BIOMARIN PHARMACEUTICAL INC

FORM 10-Q
(Quarterly Report)

Filed 10/28/13 for the Period Ending 09/30/13

Address	105 DIGITAL DRIVE NOVATO, CA 94949
Telephone	4155066700
CIK	0001048477
Symbol	BMRN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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 September 30, 2013

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	**68-0397820**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
770 Lindaro Street, San Rafael, California	**94901**
(Address of principal executive offices)	**(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 ☒ 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: 142,212,657 shares of common stock, par value $0.001, outstanding as of October 18, 2013.

Table of Contents

BIOMARIN PHARMACEUTICAL INC.

TABLE OF CONTENTS

Table of Contents

BIOMARIN PHARMACEUTICAL INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
September 30, 2013 and December 31, 2012
(In thousands of U.S. dollars, except per share amounts)

	September 30, 2013 (unaudited)	December 31, 2012 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 181,565	$ 180,527
Short-term investments	198,086	270,211
Accounts receivable, net (allowance for doubtful accounts: $376 and $348, respectively)	124,745	109,066
Inventory	148,684	128,695
Current deferred tax assets	32,238	29,454
Other current assets	28,161	25,509
Total current assets	713,479	743,462
Noncurrent assets:		
Investment in BioMarin/Genzyme LLC	854	1,080
Long-term investments	147,771	115,993
Property, plant and equipment, net	285,664	284,473
Intangible assets, net	165,791	162,980
Goodwill	54,258	51,543
Long-term deferred tax assets	238,703	225,501
Other assets	14,010	16,611
Total assets	$1,620,530	$1,601,643
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 167,633	$ 147,068
Convertible debt	0	23,365
Total current liabilities	167,633	170,433
Noncurrent liabilities:		
Long-term convertible debt	78,310	324,859
Long-term contingent acquisition consideration payable	26,500	30,618
Long-term deferred tax liabilities	37,190	33,296
Other long-term liabilities	34,411	26,674
Total liabilities	344, 044	585,880
Stockholders' equity:		
Common stock, $0.001 par value: 250,000,000 shares authorized at September 30, 2013 and December 31, 2012: 142,200,995 and 125,809,162 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively.	142	126
Additional paid-in capital	1,926,133	1,561,890
Company common stock held by Nonqualified Deferred Compensation Plan	(7,451)	(6,603)
Accumulated other comprehensive income (loss)	11,473	(202)
Accumulated deficit	(653,811)	(539,448)
Total stockholders' equity	1,276,486	1,015,763
Total liabilities and stockholders' equity	$1,620,530	$1,601,643

(1) December 31, 2012 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, 2012, filed with the Securities and Exchange Commission (the SEC) on February 26, 2013.

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 Nine Months Ended September 30, 2013 and 2012
(In thousands of U.S. dollars, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
REVENUES:				
Net product revenues	$ 134,330	$ 126,310	$ 394,074	$ 365,540
Collaborative agreement revenues	1,754	1,210	2,778	1,729
Royalty and license revenues	790	597	4,760	1,516
Total revenues	136,874	128,117	401,612	368,785
OPERATING EXPENSES:				
Cost of sales (excludes amortization of certain acquired intangible assets)	28,054	24,619	71,121	65,298
Research and development	88,064	66,209	257,468	217,855
Selling, general and administrative	61,841	46,337	163,547	143,124
Intangible asset amortization and contingent consideration	9,639	1,443	13,173	5,819
Total operating expenses	187,598	138,608	505,309	432,096
LOSS FROM OPERATIONS	(50,724)	(10,491)	(103,697)	(63,311)
Equity in the loss of BioMarin/Genzyme LLC	(147)	(336)	(711)	(968)
Interest income	574	778	1,942	1,819
Interest expense	(526)	(1,837)	(2,854)	(5,709)
Debt conversion expense	(1,732)	0	(12,152)	0
Other income (expense)	239	125	344	(15)
LOSS BEFORE INCOME TAXES	(52,316)	(11,761)	(117,128)	(68,184)
Provision for (benefit from) income taxes	704	(6,404)	(2,765)	(6,849)
NET LOSS	$ (53,020)	$ (5,357)	$ (114,363)	$ (61,335)
NET LOSS PER SHARE, BASIC AND DILUTED	$ (0.38)	$ (0.04)	$ (0.84)	$ (0.52)
Weighted average common shares outstanding, basic and diluted	140,796	123,434	136,102	118,810
COMPREHENSIVE INCOME (LOSS)	$ (43,988)	$ (7,674)	$ (102,688)	$ (63,889)

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
Nine Months Ended September 30, 2013 and 2012
(In thousands of U.S. dollars)
(Unaudited)

	Nine Months Ended September 30,	
	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (114,363)	$ (61,335)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	37,880	33,438
Accretion of discount on investments	4,149	3,075
Equity in the loss of BioMarin/Genzyme LLC	711	968
Stock-based compensation	42,638	35,414
Impairment of intangible assets	939	6,707
Deferred income taxes	(19,212)	(10,610)
Excess tax benefit from stock option exercises	(335)	(96)
Unrealized foreign exchange loss on forward contracts	(1,692)	(4,846)
Changes in the fair value of contingent acquisition consideration payable	9,816	(3,325)
Debt conversion expense	12,152	0
Changes in operating assets and liabilities:		
Accounts receivable, net	(15,679)	(12,451)
Inventory	(19,989)	9,293
Other current assets	(1,776)	(8,154)
Other assets	(307)	(6,905)
Accounts payable and accrued liabilities	11,362	15,825
Other long-term liabilities	5,368	8,625
Net cash provided by (used in) operating activities	(48,338)	5,623
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property, plant and equipment	(35,440)	(30,676)
Maturities and sales of investments	232,625	165,459
Purchase of available-for-sale investments	(179,192)	(276,817)
Business acquisitions, net of cash acquired	(9,875)	0
Investments in BioMarin/Genzyme LLC	(485)	(1,258)
Net cash provided by (used in) investing activities	7,633	(143,292)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercises of stock options and ESPP	54,088	37,667
Proceeds from public offering of common stock, net	0	235,499
Excess tax benefit from stock option exercises	335	96
Payments for debt conversion	(12,152)	0
Payment on maturity of 2013 convertible note	(98)	0
Repayment of capital lease obligations	(430)	(535)
Net cash provided by financing activities	41,743	272,727
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,038	135,058
Cash and cash equivalents:		
Beginning of period	$ 180,527	$ 46,272
End of period	$ 181,565	$ 181,330
SUPPLEMENTAL CASH FLOW DISCLOSURES:		
Cash paid for interest, net of interest capitalized into fixed assets	$ 3,238	$ 3,597
Cash paid for income taxes	13,165	5,591
Stock-based compensation capitalized into inventory	4,219	3,042
Depreciation capitalized into inventory	8,221	4,744
SUPPLEMENTAL CASH FLOW DISCLOSURES FROM INVESTING AND FINANCING ACTIVITIES:		
Decrease in accounts payable and accrued liabilities related to fixed assets	$ 7,491	$ 1,488
Conversion of convertible debt	269,816	0
Deferred offering costs reclassified into additional paid-in-capital as a result of conversion of convertible debt	2,618	0

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

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 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 September 30, 2013, the Company had accumulated losses of approximately $653.8 million. Management believes that the Company's cash, cash equivalents, short-term and long-term investments at September 30, 2013 and the proceeds from the convertible notes offering in October 2013 as discussed in Note 20, will be sufficient to meet the Company's obligations for at least the next twelve months based on management's current business plans. 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) 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, 2012 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 nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2013.

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 in Note 20.

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

Except for the clarification of the Company's inventory policy below, there have been no material changes to the Company's significant accounting policies during the nine months ended September 30, 2013, 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, 2012.

Inventory

The Company values inventory at the lower of cost or net realizable value and determines the cost of inventory using the average-cost method. Inventories consist of currently marketed products and may contain certain products awaiting regulatory approval. In evaluating the recoverability of inventories produced in preparation for product launches, the Company considers the likelihood that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process.

The Company analyzes its inventory levels quarterly and writes down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. In applying the lower of cost or net realizable value to pre-launch inventory, the Company estimates a range of likely commercial prices based on its comparable commercial products. Expired inventory is disposed of and the related costs are recognized as Cost of Sales in the Condensed Consolidated Statements of Comprehensive Loss.

Inventories Produced in Preparation for Product Launches

The Company capitalizes inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory begins when positive results have been obtained for the clinical trials that the Company believes are necessary to support regulatory approval, uncertainties regarding ultimate regulatory approval have been significantly reduced and the Company has determined it is probable that these capitalized costs will provide some future economic benefit in excess of capitalized costs. The material factors considered by the Company in evaluating these uncertainties include the receipt and analysis of positive Phase 3 clinical trial results for the underlying product candidate, results from meetings with the relevant regulatory authorities prior to the filing of regulatory applications, and the compilation of the regulatory application. The Company closely monitors the status of each respective product within the regulatory approval process, including all relevant communication with regulatory authorities. The Company also considers its historical experience with manufacturing and commercializing similar products and the relevant product candidate. If the Company is aware of any specific material risks or contingencies other than the normal regulatory review and approval process or if there are any specific issues identified relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized.

For inventories that are capitalized in preparation of product launch, anticipated future sales, expected approval date and shelf lives are evaluated in assessing realizability. The shelf life of a product is determined as part of the regulatory approval process; however in evaluating whether to capitalize pre-launch inventory production costs, the Company considers the product stability data of all of the pre-approval production to date to determine whether there is adequate expected shelf life for the capitalized pre-launch production costs.

Reclassifications

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

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

(4) RECENT ACCOUNTING PRONOUNCEMENTS

Except for Financial Accounting Standards Board (FASB) Accounting Standards Update 2013-02 (ASU 2013-02), *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*, there have been no new accounting pronouncements or changes to accounting pronouncements during the period ended September 30, 2013, as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year-ended December 31, 2012, that are of significance or potential significance to the Company. ASU 2013-02 requires an entity to present either on the face of the financial statements where income is presented or in the notes to the financial statements, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income. See Note 17 to these Condensed Consolidated Financial Statements for the expanded disclosures required by ASU 2013-02.

(5) ACQUISITION OF ZACHARON PHARMACEUTICALS, INC.

On January 4, 2013, the Company entered into a merger agreement with Zacharon Pharmaceuticals, Inc. (Zacharon), a private biotechnology company focused on developing small molecules targeting pathways of glycan and glycolipid metabolism for a total purchase price of $11.5 million.

In connection with its acquisition of Zacharon, the Company made an upfront payment of $9.7 million in cash to the Zacharon stockholders for all of the outstanding common stock of Zacharon, net of transaction costs of $0.8 million paid on behalf of the Zacharon stockholders. The Company also agreed to pay the Zacharon stockholders additional consideration in future periods of up to $134.0 million (undiscounted) in milestone payments if certain clinical, development and sales milestones are met. The fair value of the contingent acquisition consideration payments was $1.9 million and was estimated by applying a probability-based income approach utilizing an appropriate discount rate. This estimation was based on significant inputs that are not observable in the market, referred to as Level 3 inputs. Key assumptions included a discount rate of 4.7% and various probability factors. The range of outcomes and assumptions used to develop these estimates have been updated to estimate the fair value of the contingent consideration payable as of September 30, 2013. See Note 14 to these Condensed Consolidated Financial Statements for additional discussion regarding fair value measurements of the contingent acquisition consideration payable.

The following table presents the final allocation of the purchase consideration for the Zacharon acquisition, including the contingent acquisition consideration payable, based on fair value. The final allocation includes an adjustment to goodwill and the deferred tax assets of approximately $0.7 million resulting from the finalization of Zacharon's tax returns.

Cash and cash equivalents	$ 560
Other current assets	216
Property, plant and equipment	398
Acquired deferred tax assets	2,625
Other assets	38
Intangible assets—In Process Research & Development (IPR&D)	11,680
Total identifiable assets acquired	$15,517
Accounts payable and accrued expenses	$ (1,182)
Debt assumed	(1,313)
Deferred tax liability	(4,217)
Total liabilities assumed	$ (6,712)
Net identifiable assets acquired	$ 8,805
Goodwill	2,715
Net assets acquired	$11,520

A substantial portion of the assets acquired consisted of intangible assets related to Zacharon's SENSI-Pro assay. The Company determined that the estimated acquisition-date fair value of the intangible assets related to the SENSI-Pro assay was $11.7 million.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

The $2.6 million of deferred tax assets resulting from the acquisition was primarily related to federal and state net operating loss and tax credit carryforwards. The $4.2 million of deferred tax liabilities relates to the tax impact of future amortization or possible impairments associated with the identified intangible assets acquired, which are not deductible for tax purposes.

The excess of the consideration transferred over the fair values assigned to the assets acquired and liabilities assumed was $2.7 million, which represents the amount of goodwill resulting from the acquisition. The Company believes that the goodwill primarily represents synergies expected from the acquisition and other benefits that do not qualify for separate recognition as acquired intangible assets. None of the goodwill is expected to be deductible for income tax purposes. The Company recorded the goodwill in the Company's Condensed Consolidated Balance Sheet as of the acquisition date.

Zacharon's results of operations prior to and since the acquisition date are insignificant to the Company's Condensed Consolidated Financial Statements.

See Note 8 to these Condensed Consolidated Financial Statements for further discussion of the acquired intangible assets.

(6) INVESTMENTS

All investments were classified as available-for-sale at September 30, 2013 and December 31, 2012.

The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's available-for-sale securities by major security type at September 30, 2013 were as follows:

	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Certificates of deposit	$ 45,530	$ 3	$ 0	$ 45,533
Corporate debt securities	218,767	231	(256)	218,742
Corporate equity securities	3,000	17,333	0	20,333
Commercial paper	52,182	38	0	52,220
U.S. Government agency securities	8,900	1	0	8,901
Greek government-issued bonds	51	77	0	128
Total	$328,430	$ 17,683	$ (256)	$345,857

The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's available-for-sale securities by major security type at December 31, 2012 were as follows:

	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Certificates of deposit	$ 48,741	$ 14	$ (1)	$ 48,754
Corporate debt securities	316,709	402	(211)	316,900
Corporate equity securities	3,000	0	(67)	2,933
U.S. Government agency securities	17,512	5	0	17,517
Greek government-issued bonds	48	52	0	100
Total	$386,010	$ 473	$ (279)	$386,204

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

The fair values of available-for-sale securities by contractual maturity at September 30, 2013 and December 31, 2012 were as follows:

	September 30, 2013	December 31, 2012
Maturing in one year or less	$ 198,086	$ 270,211
Maturing after one year through two years	147,771	115,993
Total	$ 345,857	$ 386,204

Impairment assessments are made at the individual security level each reporting period. When the fair value of an investment is less than its cost at the balance sheet date, a determination is made as to whether the impairment is other-than-temporary and, if it is other-than-temporary, an impairment loss is recognized in earnings equal to the difference between the investment's amortized cost and fair value at such date. As of September 30, 2013, some of the Company's investments were in an unrealized loss position. However, none of the underlying investments has been in a continuous loss position longer than twelve months, and no other-than-temporary impairment is deemed to have occurred.

See Note 14 to these Condensed Consolidated Financial Statements for additional discussion regarding the fair value of the Company's available-for-sale securities.

(7) GOODWILL

Goodwill is tested for impairment on an annual basis and between annual tests if the Company becomes aware of any events occurring or changes in the circumstances that would indicate a reduction in the fair value of the goodwill below its carrying amount.

The following table represents the changes in goodwill for the nine months ended September 30, 2013:

Balance at December 31, 2012	$51,543
Addition of goodwill related to the acquisition of Zacharon	2,715
Balance at September 30, 2013	$54,258

(8) INTANGIBLE ASSETS

Intangible assets consisted of the following:

	September 30, 2013	December 31, 2012
Intangible assets:		
Finite-lived intangible assets	$ 118,242	$ 118,242
Indefinite-lived intangible assets	74,430	63,689
Gross intangible assets:	192,672	181,931
Less: Accumulated amortization	(26,881)	(18,951)
Net carrying value	$ 165,791	$ 162,980

Indefinite-Lived Intangible Assets

Indefinite-lived intangible assets consist of 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), ZyStor Therapeutics, Inc. (ZyStor) and Zacharon.

Intangible assets related to IPR&D assets are considered to be indefinite-lived until the completion or

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

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.

See Note 6 to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012, for additional information related to the Company's intangible assets.

(9) PROPERTY, PLANT AND EQUIPMENT

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

	September 30, 2013	December 31, 2012
Leasehold improvements	$ 67,083	$ 65,918
Building and improvements	154,479	144,700
Manufacturing and laboratory equipment	88,865	79,915
Computer hardware and software	63,164	56,011
Furniture and equipment	12,152	11,143
Land	11,608	11,608
Construction-in-progress	64,756	64,300
	462,107	433,595
Less: Accumulated depreciation	(176,443)	(149,122)
Total property, plant and equipment, net	$ 285,664	$ 284,473

Depreciation expense for the three and nine months ended September 30, 2013 was $9.2 million and $27.3 million, respectively, of which $2.8 million and $8.2 million was capitalized into inventory, respectively. Depreciation expense for the three and nine months ended September 30, 2012 was $8.9 million and $25.7 million, respectively, of which $2.5 million and $4.7 million was capitalized into inventory, respectively.

Capitalized interest related to the Company's property, plant and equipment purchases for the three and nine months ended September 30, 2013 and 2012 was insignificant.

(10) INVENTORY

Inventory consisted of the following:

	September 30, 2013	December 31, 2012
Raw materials	$ 15,350	$ 11,943
Work-in-process	80,996	71,443
Finished goods	52,338	45,309
Total inventory	$ 148,684	$ 128,695

Inventory as of September 30, 2013 and December 31, 2012 included $32.7 million and $0, respectively, of Vimizim raw materials and work-in-progress related to the pre-launch Vimizim manufacturing campaign. The Company believes that all material uncertainties related to the ultimate regulatory approval of Vimizim for commercial sale have been significantly reduced based on positive data from Phase 3 clinical trial results, successful pre-filing meetings with the Food and Drug Administration (FDA) for the Biologics License Application (BLA), the filing of the BLA with the FDA in the first quarter of 2013, and the filing of the Marketing Authorization Application (MAA) filed with the European Medicines Agency (EMA) in April 2013. In its evaluation, the Company also considered its historical experience with developing and commercially producing similar products.

