Certain items in the Company's prior year Condensed Consolidated Financial Statements have been reclassified to conform to the current presentation.

(4) RECENT ACCOUNTING PRONOUNCEMENTS

Except as described below, there have been no new accounting pronouncements or changes to accounting pronouncements during the six months ended June 30, 2014, as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year-ended December 31, 2013, that are of significance or potential significance to the Company.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2014-09 (ASU 2014-09), *Revenue from Contracts with Customers*. ASU 2014-09 will supersede the revenue recognition requirements in *Revenue Recognition (Topic 605)* and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period, which for the Company is January 1, 2017. Early adoption is not permitted. The Company is currently evaluating the potential impact the adoption of ASU 2014-09 will have on its consolidated financial statements.

(5) ACQUISITION OF SAN RAFAEL CORPORATE CENTER

On March 10, 2014, the Company completed the acquisition of the real estate commonly known as the San Rafael Corporate Center (SRCC), located in San Rafael, California. SRCC is a multi-building, commercial property where, prior to the transaction, the Company was leasing a certain portion of the space for its headquarters and related operating activities. The purpose of this acquisition is to allow for future expansion of the Company's corporate headquarters to accommodate anticipated headcount growth. The acquisition of SRCC has been accounted for as a business combination because the building and the in-place leases met the definition of a business in Accounting Standards Codification 805 (ASC 805), *Business Combinations*. The purchase price for SRCC was \$116.5 million. The fair value of the consideration paid was \$116.5 million, all of which was paid in cash, which was held in escrow as of December 31, 2013.

The following table summarizes the estimated fair values of assets acquired as of the date of acquisition:

