

BIOMARIN PHARMACEUTICAL INC

Form 10-Q

April 30, 2012

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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 March 31, 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: 000-26727

BioMarin Pharmaceutical Inc.

(Exact name of registrant as specified in its charter)

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Delaware (State or other jurisdiction of incorporation or organization)	68-0397820 (I.R.S. Employer Identification No.)
105 Digital Drive, Novato, California (Address of principal executive offices)	94949 (Zip Code)
(415) 506-6700 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 <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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: 115,700,983 shares of common stock, par value \$0.001, outstanding as of April 13, 2012.

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BIOMARIN PHARMACEUTICAL INC.

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Table of Contents**BIOMARIN PHARMACEUTICAL INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

March 31, 2012 and December 31, 2011

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

	March 31, 2012 (unaudited)	December 31, 2011(1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 82,586	\$ 46,272
Short-term investments	150,393	148,820
Accounts receivable, net (allowance for doubtful accounts: \$471 and \$513, respectively)	105,828	104,839
Inventory	124,064	130,118
Other current assets	50,519	39,753
Total current assets	513,390	469,802
Investment in BioMarin/Genzyme LLC	1,082	559
Long-term investments	54,751	94,385
Property, plant and equipment, net	264,317	268,971
Intangible assets, net	170,914	180,277
Goodwill	51,543	51,543
Long-term deferred tax assets	221,239	222,649
Other assets	19,849	15,495
Total assets	\$ 1,297,085	\$ 1,303,681
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 96,359	\$ 94,125
Convertible debt	23,455	0
Total current liabilities	119,814	94,125
Long-term convertible debt	324,872	348,329
Other long-term liabilities	80,449	88,179
Total liabilities	525,135	530,633
Stockholders' equity:		
Common stock, \$0.001 par value: 250,000,000 shares authorized at March 31, 2012 and December 31, 2011: 115,681,825 and 114,789,732 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively.	116	115
Additional paid-in capital	1,221,933	1,197,082
Company common stock held by Nonqualified Deferred Compensation Plan	(3,538)	(3,935)
Accumulated other comprehensive income	2,512	4,887
Accumulated deficit	(449,073)	(425,101)
Total stockholders' equity	771,950	773,048

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Total liabilities and stockholders' equity	\$ 1,297,085	\$ 1,303,681
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- (1) December 31, 2011 balances were derived from the audited consolidated financial statements.
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 Months Ended March 31, 2012 and 2011****(In thousands of U.S. dollars, except per share amounts)****(Unaudited)**

	2012	2011
REVENUES:		
Net product revenues	\$ 116,239	\$ 109,076
Collaborative agreement revenues	96	125
Royalty and license revenues	314	255
Total revenues	116,649	109,456
OPERATING EXPENSES:		
Cost of sales (excludes amortization of certain acquired intangible assets)	17,105	20,796
Research and development	73,834	45,017
Selling, general and administrative	45,248	41,037
Intangible asset amortization and contingent consideration	2,328	312
Total operating expenses	138,515	107,162
INCOME (LOSS) FROM OPERATIONS	(21,866)	2,294
Equity in the loss of BioMarin/Genzyme LLC	(734)	(542)
Interest income	505	782
Interest expense	(1,947)	(2,163)
Other income (expense)	36	22
INCOME (LOSS) BEFORE INCOME TAXES	(24,006)	393
Provision for (benefit from) income taxes	(34)	4,764
NET LOSS	\$ (23,972)	\$ (4,371)
NET LOSS PER SHARE, BASIC AND DILUTED	\$ (0.21)	\$ (0.04)
Weighted average common shares outstanding, basic	115,070	110,652
Weighted average common shares outstanding, diluted	115,070	110,743
COMPREHENSIVE LOSS	\$ (26,347)	\$ (10,346)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents**BIOMARIN PHARMACEUTICAL INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****Three Months Ended March 31, 2012 and 2011****(In thousands of U.S. dollars)****(Unaudited)**

	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (23,972)	\$ (4,371)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	10,598	8,585
Amortization of discount on investments	852	1,080
Equity in the loss of BioMarin/Genzyme LLC	734	542
Stock-based compensation	11,155	10,151
Deferred income taxes	712	3,910
Excess tax benefit from stock option exercises	(18)	(415)
Impairment of intangible assets	6,704	0
Unrealized foreign exchange gain on forward contracts	(1,878)	(401)
Changes in the fair value of contingent acquisition consideration payable	(5,181)	(493)
Changes in operating assets and liabilities:		
Accounts receivable, net	(989)	(19,622)
Inventory	6,054	(369)
Other current assets	(11,113)	(2,051)
Other assets	(6,040)	1,599
Accounts payable and accrued liabilities	3,826	(2,204)
Other long-term liabilities	1,385	560
Net cash used in operating activities	(7,171)	(3,499)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(6,179)	(6,241)
Maturities and sales of investments	74,037	84,013
Purchase of available-for-sale investments	(36,562)	(74,210)
Investments in BioMarin/Genzyme LLC	(1,258)	(593)
Net provided by investing activities	30,038	2,969
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options and Employee Stock Purchase Plan	13,679	3,133
Excess tax benefit from stock option exercises	18	415
Repayment of capital lease obligations	(250)	(315)
Net cash provided by financing activities	13,447	3,233
NET INCREASE IN CASH AND CASH EQUIVALENTS		
Cash and cash equivalents:		
Beginning of period	\$ 46,272	\$ 88,079