Inventory as of September 30, 2013 and December 31, 2012 also included $2.2 million and $12.0 million,

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

respectively, of product manufactured using certain process and specification changes that have not yet received regulatory approval. Although a product may have been approved by a regulatory agency, the process and specification changes must also be approved before product produced with the alternate processes and specifications can be sold commercially.

The Company expects to receive regulatory approval and has determined that it is probable that the Company will realize the future economic benefit associated with the costs of these inventories through future sales.

(11) SUPPLEMENTAL BALANCE SHEET INFORMATION

Accounts payable and accrued liabilities consisted of the following:

	September 30, 2013	December 31, 2012
Accounts payable	$ 15,632	$ 23,993
Accrued accounts payable	58,666	43,156
Accrued vacation expense	9,717	8,403
Accrued compensation expense	28,574	27,530
Accrued royalties payable	5,279	4,991
Accrued rebates payable	10,147	9,625
Other accrued operating expenses	1,891	6,179
Current portion of nonqualified deferred compensation liability	1,559	6,440
Value added taxes payable	4,240	2,072
Current portion of contingent acquisition consideration payable	26,536	10,764
Other	5,392	3,915
Total accounts payable and accrued liabilities	$ 167,633	$ 147,068

(12) DERIVATIVE INSTRUMENTS AND HEDGING STRATEGIES

Foreign Currency Exchange Rate Exposure

The Company uses forward foreign currency exchange contracts to hedge certain operational exposures resulting from changes in foreign currency exchange rates. Such exposures result from portions of the Company's forecasted revenues and operating expenses being denominated in currencies other than the U.S. dollar, primarily the Euro and Brazilian Real, respectively.

The Company designates certain of these forward foreign currency exchange contracts as hedging instruments and enters into some forward foreign currency exchange contracts that are considered to be economic hedges that are not designated as hedging instruments. Whether designated or undesignated, these forward foreign currency exchange contracts protect against the reduction in value of forecasted foreign currency cash flows resulting from Naglazyme product revenues, Aldurazyme royalty revenues, operating expenses and net asset or liability positions designated in currencies other than the U.S. dollar. The fair values of forward foreign currency exchange contracts are estimated using current exchange rates and interest rates, and take into consideration the current creditworthiness of the counterparties or the Company, as applicable. Details of the specific instruments used by the Company to hedge its exposure to foreign currency exchange rate fluctuations are discussed below. See Note 14 to these Condensed Consolidated Financial Statements for additional discussion regarding the fair value of forward foreign currency exchange contracts.

At September 30, 2013, the Company had 58 forward foreign currency exchange contracts outstanding to sell a total of 57.1 million Euros with expiration dates ranging from October 31, 2013 through December 31, 2014. These hedges were entered into in order to protect against the fluctuations in revenue associated with Euro denominated Naglazyme and Aldurazyme sales. The Company has formally designated these forward foreign currency exchange contracts as cash flow hedges and expects them to be highly effective within the meaning of FASB Accounting Standards Codification (ASC) Subtopic 815-30, *Derivatives and Hedging-Cash Flow Hedges*, in offsetting fluctuations in revenues denominated in Euros and operating expenses denominated in the Brazilian Real related to changes in foreign currency exchange rates.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

The Company also enters into forward foreign currency exchange contracts that are not designated as hedges for accounting purposes. The changes in fair value of these forward foreign currency exchange contracts are included as a part of Selling, General and Administrative expense in the Condensed Consolidated Statements of Comprehensive Loss. At September 30, 2013, separate from the 58 contracts discussed above, the Company had one outstanding forward foreign currency exchange contract to sell 28.1 million Euros, which was not designated as a hedge for accounting purposes and which will mature on October 31, 2013.

The maximum length of time over which the Company is hedging its exposure to the reduction in value of forecasted foreign currency cash flows through forward foreign currency exchange contracts is through December 31, 2014. Over the next twelve months, the Company expects to reclassify $2.0 million from accumulated other comprehensive income to earnings as the forecasted revenue transactions and operating expenses occur.

The fair value carrying amounts of the Company's derivative instruments were as follows:

	Asset Derivatives September 30, 2013		Liability Derivatives September 30, 2013	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Forward foreign currency exchange contracts	Other current assets	$ 0	Accounts payable and accrued liabilities	$ 1,674
Forward foreign currency exchange contracts	Other assets	0	Other long-term liabilities	131
Total		$ 0		$ 1,805
Derivatives not designated as hedging instruments:				
Forward foreign currency exchange contracts	Other current assets	$ 0	Accounts payable and accrued liabilities	$ 146
Total		0		146
Total value of derivative contracts		$ 0		$ 1,951

	Asset Derivatives December 31, 2012		Liability Derivatives December 31, 2012	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
Derivatives designated as hedging instruments:				
Forward foreign currency exchange contracts	Other current assets	$ 1,463	Accounts payable and accrued liabilities	$ 1,078
Forward foreign currency exchange contracts	Other assets	0	Other long-term liabilities	368
Total		$ 1,463		$ 1,446
Derivatives not designated as hedging instruments:				
Forward foreign currency exchange contracts	Other current assets	$ 84	Accounts payable and accrued liabilities	$ 0
Total		84		0
Total value of derivative contracts		$ 1,547		$ 1,446

The effect of the Company's derivative instruments on the Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2013 and 2012 was as follows:

	Forward Foreign Currency Exchange Contracts			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Derivatives Designated as Hedging Instruments:				
Net gain (loss) recognized in Other Comprehensive Income (OCI) (1)	$ (3,177)	$ (3,952)	$ (1,918)	$ (4,612)
Net gain reclassified from accumulated OCI into				

income (2)	102	2,362	968	4,916
Net gain recognized in income (3)	10	218	214	753
Derivatives Not Designated as Hedging Instruments:				
Net gain (loss) recognized in income (4)	$ (1,437)	$ (1,388)	$ (1,129)	$ 1,286

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

(1) Net change in the fair value of the effective portion classified as OCI.
(2) Effective portion classified as net product revenue.
(3) Ineffective portion and amount excluded from effectiveness testing classified as selling, general and administrative expense.
(4) Classified as selling, general and administrative expense.

At September 30, 2013 and December 31, 2012, accumulated other comprehensive income before taxes associated with forward foreign currency exchange contracts qualifying for hedge accounting treatment were losses of $2.1 million and $0.2 million, respectively.

The Company is exposed to counterparty credit risk on all of its derivative financial instruments. The Company has established and maintained strict counterparty credit guidelines and enters into hedges only with financial institutions that are investment grade or better to minimize the Company's exposure to potential defaults. The Company does not require collateral to be pledged under these agreements.

(13) CONVERTIBLE DEBT

In April 2007, the Company sold approximately $324.9 million of senior subordinated convertible notes due in April 2017 (the 2017 Notes), of which $78.3 million remains outstanding at September 30, 2013. The debt was issued at face value and bears interest at the rate of 1.875% per annum, payable semi-annually in cash. The debt is convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of the Company's common stock at a conversion price of approximately $20.36 per share, subject to adjustment in certain circumstances. The debt does not include a call provision and the Company is unable to unilaterally redeem the debt prior to maturity on April 23, 2017. The Company also must repay the debt if there is a qualifying change in control or termination of trading of its common stock. If a change of control occurs, the Company will pay a make whole premium by increasing the conversion rate applicable to the notes.

In connection with the placement of the 2017 Notes, the Company paid approximately $8.5 million in offering costs, which have been deferred and are included in other assets. The deferred offering costs are being amortized as interest expense over the life of the debt. The Company recognized amortization expense of $0.1 million and $0.3 million for the three and nine months ended September 30, 2013, compared to $0.2 million and $0.6 million for the three and nine months ended September 30, 2012, respectively.

In August 2013, the Company entered into separate agreements with three of the existing holders of its 2017 Notes pursuant to which such holders converted $31.5 million in aggregate principal amount of the 2017 Notes into 1,547,629 shares of the Company's common stock. In addition to issuing the requisite number of shares of the Company's common stock pursuant to the 2017 Notes, the Company also made varying cash payments to each of the holders, totaling $1.9 million in the aggregate, of which $1.7 million was recognized in total as Debt Conversion Expense on the Condensed Consolidated Statement of Comprehensive Loss for the three and nine months ended September 30, 2013 and $0.2 million was for accrued interest. Additionally, the Company reclassified $0.3 million of deferred offering costs to additional paid-in capital in connection with the conversion of the 2017 Notes.

In March 2013, the Company entered into separate agreements with 13 of the existing holders of its 2017 Notes pursuant to which such holders converted $215.0 million in aggregate principal amount of the 2017 Notes into 10,560,164 shares of the Company's common stock. In addition to issuing the requisite number of shares of the Company's common stock pursuant to the 2017 Notes, the Company also made varying cash payments to each of the holders, totaling $12.0 million in the aggregate, of which $10.4 million was recognized in total as Debt Conversion Expense on the Condensed Consolidated Statement of Comprehensive Loss for the nine months ended September 30, 2013 and $1.6 million was for accrued interest. Additionally, the Company reclassified $2.3 million of deferred offering costs to additional paid-in capital in connection with the conversion of the 2017 Notes.

In March 2006, the Company sold $172.5 million of senior subordinated convertible notes due in March 2013 (the 2013 Notes), which fully matured on March 29, 2013. The debt was issued at face value and bore interest at the rate of 2.5% per annum, payable semi-annually in cash. The debt was convertible, at the option of the holder, at any time prior to maturity or redemption, into shares of the Company's common stock at a conversion price of

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

approximately $16.58 per share, subject to adjustment in certain circumstances. The debt did not include a call provision and the Company was unable to unilaterally redeem the debt prior to maturity on March 29, 2013. Upon maturity of the remaining convertible notes outstanding in March 2013, the Company issued the requisite 1,403,735 shares of common stock pursuant to the 2013 Notes to the bond holders, in exchange for $23.3 million in aggregate principal and paid one bond holder the par value at maturity in cash totaling $98.

The Company's total fixed rate convertible debt outstanding was as follows:

	September 30, 2013	December 31, 2012
Fixed rate convertible debt on balance sheet	$ 78,310	$ 348,224
Fair value of fixed rate convertible debt	$ 280,387	$ 811,798

The fair value of the Company's fixed rate convertible debt is based on open market trades and is classified as Level 1 in the fair value hierarchy.

Interest expense on the Company's convertible debt for the three and nine months ended September 30, 2013 was $0.5 million and $2.5 million, respectively, compared to $1.7 million and $5.0 million for the three months and nine months ended September 30, 2012, respectively.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

(14) FAIR VALUE MEASUREMENTS

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including available-for-sale fixed income securities and foreign currency derivatives. The tables below present the fair value of these financial assets and liabilities determined using the following input levels.

	Fair Value Measurements at September 30, 2013			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Overnight deposits	$ 170,717	$ 0	$ 0	$170,717
Money market instruments	0	10,848	0	10,848
Total cash and cash equivalents	$ 170,717	$ 10,848	$ 0	$181,565
Available-for-sale securities:				
Short-term:				
Certificates of deposit	$ 0	$ 31,061	$ 0	$ 31,061
Corporate debt securities	0	94,472	0	94,472
Corporate equity securities	0	20,333	0	20,333
Commercial paper	0	52,220	0	52,220
Long-term:				
Certificates of deposit	0	14,472	0	14,472
Corporate debt securities	0	124,270	0	124,270
U.S. Government agency securities	0	8,901	0	8,901
Greek government-issued bonds	0	128	0	128
Total available-for-sale securities	$ 0	$ 345,857	$ 0	$345,857
Other Current Assets:				
Nonqualified Deferred Compensation Plan assets	$ 0	$ 49	$ 0	$ 49
Restricted investments (2)	0	2,528	0	2,528
Total other current assets	$ 0	$ 2,577	$ 0	$ 2,577
Other Assets:				
Nonqualified Deferred Compensation Plan assets	$ 0	$ 3,350	$ 0	$ 3,350
Restricted investments (2)	0	1,489	0	1,489
Total other assets	$ 0	$ 4,839	$ 0	$ 4,839
Total assets	$ 170,171	$ 364,121	$ 0	$534,838
Liabilities:				
Current Liabilities:				
Nonqualified Deferred Compensation Plan liability	$ 1,510	$ 49	$ 0	$ 1,559
Forward foreign currency exchange contract liability (1)	0	1,820	0	1,820
Contingent acquisition consideration payable	0	0	26,536	26,536
Total current liabilities	$ 1,510	$ 1,869	$ 26,536	$ 29,915
Other long-term liabilities:				
Nonqualified Deferred Compensation Plan liability	$ 12,468	$ 3,350	$ 0	$ 15,818
Forward foreign currency exchange contract liability (1)	0	131	0	131
Contingent acquisition consideration payable	0	0	26,500	26,500
Asset retirement obligation	0	0	4,014	4,014
Total other long-term liabilities	$ 12,468	$ 3,481	$ 30,514	$ 46,463
Total liabilities	$ 13,978	$ 5,350	$ 57,050	$ 76,378

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

	Fair Value Measurements at December 31, 2012			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Overnight deposits	$ 54,018	$ 0	$ 0	$ 54,018
Money market instruments	0	126,509	0	126,509
Total cash and cash equivalents	$ 54,018	$ 126,509	$ 0	$180,527
Available-for-sale securities:				
Short-term:				
Certificates of deposit	$ 0	$ 36,615	$ 0	$ 36,615
Corporate debt securities	0	222,147	0	222,147
Corporate equity securities	0	2,933	0	2,933
U.S. Government agency securities	0	8,516	0	8,516
Long-term:				
Certificates of deposit	0	12,139	0	12,139
Corporate debt securities	0	94,753	0	94,753
U.S. Government agency securities	0	9,001	0	9,001
Greek government-issued bonds	0	100	0	100
Total available-for-sale securities	$ 0	$ 386,204	$ 0	$386,204
Other Current Assets:				
Nonqualified Deferred Compensation Plan assets	$ 0	$ 2,052	$ 0	$ 2,052
Forward foreign currency exchange contract asset (1)	0	1,547	0	1,547
Restricted investments (2)	0	2,243	0	2,243
Total other current assets	$ 0	$ 5,842	$ 0	$ 5,842
Other Assets:				
Nonqualified Deferred Compensation Plan assets	$ 0	$ 2,375	$ 0	$ 2,375
Restricted investments (2)	0	3,492	0	3,492
Total other assets	$ 0	$ 5,867	$ 0	$ 5,867
Total assets	$ 54,018	$ 524,422	$ 0	$578,440
Liabilities:				
Current Liabilities:				
Nonqualified Deferred Compensation Plan liability	$ 6,440	$ 0	$ 0	$ 6,440
Forward foreign currency exchange contract liability (1)	0	1,078	0	1,078
Contingent acquisition consideration payable	0	0	10,764	10,764
Asset retirement obligation	0	0	1,685	1,685
Total current liabilities	$ 6,440	$ 1,078	$ 12,449	$ 19,967
Other long-term liabilities:				
Nonqualified Deferred Compensation Plan liability	$ 5,041	$ 4,427	$ 0	$ 9,468
Forward foreign currency exchange contract liability (1)	0	368	0	368
Contingent acquisition consideration payable	0	0	30,618	30,618
Asset retirement obligation	0	0	2,192	2,192
Total other long-term liabilities	$ 5,041	$ 4,795	$ 32,810	$ 42,646
Total liabilities	$ 11,481	$ 5,873	$ 45,259	$ 62,613

(1) See Note 12 to these Condensed Consolidated Financial Statements for further information regarding the derivative instruments.
(2) The restricted investments secure the Company's irrevocable standby letter of credit obtained in connection with the Company's new corporate facility lease agreements and certain commercial agreements.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

There were no transfers between levels during the three and nine months ended September 30, 2013.

The Company's Level 2 securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

The Company validates the prices provided by its third-party pricing services by understanding the models used, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming those securities traded in active markets. Due to the continued volatility associated with market conditions in Greece and reduced trading activity in its sovereign debt, the Company classified its Greek government-issued bonds as Level 2 on September 30, 2013 and December 31 2012. See Note 6 to these Condensed Consolidated Financial Statements for further information regarding the Company's financial instruments.

Liabilities measured at fair value using Level 3 inputs were comprised of contingent acquisition consideration payable and asset retirement obligations.

The Company's contingent acquisition consideration payable is estimated using a probability-based income approach utilizing an appropriate discount rate. Key assumptions used by management to estimate the fair value of contingent acquisition consideration payable include estimated probabilities, the estimated timing of when a milestone may be attained and assumed discount periods and rates. Subsequent changes in the fair value of the contingent acquisition consideration payable, resulting from management's revision of key assumptions, will be recorded in Intangible Asset Amortization and Contingent Consideration on the Condensed Consolidated Statements of Comprehensive Loss.

Contingent acquisition consideration payable at December 31, 2012	$41,382
Changes in the fair value of the contingent acquisition consideration payable	9,816
Addition of contingent consideration payable related to the Zacharon acquisition	1,857
Milestone payment to former LEAD shareholders	(19)
Contingent acquisition consideration payable at September 30, 2013	$53,036

Under certain of the Company's lease agreements, the Company is contractually obligated to return leased space to its original condition upon termination of the lease agreement. The Company records an asset retirement obligation liability and a corresponding capital asset in an amount equal to the estimated fair value of the obligation when estimable. In subsequent periods, for each such lease, the Company records interest expense to accrete the asset retirement obligation liability to full value and depreciates each capitalized asset retirement obligation asset, both over the term of the associated lease agreement. The Company's asset retirement obligations were $4.0 million at September 30, 2013 and $3.9 million at December 31, 2012.

The Company acquired intangible assets as a result of various business acquisitions. The estimated fair value of these long-lived assets was measured using Level 3 inputs as of the acquisition date.

(15) STOCK-BASED COMPENSATION

On May 8, 2012, the Company's Board of Directors approved the BioMarin Pharmaceutical Inc. 2012 Inducement Plan (the 2012 Inducement Plan), which provided for grants of up to 750,000 share-based awards to new employees including grants of restricted stock units and grants of options to purchase common stock at a price equal to the fair market value of such shares. The awards granted under the 2012 Inducement Plan are substantially similar to those granted under the Company's 2006 Share Incentive Plan as amended and restated on March 22, 2010 and as further amended on May 15, 2013 (the 2006 Share Incentive Plan). The 2012 Inducement Plan expired in May 2013 and no further awards will be made under the plan.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

In addition to the 2012 Inducement Plan, the Company's stock-based compensation plans include the 2006 Share Incentive Plan and the Employee Stock Purchase Plan (the ESPP). The Company's stock-based compensation plans are administered by the Compensation Committee of the Board of Directors, which selects persons to receive awards and determines the number of shares subject to each award and the terms, conditions, performance measures and other provisions of the award. See Note 13 to the Consolidated Financial Statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012, for additional information related to these stock-based compensation plans.