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End of period	\$ 82,586	\$ 90,782
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SUPPLEMENTAL CASH FLOW DISCLOSURES:

Cash paid for interest, net of interest capitalized into fixed assets	\$ 293	\$ 637
Cash paid for income taxes	1,739	616
Stock-based compensation capitalized into inventory	894	1,173
Depreciation capitalized into inventory	1,062	2,651

SUPPLEMENTAL CASH FLOW DISCLOSURES FROM INVESTING AND FINANCING ACTIVITIES:

Decrease in accrued liabilities related to fixed assets	\$ (3,149)	\$ (3,239)
Equipment acquired through capital leases	0	366
Change in asset retirement obligation	44	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

March 31, 2012

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

(Unaudited)

(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 four approved products and multiple investigational product candidates. The Company's approved products are Naglazyme (galsulfase), Kuvan (sapropterin dihydrochloride), Firdapse (amifampridine phosphate) and Aldurazyme (laronidase).

Through March 31, 2012, the Company had accumulated losses of approximately \$449.1 million. Management believes that the Company's cash, cash equivalents and short-term and long-term investments at March 31, 2012 will be sufficient to meet the Company's obligations for the foreseeable future based on management's current long-term business plans and assuming that the Company achieves its long-term goals. 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 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.

The Company is subject to a number of risks, including the financial performance of Naglazyme, Kuvan, Firdapse and Aldurazyme; the potential need for additional financings; its ability to successfully commercialize its product candidates, if approved; the uncertainty of the Company's research and development efforts resulting in future successful commercial products; obtaining 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) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying Condensed Consolidated Financial Statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (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, 2011 included in the Company's Annual Report on Form 10-K filed with the SEC on February 22, 2012.

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 months ended March 31, 2012 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2012.

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.

Table of Contents**BIOMARIN PHARMACEUTICAL INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2012****(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)****(Unaudited)****Significant Accounting Policies**

There have been no material changes to the Company's significant accounting policies during the three months ended March 31, 2012, as compared to the significant accounting policies disclosed in Note 2 of the Company's Consolidated Financial Statements in the Annual Report on Form 10-K for the year ended December 31, 2011.

Reclassifications

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

(3) RECENT ACCOUNTING PRONOUNCEMENTS

There have been no new accounting pronouncements or changes in accounting pronouncements during the three months ended March 31, 2012, as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2011, that are of significance or potential significance to the Company.

(4) SHORT-TERM AND LONG-TERM INVESTMENTS

All investments were classified as available-for-sale at March 31, 2012 and December 31, 2011. The principal amounts of short-term and long-term investments by contractual maturity are summarized in the tables below:

	Contractual Maturity Date for the Years Ending December 31,				Total Book	Unrealized Gain (Loss)	Aggregate Fair Value at March 31, 2012
	2012	2013	2014	2015	Value at March 31, 2012		
Certificates of deposit	\$ 31,874	\$ 22,325	\$ 328	\$ 0	\$ 54,527	\$ 18	\$ 54,545
Commercial paper	16,473	0	0	0	16,473	(5)	16,468
Corporate securities	59,629	40,701	3,100	0	103,430	347	103,777
U.S. Government agency securities	0	8,556	13,372	8,400	30,328	(23)	30,305
Greek government-issued bonds	0	0	0	49	49	0	49
Total	\$ 107,976	\$ 71,582	\$ 16,800	\$ 8,449	\$ 204,807	\$ 337	\$ 205,144

	Contractual Maturity Date for the Years Ending December 31,			Total Book Value at	Unrealized Gain (Loss)	Aggregate Fair Value at
	2012	2013	2014			

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				December 31, 2011		December 31, 2011	
Certificates of deposit	\$ 38,547	\$ 17,195	\$ 0	\$ 55,742	\$ 13	\$ 55,755	
Commercial paper	24,730	0	0	24,730	(9)	24,721	
Corporate securities	85,595	40,899	3,100	129,594	53	129,647	
U.S. Government agency securities	0	32,877	0	32,877	13	32,890	
Greek government-issued bonds	0	192	0	192	0	192	
Total	\$ 148,872	\$ 91,163	\$ 3,100	\$ 243,135	\$ 70	\$ 243,205	

The Company completed an evaluation of its investments and determined that it did not have any other-than-temporary impairments as of March 31, 2012. The investments are held in accounts with financial institutions that have strong credit ratings and management expects full recovery of the carrying amounts.

See Notes 10 and 13 for additional discussion regarding the Greek government-issued bonds held by the Company.

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The aggregate amounts of unrealized losses and related fair value of investments with unrealized losses as of March 31, 2012 and December 31, 2011 were as follows:

	Less Than 12 Months to Maturity		12 Months or More to Maturity		Totals at March 31, 2012	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Certificates of deposit	\$ 11,753	\$ (3)	\$ 2,688	\$ (1)	\$ 14,441	\$ (4)
Commercial paper	12,719	(7)	0	0	12,719	(7)
Corporate securities	10,471	(6)	0	0	10,471	(6)
U.S. Government agency securities	0	0	20,734	(38)	20,734	(38)
Total	\$ 34,943	\$ (16)	\$ 23,422	\$ (39)	\$ 58,365	\$ (55)

	Less Than 12 Months to Maturity		12 Months or More to Maturity		Totals at December 31, 2011	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Certificates of deposit	\$ 7,489	\$ 0	\$ 8,118	\$ (5)	\$ 15,607	\$ (5)
Commercial paper	7,474	(12)	0	0	7,474	(12)
Corporate securities	26,840	(184)	9,571	(29)	36,411	(213)
U.S. Government agency securities	0	0	11,252	(1)	11,252	(1)
Total	\$ 41,803	\$ (196)	\$ 28,941	\$ (35)	\$ 70,744	\$ (231)

(5) PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, net consisted of the following:

	March 31, 2012	December 31, 2011
Leasehold improvements	\$ 49,816	\$ 49,456
Building and improvements	142,711	141,484
Manufacturing and laboratory equipment	74,032	72,039
Computer hardware and software	48,343	48,566

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Furniture and equipment	7,773	7,679
Land	10,056	10,056
Construction-in-progress	55,028	55,436
	\$ 387,759	\$ 384,716
Less: Accumulated depreciation	(123,442)	(115,745)
Total property, plant and equipment, net	\$ 264,317	\$ 268,971

Depreciation expense for the three months ended March 31, 2012 and 2011 was \$8.4 million and \$7.4 million, respectively, of which \$1.1 million and \$2.7 million was capitalized into inventory, respectively.

Capitalized interest related to the Company's property, plant and equipment purchases for the three months ended March 31, 2012 and 2011 was insignificant.

Table of Contents**BIOMARIN PHARMACEUTICAL INC.****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****March 31, 2012****(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)****(Unaudited)****(6) INTANGIBLE ASSETS**

Intangible assets consisted of the following:

	March 31, 2012	December 31, 2011
Intangible assets:		
Finite-lived intangible assets	\$ 118,242	\$ 118,242
Indefinite-lived intangible assets	63,692	70,396
Total intangible assets, gross	181,934	188,638
Less: Accumulated amortization	(11,020)	(8,361)
Total intangible assets, net	\$ 170,914	\$ 180,277

Finite-Lived Intangible Assets

The Company's intangible assets consist of marketing rights in the U.S. and EU for Naglazyme, Kuvan and Firdapse, which are being amortized over their estimated useful lives using the straight-line method. The Company reviews these finite-lived intangible assets for impairment when facts or circumstances indicate a reduction in the fair value below their carrying amount.

Indefinite-Lived Intangible Assets

The Company's indefinite-lived intangible assets consist of in-process research and development (IPR&D) assets related to both early and late stage product candidates purchased in the acquisitions of Huxley Pharmaceuticals Inc. (Huxley), LEAD Therapeutics, Inc. (LEAD) and ZyStor Therapeutics, Inc. (ZyStor).

Intangible assets related to IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment on an annual basis and between annual tests if the Company becomes aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D assets below their respective carrying amounts. During the three months ended March 31, 2012, the Company recorded an impairment charge of \$6.7 million related to certain Firdapse IPR&D assets. These IPR&D assets are associated with marketing rights in the U.S. for Firdapse, a product candidate that is in Phase 3 clinical trials in the U.S. for the treatment of Lambert-Eaton Myasthenic Syndrome. The Company was exploring strategic options for the Firdapse U.S. program, including the potential outlicense of rights in the U.S. In March 2012, the Company determined to suspend business development efforts. As a result, management evaluated its plans and expectations regarding clinical development and commercialization of Firdapse in the U.S. The revised discounted cash flow projections no longer supported the carrying-value of the IPR&D intangible assets and the Company recognized an impairment charge for the three months ended March 31, 2012. The impairment charge is included in Intangible Asset Amortization and Contingent Consideration on the Company's Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2012.

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See Note 10 to the Company's Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2011, for additional information related to the Company's intangible assets.

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Inventory consisted of the following:

	March 31, 2012	December 31, 2011
Raw materials	\$ 13,191	\$ 12,145
Work-in-process	69,943	75,903
Finished goods	40,930	42,070
Total inventory	\$ 124,064	\$ 130,118

Other current assets consisted of the following:

	March 31, 2012	December 31, 2011
Non-trade receivables	\$ 6,827	\$ 6,093
Prepaid expenses	12,107	7,551
Foreign currency exchange forward contract asset	2,743	4,705
Current deferred tax assets	21,115	21,115
Deferred cost of goods sold	6,419	0
Short-term restricted investments	1,085	0
Other	223	289
Total other current assets	\$ 50,519	\$ 39,753

See Note 10 for additional discussion regarding the fair value of restr