Determining the Fair Value of Stock Options and Stock Purchase Rights

The fair value of each option award is estimated on the date of grant using the Black-Scholes valuation model and the assumptions noted in the tables below. The expected life of options is based on observed historical exercise patterns. Groups of employees that have similar historical exercise patterns were considered separately for valuation purposes, but none were identified that had distinctly different exercise patterns as of September 30, 2013. The expected volatility of stock options is based upon the weighted average of the historical volatility of the Company's common stock and the implied volatility of traded options on the Company's common stock for fiscal periods in which there is sufficient trading volume in options on the Company's common stock. The risk-free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that the Company has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future. The assumptions used to estimate the per share fair value of stock options granted under the 2012 Inducement Plan and the 2006 Share Incentive Plan were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Expected volatility	44%	46%	44 – 45%	45 – 46%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Expected life	6.8 years	6.5 years	6.6-6.8 years	6.5 years
Risk-free interest rate	2.2%	0.9%	1.0 – 2.4%	0.8 – 1.1%

During the nine months ended September 30, 2013, the Company granted 2,403,722 million options with a weighted average option value of $30.62 per option.

The Company did not grant any new stock purchase rights under the ESPP during the three months ended September 30, 2013.

Restricted Stock Unit Awards with Service-Based Vesting Conditions

Restricted stock units (RSUs) are generally subject to forfeiture if employment terminates prior to the release of vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse. During the nine months ended September 30, 2013, the Company granted 558,231 RSUs with a weighted average fair market value of $66.74 per share.

Restricted Stock Unit Awards with Performance and Market-Based Vesting Conditions

Pursuant to the approval of the Board of Directors, the Company granted RSU awards with performance and market-based vesting conditions during 2012 and 2011 to certain executive officers. As of September 30, 2013, these awards provide for a base award of 860,000 RSUs (Base RSUs), with a weighted-average grant date fair value of $34.66. The number of RSUs that could potentially vest from the Base RSUs granted is contingent upon achievement of specific performance goals and will be multiplied by the Total Shareholder Return multiplier which could range from 75% to 125% to determine the number of earned RSUs.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

Stock-based compensation expense for this award will be recognized over the remaining service period beginning in the period the Company determines that achievement of strategic performance goal or goals is probable. Accordingly, because the Company's management has not determined that the achievement of the goals is probable as of September 30, 2013, no compensation expense has been recognized for these awards for the three and nine months ended September 30, 2013 and 2012.

Compensation expense included in the Condensed Consolidated Statements of Comprehensive Loss for all stock-based compensation arrangements was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Cost of sales	$ 1,489	$ 1,327	$ 3,663	$ 3,535
Research and development	7,116	5,060	18,821	15,351
Selling, general and administrative	7,600	5,752	19,214	17,021
Total stock-based compensation expense	$ 16,205	$ 12,139	$ 41,698	$ 35,907

Stock-based compensation of $4.2 million and $3.0 million was capitalized into inventory for the nine months ended September 30, 2013 and 2012, respectively. Capitalized stock-based compensation is recognized as cost of sales when the related product is sold.

(16) NET LOSS PER COMMON SHARE

Potentially issuable shares of common stock include shares issuable upon the exercise of outstanding employee stock option awards, common stock issuable under the ESPP, unvested restricted stock, common stock held by the Company's Nonqualified Deferred Compensation Plan and contingent issuances of common stock related to convertible debt. The table below presents potential shares of common stock that were excluded from the computation as they were anti-dilutive using the treasury stock method (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Options to purchase common stock	13,421	15,998	13,421	15,998
Common stock issuable under convertible debt	3,846	17,370	3,846	17,370
Unvested restricted stock units	1,235	1,297	1,180	1,256
Potentially issuable common stock for ESPP purchases	290	263	282	254
Common stock held by the Nonqualified Deferred Compensation Plan	194	233	194	233
Total number of potentially issuable shares	18,986	35,161	18,923	35,111

See Note 20 to these Condensed Consolidated Financial Statements for additional discussion regarding potential common shares outstanding at September 30, 2013 had the issuance of the Company's Senior Subordinated Convertible Notes due in October 2018 and 2020 occurred on or before September 30, 2013.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

(17) COMPREHENSIVE INCOME

The following table summarizes amounts reclassified out of Accumulated Other Comprehensive Income/(Loss) (AOCI) and their effect on the Company's Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2013.

	Amount Reclassified from AOCI (Gain)/Loss		
Details about AOCI Components	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2013	Condensed Consolidated Statement of Comprehensive Loss Classification
Gains on cash flow hedges:			
Forward foreign currency exchange contracts	$ (101)	$ (928)	Net product revenues
Forward foreign currency exchange contracts	0	(40)	Selling, general and administrative
	36	349	Provision for income taxes
	$ (65)	$ (619)	Net loss

The following table summarizes changes in the accumulated balances for each component, of other comprehensive income/(loss), including current period other comprehensive income and reclassifications act of AOCI, for the nine months ended September 30, 2013.

	Gains/(Losses) on Cash Flow Hedges	Unrealized Gain/(Losses) on Available-for-sale Securities	Foreign Currency Translation Adjustments	Total
AOCI balance, net of tax at December 31, 2012	$ (97)	$ 133	$ (238)	$ (202)
Other comprehensive income before reclassifications	(606)	11,007	1,893	12,294
Amounts reclassified from AOCI	(619)	0	0	(619)
Net increase in other comprehensive income (loss)	(1,225)	11,007	1,893	11,675
AOCI balance, net of tax at September 30, 2013	$ (1,322)	$ 11,140	$ 1,655	$11,473

(18) REVENUE AND CREDIT CONCENTRATIONS

Net Product Revenue— The Company considers there to be revenue concentration risks for regions where net product revenue exceeds ten percent of consolidated net product revenue. The concentration of the Company's net product revenue within the regions below may have a material adverse effect on the Company's revenue and results of operations if sales in the respective regions experience difficulties.

The table below summarizes net product revenue concentrations based on patient location for Naglazyme, Kuvan and Firdapse and Genzyme's headquarters for Aldurazyme. Although Genzyme sells Aldurazyme worldwide, the royalties earned by the Company on Genzyme's net sales are included in the U.S. region, as the transactions are with Genzyme whose headquarters are located in the U.S.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Region:				
United States	54%	53%	51%	50%
Europe	21%	21%	21%	22%
Latin America	8%	14%	12%	15%
Rest of world	17%	12%	16%	13%
Total net product revenue	100%	100%	100%	100%

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

The following table illustrates the percentage of the consolidated net product revenue attributed to the Company's four largest customers.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Customer A	15%	14%	15%	15%
Customer B (1)	17%	18%	15%	15%
Customer C	4%	11%	8%	12%
Customer D	11%	9%	11%	9%
Total	47%	52%	49%	51%

(1) Genzyme is the Company's sole customer for Aldurazyme and is responsible for marketing and selling Aldurazyme to third-parties. Net product revenues from Genzyme are comprised of royalties on worldwide net Aldurazyme sales and incremental product transfer revenue.

The accounts receivable balances at September 30, 2013 and December 31, 2012 were comprised of amounts due from customers for net product sales of Naglazyme, Kuvan and Firdapse and Aldurazyme product transfer and royalty revenues. On a consolidated basis, the Company's two largest customers accounted for 39% and 13% of the September 30, 2013 accounts receivable balance, respectively, compared to December 31, 2012 when the two largest customers accounted for 51% and 13% of the accounts receivable balance, respectively. As of September 30, 2013 and December 31, 2012, accounts receivable for the Company's largest customer balance included $28.2 million and $32.4 million, respectively, of unbilled accounts receivable related to net incremental Aldurazyme product transfers to Genzyme. The Company does not require collateral from its customers, but does perform periodic credit evaluations of its customers' financial condition and requires immediate payment in certain circumstances.

The Company's product sales to government-owned or government-funded customers in certain European countries, including Italy, Spain, Portugal and Greece, are subject to payment terms that are statutorily determined. Because these customers are government-owned or government-funded, the Company may be impacted by declines in sovereign credit ratings or sovereign defaults in these countries. A significant or further decline in sovereign credit ratings or a default in these countries may decrease the likelihood that the Company will collect accounts receivable or may increase the discount rates and the length of time until receivables are collected, which could result in a negative impact to the Company's operating results. In both the three and nine months ended September 30, 2013, approximately 4% of the Company's net product revenues were from these countries. Additionally, approximately 12% of the Company's outstanding accounts receivable at September 30, 2013 related to such countries.

The following table summarizes the accounts receivable by country that were past due related to Italy, Spain, Portugal and Greece, the number of days past due and the total allowance for doubtful accounts related to each of these countries at September 30, 2013.

	Days Past Due				
	< 180 Days	180 —360 Days	> 360 Days	Total Amount Past Due	Allowance for Doubtful Accounts
Italy	$ 0	$ 0	$ 0	$ 0	$ 0
Spain	1,920	1,467	1,216	4,603	0
Portugal	267	0	0	267	0
Greece	0	0	359	359	359
Total	$ 2,187	$ 1,467	$ 1,575	$ 5,229	$ 359

The Company has not historically experienced a significant level of uncollected receivables and has received continued payments from its more aged accounts. The Company believes that the allowances for doubtful accounts related to these countries is adequate based on its analysis of the specific business circumstances and expectations of collection for each of the underlying accounts in these countries.

BIOMARIN PHARMACEUTICAL INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS – (Continued)
(In thousands of U.S. dollars, except per share amounts or as otherwise disclosed)

(19) COMMITMENTS AND CONTINGENCIES

The Company is also subject to contingent payments totaling approximately $438.4 million as of September 30, 2013, which are due upon achievement of certain regulatory and licensing milestones if they occur before certain dates in the future. Of this amount, $57.6 million relates to programs that are no longer being developed.

(20) SUBSEQUENT EVENT

On October 15, 2013, the Company completed an offering of $750.0 million in aggregate principal of senior subordinated convertible notes consisting of $375.0 million 0.75% Senior Subordinated Convertible Notes due in October 2018 (the 2018 Notes) and $375.0 million 1.50% Senior Subordinated Convertible Notes due in October 2020 (the 2020 Notes and collectively the Notes). The net proceeds from the offering were approximately $726.4 million, after deducting commissions and estimated offering expenses payable by the Company. The 2018 Notes and the 2020 Notes accrue interest at annual rates of 0.75% and 1.50%, respectively, with interest payable semiannually in arrears on April 15 and October 15 of each year beginning on April 15, 2014. The Notes are convertible, under certain circumstances, into cash, shares of the Company's common stock or a combination at the Company's election. The initial conversion rate is 10.6213 shares of common stock per $1,000 principal amount of Notes, representing the initial conversion price of approximately $94.15 per common share.

Concurrent with the issuance of the Notes, the Company used approximately $29.8 million of proceeds to enter into privately-negotiated capped call transactions with respect to 50% of the principal amount of the 2018 Notes and 50% of the principal amount of the 2020 Notes with certain of the underwriters of the Notes or their affiliates. The capped call transactions are generally expected to reduce potential dilution of the Company's common stock upon conversion of the relevant Notes in excess of the principal amount of the Notes. The capped call transactions have a cap price of approximately $121.05, subject to certain adjustments under the terms of the capped call transactions.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined under securities laws. Many of these statements can be identified by the use of terminology such as "believes," "expects," "anticipates," "plans," "may," "will," "projects," "continues," "estimates," "potential," "opportunity" or the negative versions of these terms and other similar expressions. These forward-looking statements may be found in " *Overview* ," of this Item 2 and other sections of this Quarterly Report on Form 10-Q. Our actual results or experience could differ significantly from the forward-looking statements. Factors that could cause or contribute to these differences include those discussed in "Risk Factors," in Part II, Item 1A of this Quarterly Report on Form 10-Q as well as information provided elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year end December 31, 2012. You should carefully consider that information before you make an investment decision.

You should not place undue reliance on these types of forward-looking statements, which speak only as of the date that they were made. These forward-looking statements are based on the beliefs and assumptions of our management based on information currently available to management and should be considered in connection with any written or oral forward-looking statements that we may issue in the future as well as other cautionary statements we have made and may make. We do not undertake any obligation to release publicly any revisions to these forward-looking statements after completion of the filing of this Quarterly Report on Form 10-Q to reflect later events or circumstances or the occurrence of unanticipated events.

The following discussion of our financial condition and results of operations should be read in conjunction with our Condensed Consolidated Financial Statements and the related Notes thereto included elsewhere in this Quarterly Report on Form 10-Q.

Overview

We develop and commercialize innovative biopharmaceuticals for serious diseases and medical conditions. We select 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.

Key components of our results of operations include the following (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Total net product revenues	$ 134.3	$ 126.3	$ 394.1	$ 365.5
Cost of sales	28.1	24.6	71.1	65.3
Research and development expense	88.1	66.2	257.5	217.9
Selling, general and administrative expense	61.8	46.3	163.5	143.1
Intangible asset amortization and contingent consideration	9.6	1.4	13.2	5.8
Net loss	(53.0)	(5.4)	(114.4)	(61.3)
Stock-based compensation expense	16.2	12.1	41.7	35.9

See *"Results of Operations"* below for a discussion of the detailed components and analysis of the amounts above.

Our product portfolio is comprised of four approved products and multiple investigational product candidates. Our approved products are Naglazyme (galsulfase), Kuvan (sapropterin dihydrochloride), Firdapse (amifampridine phosphate) and Aldurazyme (laronidase).

Management's Discussion and Analysis of Financial Condition and Results of Operations – (Continued)

Naglazyme, a recombinant form of N-acetylgalactosamine 4-sulfatase indicated for patients with mucopolysaccharidosis VI (MPS VI), a debilitating life-threatening genetic disease for which no other drug treatment currently exists and which is caused by the deficiency of arylsufatase B, received marketing approval in the U.S. in May 2005, in the EU in January 2006 and subsequently in other countries. Naglazyme net product revenues for the three and nine months ended September 30, 2013 totaled $63.2 million and $202.5 million, respectively, compared to $62.5 million and $193.9 million for the three and nine months ended September 30, 2012, respectively.

Kuvan was granted marketing approval for the treatment of phenylketonuria (PKU) in the U.S. and in the EU in December 2007 and December 2008, respectively. Our Kuvan net product revenues for the three and nine months ended September 30, 2013 totaled $43.6 million and $122.1 million, respectively, compared to $36.4 million and $103.1 million for the three and nine months ended September 30, 2012, respectively.

In December 2009, the European Medicines Agency granted marketing approval for Firdapse, a proprietary form of 3-4-diaminopyridine (amifampridine phosphate), for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS). We launched this product on a country-by-country basis in the EU beginning in April 2010. Firdapse net product revenues for each of the three and nine months ended September 30, 2013 totaled $4.1 million and $11.8 million, respectively, compared to $3.6 million and $10.8 million for the three and nine months ended September 30, 2012, respectively.

Aldurazyme (laronidase), which was developed in collaboration with Genzyme Corporation (Genzyme), was approved in 2003 for marketing in the U.S. and the EU and subsequently in other countries for patients with mucopolysaccharidosis I (MPS I). Our Aldurazyme net product revenues for the three and nine months ended September 30, 2013 totaled $23.4 million and $57.7 million, respectively, compared to $23.8 million and $57.7 million for the three and nine months ended September 30, 2012.

We are conducting clinical trials on several investigational product candidates for the treatment of various diseases including:

- Vimizim ™, formerly referred to as GALNS, an enzyme replacement therapy for the treatment of mucopolysaccharidosis Type IV or Morquio Syndrome Type A, a lysosomal storage disorder;
- PEG-PAL, an enzyme substitution therapy for the treatment of PKU;
- BMN-701, an enzyme replacement therapy for Pompe disease, a glycogen storage disorder;
- BMN-673, an orally available poly-ADP ribose polymerase inhibitor for the treatment of patients with certain cancers;
- BMN-111, a peptide therapeutic for the treatment of achondroplasia, the leading cause of dwarfism: and
- BMN-190 for the treatment of late infantile neuronal ceroid lipofuscinosis, or CLN2, lysomal storage disorder primarily affecting the brain.

We are conducting or planning to conduct preclinical development of several other enzyme product candidates for genetic and other metabolic diseases and have recently licensed a Factor VIII gene therapy program for Hemophilia A from University College London and St. Jude's Children's Research Hospital.

Cost of sales includes raw materials, personnel and facility and other costs associated with manufacturing Naglazyme and Aldurazyme at our production facility in Novato, California. Cost of sales also includes third-party manufacturing costs for the production of the active ingredient in Kuvan and Firdapse and third-party production costs related to final formulation and packaging services for all products and cost of royalties payable to third-parties for all products.

Research and development includes costs associated with the research and development of product candidates and post-marketing research commitments related to our approved products. These costs primarily include preclinical and clinical studies, personnel and raw materials costs associated with manufacturing product candidates, quality control and assurance, research and development facilities and regulatory costs.

Selling, general and administrative expense primarily includes expenses associated with the commercialization of approved products and general and administrative costs to support our operations. These expenses include: product marketing and sales operations personnel; corporate facility operating expenses; information technology expenses and depreciation; and core corporate support functions, including human resources, finance and legal, and other external corporate costs such as insurance, legal fees and other professional services.

Intangible asset amortization and contingent consideration includes amortization expense related to our finite-lived intangible assets associated with marketing rights in the EU for Firdapse, impairment losses (if any) on intangible assets and changes in the fair value of contingent acquisition consideration payable. Changes in fair value can result from changes in estimated probability adjustments, changes in estimated timing of when a milestone may be achieved, changes in assumed discount periods and rates and passage of time.

Our cash, cash equivalents, short-term investments and long-term investments totaled $527.5 million as of September 30, 2013, compared to $566.7 million as of December 31, 2012. We have historically financed our operations primarily through our cash flows from operating activities, the issuance of common stock and convertible debt and by relying on equipment and other commercial financing. We will be highly dependent on our net product revenue to supplement our current liquidity and fund our operations for the foreseeable future. We may in the future elect to supplement this with further debt or equity offerings or commercial borrowing, even after giving effect to our October 2013 senior subordinated convertible note offering. Further, depending on market conditions, our financial position and performance and other factors, we may in the future choose to use a portion of our cash or cash equivalents to repurchase our convertible debt or other securities. See *"Financial Position, Liquidity and Capital Resources"* below for a further discussion of our liquidity and capital resources.

Critical Accounting Policies and Estimates

In preparing our Condensed Consolidated Financial Statements in accordance with accounting principles generally accepted in the U.S. and pursuant to the rules and regulations promulgated by the SEC, we make assumptions, judgments and estimates that can have a significant impact on our net income/(loss) and affect the reported amounts of certain assets, liabilities, revenue and expenses, and related disclosures. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis, we evaluate our assumptions, judgments and estimates. We also discuss our critical accounting policies and estimates with the Audit Committee of our Board of Directors.

We believe that the assumptions, judgments and estimates involved in the accounting for business combinations, contingent acquisition consideration payable, income taxes, long-lived assets, revenue recognition and inventory have the greatest impact on our Condensed Consolidated Financial Statements, so we consider these to be our critical accounting policies. Historically, our assumptions, judgments and estimates relative to our critical accounting policies have not differed materially from actual results.

Except for the clarification of our inventory policy below, there have been no significant changes to our critical accounting policies and estimates during the nine months ended September 30, 2013, as compared to the critical accounting policies and estimates disclosed in " *Management's Discussion and Analysis of Financial Condition and Results of Operations* " included in our Annual Report on Form 10-K for the year ended December 31, 2012, which was filed with the SEC on February 26, 2013.

Inventory

We value inventory at the lower of cost or net realizable value and determine the cost of inventory using the average-cost method. Inventories consist of currently marketed products and may contain certain products awaiting regulatory approval. In evaluating the recoverability of inventories produced in preparation for product launches, we consider the likelihood that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process.

We analyze our inventory levels quarterly and write down inventory that has become obsolete, or has a cost basis in excess of its expected net realizable value and inventory quantities in excess of expected requirements. In applying the lower of cost or net realizable value to pre-launch inventory, we estimate a range of likely commercial prices based on our comparable commercial products. Expired inventory is disposed of and the related costs are recognized as Cost of Sales in the Condensed Consolidated Statements of Comprehensive Loss.

Management's Discussion and Analysis of Financial Condition and Results of Operations – (Continued)

Inventories Produced in Preparation for Product Launches

We capitalize inventories produced in preparation for product launches sufficient to support estimated initial market demand. Typically, capitalization of such inventory begins when positive results have been obtained for the clinical trials that we believe are necessary to support regulatory approval, uncertainties regarding ultimate regulatory approval have been significantly reduced and we have determined it is probable that these capitalized costs will provide future economic benefit in excess of capitalized costs. The factors considered by us in evaluating these uncertainties include the receipt and analysis of positive Phase 3 clinical trial results for the underlying product candidate, results from meetings with the relevant regulatory authorities prior to the filing of regulatory applications, and the compilation of the regulatory application. We closely monitor the status of each respective product within the regulatory approval process, including all relevant communication with regulatory authorities. We also consider our historical experience with manufacturing and commercializing similar products and the relevant product candidate. If we are aware of any specific material risks or contingencies other than the normal regulatory review and approval process or if there are any specific issues identified relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized.

For inventories that are capitalized in preparation of product launch, anticipated future sales, expected approval date and shelf lives are evaluated in assessing realizability. The shelf life of a product is determined as part of the regulatory approval process; however in evaluating whether to capitalize pre-launch inventory production costs, we consider the product stability data of all of the pre-approval production to date to determine whether there is adequate expected shelf life for the capitalized pre-launch production costs.

Recent Accounting Pronouncements

See Note 4 to our accompanying Condensed Consolidated Financial Statements for a full description of recent accounting pronouncements and our expectation of their impact, if any, on our results of operations and financial condition.

Results of Operations

Net Loss

Our net loss for the three months ended September 30, 2013 was $53.0 million, compared to a net loss of $5.4 million for the three months ended September 30, 2012. Our net loss for the nine months ended September 30, 2013 was $114.4 million, compared to a net loss of $61.3 million for the nine months ended September 30, 2012. The change in net loss was primarily a result of the following (in millions):

	Three Months	Nine months
Net loss for the period ended September 30, 2012	$ (5.4)	$ (61.3)
Increased research and development expense	(21.9)	(39.6)
Increased selling, general and administrative expense	(15.5)	(20.4)
Debt conversion expense	(1.7)	(12.2)
Decreased intangible asset amortization and contingent consideration expense	(8.2)	(7.4)
Decrease in provision for/benefit from income taxes	(7.1)	(4.1)
Increased gross profit from product sales	4.6	22.7
Increased royalty and license revenues	0.2	3.2
Other individually insignificant fluctuations	2.0	4.7
Net loss for the period ended September 30, 2013	$ (53.0)	$ (114.4)

The increase in gross profit from product sales during the three and nine months ended September 30, 2013, as compared to three and nine months ended September 30, 2012, was primarily a result of additional Naglazyme patients initiating therapy globally and additional Kuvan patients initiating therapy in the U.S. The increase in research and development expense was primarily attributed to increased development expenses for our BMN-701, BMN-673 and PEG-PAL programs. The increase in selling, general and administrative expense during the nine months ended September 30, 2013 was primarily due to increased sales and marketing expenses related to our commercial products and increased pre-commercial Vimizim expenses.

Management's Discussion and Analysis of Financial Condition and Results of Operations – (Continued)

See below for additional information related to the primary net loss fluctuations presented above, including details of our operating expense fluctuations.

Net Product Revenues, Cost of Sales and Gross Profit

Net product revenues were as follows (in millions):

	Three Months Ended September 30,			Nine months Ended September 30,		
	2013	2012	Change	2013	2012	Change
Naglazyme	$ 63.2	$ 62.5	$ 0.7	$ 202.5	$ 193.9	$ 8.6
Kuvan	43.6	36.4	7.2	122.1	103.1	19.0
Firdapse	4.1	3.6	0.5	11.8	10.8	1.0
Aldurazyme	23.4	23.8	(0.4)	57.7	57.7	0
Total net product revenues	$ 134.3	$ 126.3	$ 8.0	$ 394.1	$ 365.5	$ 28.6

Gross profit by product was as follows (in millions):

	Three Months Ended September 30,			Nine months Ended September 30,		
	2013	2012	Change	2013	2012	Change
Naglazyme	$ 54.0	$ 53.4	$ 0.6	$ 173.6	$ 165.6	$ 8.0
Kuvan	36.2	30.7	5.5	102.5	86.6	15.9
Firdapse	3.1	2.9	0.2	9.2	8.8	0.4
Aldurazyme	13.0	14.7	(1.7)	37.6	39.2	(1.6)
Total gross profit	$ 106.3	$ 101.7	$ 4.6	$ 322.9	$ 300.2	$ 22.7

Net product revenues attributed to our collaboration with Genzyme were as follows (in millions):

	Three Months Ended September 30,			Nine months Ended September 30,		
	2013	2012	Change	2013	2012	Change
Aldurazyme revenue reported by Genzyme	$ 50.8	$ 48.3	$ 2.5	$ 152.9	$ 140.0	$ 12.9

	Three Months Ended September 30,			Nine months Ended September 30,		
Royalties earned from Genzyme	$ 20.5	$ 19.7	$ 0.8	$ 61.0	$ 56.6	$ 4.4
Incremental (previously recognized) Aldurazyme product transfer revenue	2.9	4.1	(1.2)	(3.3)	1.1	(4.4)
Total Aldurazyme net product revenues	$ 23.4	$ 23.8	$ (0.4)	$ 57.7	$ 57.7	$ 0

Naglazyme net product revenues for the three and nine months ended September 30, 2013 totaled $63.2 million and $202.5 million, respectively, of which $54.4 million and $174.7 million, respectively, was earned from customers based outside the U.S. The increase in Naglazyme net product revenues in the three and nine months ended September 30, 2013 was attributed to new patients initiating therapy. The impact of foreign currency exchange rates on Naglazyme sales denominated in currencies other than the U.S. dollar was insignificant for the three months ended September 30, 2013 and negative $0.9 million for the nine months ended September 30, 2013. Naglazyme gross margins for the three and nine months ended September 30, 2013 were 85% and 86% in the three and nine months ended September 30, 2013, compared to the three and nine months ended September 30, 2012 when Naglazyme gross margins were 85% in both periods. Naglazyme gross margins for the three and nine months ended September 30, 2013 were consistent with expectations and are not expected to fluctuate significantly in the future.

Net product revenue for Kuvan for the three and nine months ended September 30, 2013 was $43.6 million and $122.1 million, respectively, compared to $36.4 million and $103.1 million for the three and nine months ended September 30, 2012, respectively. The increase in Kuvan net product revenues in the three and nine months ended September 30, 2013 was attributed to new patients initiating therapy. Kuvan gross margins for the three and nine months ended September 30, 2013 were 83% and 84%, respectively, compared to the three and nine months ended September 30, 2012 when gross margins were 84% in both periods. Cost of goods sold for the three and nine months ended September 30, 2013 and 2012 reflect royalties paid to third-parties of approximately 10%. Kuvan gross margins for the three and nine months ended September 30, 2013 were consistent with expectations and are not expected to fluctuate significantly in the future. The 4% royalties earned from Merck Serono's net sales of Kuvan for the three and nine months ended September 30, 2013 were $0.6 million and $1.6 million, respectively, compared to $0.5 million and $1.5 million for the three and nine months ended September 30, 2012, respectively.

Management's Discussion and Analysis of Financial Condition and Results of Operations – (Continued)

The Hatch Waxman Act permits the FDA to approve abbreviated new drug applications, (ANDA), for generic versions of branded drugs. Pursuant to the Hatch-Waxman Act, other companies were able to file an ANDA for the active ingredient in Kuvan at any time after December 2011. If a generic competitor were to enter the market following the expiration of orphan exclusivity, it would have an adverse effect on our sales of Kuvan.

Net product revenue for Firdapse for three and nine months ended September 30, 2013 was $4.1 million and $11.8 million, respectively, compared to $3.6 million and $10.8 million for the three and nine months ended September 30, 2012, respectively. Firdapse gross margins for the three and nine months ended September 30, 2013 were 77% and 78%, respectively, compared to the three and nine months ended September 30, 2012 when gross margins were 82% and 81%, respectively. Cost of goods sold for the three and nine months ended September 30, 2013 and 2012 reflect royalties paid to third-parties of approximately 8%. Firdapse gross margins for the three and nine months ended September 30, 2013 decreased compared to the three and nine months ended September 30, 2012 due to increased manufacturing costs and the depletion of manufactured product that was previously expensed as research and development expense. Firdapse gross margins for the three and nine months ended September 30, 2013 were consistent with expectations and are not expected to fluctuate significantly in the future.

Aldurazyme gross margins were 55% and 65% for the three and nine months ended September 30, 2013, respectively, compared to 62% and 68% for the three and nine months ended September 30, 2012, respectively. Aldurazyme gross margins reflect the profit earned on royalty revenue and net incremental product transfer revenue. The change in margins is attributed to the shift in revenue mix between royalty revenue and net product transfer revenues. Aldurazyme gross margins are expected to fluctuate depending on the mix of royalty revenue, from which we earn higher gross profit, and product transfer revenue, from which we earn lower gross profit.

Total cost of sales for the three and nine months ended September 30, 2013 was $28.1 million and $71.1 million, respectively, compared to $24.6 million and $65.3 million for the three and nine months ended September 30, 2012, respectively. The increase in cost of sales was primarily attributed to the increase in product sales and the shift in Aldurazyme revenue mix between royalty revenue and net product revenues.

Research and Development

We manage our research and development expense by identifying the research and development activities we anticipate will be performed during a given period and then prioritize efforts based on scientific data, probability of successful development, market potential, available human and capital resources and other similar considerations. We continually review our pipeline and the development status of product candidates and, as necessary, reallocate resources among the research and development portfolio that we believe will best support the future growth of our business.

Research and development expense increased to $88.1 million for the three months ended September 30, 2013, from $66.2 million for the three months ended September 30, 2012. Research and development expense increased to $257.5 million for the nine months ended September 30, 2013, from $217.9 million for the nine months ended September 30, 2012. The increase in research and development expense was primarily a result of the following (in millions):

	Three Months	Nine Months
Research and development expense for the period ended September 30, 2012	$ 66.2	$ 217.9
Increased BMN-701 development expenses	4.8	19.1
Increased PEG-PAL development expenses	9.9	18.1
Increased BMN-673 development expenses	5.8	10.6
Increased development expenses related to commercial products	2.9	2.5
Increased development expenses on early development stage programs	2.3	8.8
Increased stock-based compensation expenses related to research and development	2.1	3.5
Increased BMN-111 development expenses	0.9	0.8
(Decreased) increased BMN-190 development expenses	(0.3)	1.8
Decreased Vimizim development expenses	(1.6)	(13.3)
Decrease in non-allocated research and development expenses and other net changes	(4.9)	(12.3)
Research and development expense for the period ended September 30, 2013	$ 88.1	$ 257.5

The increases in BMN-701 and BMN-673 development expenses were attributed to increased clinical trial activities related to these product candidates. The increase in development expense on early stage programs was primarily attributed to the $2.0 million license fee paid in connection with the Factor VIII gene therapy program for Hemophilia A from University College London and St. Jude's Children's Research Hospital and development costs related to the programs acquired from Zacharon Pharmaceuticals, Inc. (Zacharon). The increase in PEG-PAL development expense was attributed to an increase in clinical trial activity. The increase in BMN-190 development expense was attributed to increased pre-clinical activities related to this product candidate. During the first quarter of 2013, we evaluated the facts and circumstances supporting recoverability of pre-launch manufacturing costs related to Vimizim and concluded that recoverability was probable resulting in the capitalization of approximately $14.7 million and $32.7 million pre-launch manufacturing costs during the three and nine months ended September 30, 2013, respectively. Pre-launch Vimizim manufacturing costs incurred during the three and nine months ended September 30, 2012 were expensed to research and development expense as significant uncertainty existed over the recoverability of the costs. The increase in stock-based compensation expense is a result of an increased number of options outstanding due to an increased number of employees and an increase in the weighted-average fair value of the equity awards granted during 2013. The decrease in non-allocated research and development expense primarily includes increased research and development personnel and facility costs that are not allocated to specific programs.

For the remainder of 2013, we expect research and development spending to increase over 2012 levels due to our PEG-PAL, BMN-673, BMN-701, BMN-111 and BMN-190 programs progressing, including a few of those programs progressing to more advanced phases of clinical studies. Phase 3 clinical trials for PEG-PAL and BMN-673 were initiated in the second and fourth quarters of 2013, respectively and we expect to initiate a Phase 3 trial of BMN-701 in either the fourth quarter of 2013 or the first quarter of 2014. We also expect increased spending on pre-clinical and clinical activities for our early development stage programs. Additionally, we expect to continue incurring significant research and development expense for the foreseeable future due to long-term clinical activities related to post-approval regulatory commitments for our approved products. We continuously evaluate the recoverability of costs associated with pre-launch manufacturing activities, and if it is determined that regulatory approval and recoverability are highly likely and therefore future revenues are expected, the costs related to pre-launch manufacturing activities may be capitalized. When regulatory approval and the likelihood of future revenues for a product candidate are less certain, the related manufacturing costs are expensed as research and development expenses.

Selling, General and Administrative

Selling, general and administrative expense decreased to $61.8 million for the three months ended September 30, 2013, from $46.3 million for the three months ended September 30, 2012. Selling, general and administrative expense increased to $163.5 million for the nine months ended September 30, 2013, from $143.1 million for the nine months ended September 30, 2012. The increase in selling, general and administrative expenses was primarily a result of the following (in millions):

	Three Months	Nine Months
Selling, general and administrative expense for the period ended September 30, 2012	$ 46.3	$ 143.1
Increased sales and marketing expenses related to commercial products	4.5	9.8
Increased Vimizim pre-commercial expenses	5.6	8.7
Increased stock-based compensation	1.7	2.1
Increased foreign exchange losses on unhedged transactions	1.2	1.3
Net increase (decrease) in corporate support and other administrative expenses	2.5	(1.5)
Selling, general and administrative expense for the period ended September 30, 2013	$ 61.8	$ 163.5

We continue to incur sales and marketing expense for Naglazyme and Kuvan as a result of continued expansion of our international and U.S. activities, respectively. We expect selling, general and administrative expenses to increase in future periods as a result of the international expansion of Naglazyme, the U.S. commercialization activities for Kuvan, pre-commercial activities for Vimizim and the administrative support of our expanding operations.

Management's Discussion and Analysis of Financial Condition and Results of Operations – (Continued)

Intangible Asset Amortization and Contingent Consideration

Intangible asset amortization and contingent consideration expense is comprised of amortization of the European marketing rights for Firdapse, changes in the fair value of contingent acquisition consideration payable to former stockholders of our acquired businesses and impairment loss (if any) on intangible assets. Changes in the fair value of contingent acquisition consideration payable result from updates to the estimated probability of achievement or assumed timing of milestones and adjustments to the discount periods and rates. Intangible asset amortization and contingent consideration expense consisted of the following (in millions):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2013	2012	Change	2013	2012	Change
Amortization of Firdapse European marketing rights	$ 0.8	$ 0.8	$ 0	$ 2.4	$ 2.4	$ 0
Impairment loss on intangible assets	0	0	0	0.9	6.7	(5.8)
Changes in the fair value of contingent acquisition consideration payable	8.8	0.6	8.2	9.9	(3.3)	13.2
Total intangible asset amortization and contingent consideration	$ 9.6	$ 1.4	$ 8.2	$ 13.2	$ 5.8	$ 7.4

In the second quarter of 2013, we recorded an impairment charge of $0.9 million related to in-process research and development (IPR&D) assets related to acquired pre-clinical compounds based on the status of current development efforts and the related discounted cash flows that no longer supported the carrying-value of the IPR&D assets.

In the first quarter of 2012, we recorded an impairment charge of $6.7 million related to the U.S. Firdapse IPR&D assets based on the status of business development efforts at the time and the related discounted cash flows that no longer supported the carrying-value of the IPR&D assets. The IPR&D assets impaired were associated with the marketing rights for Firdapse in the U.S.

The changes in the fair value of the contingent acquisition consideration payable were primarily attributed to changes in the estimated probability of achieving development milestones based on the current status of the related development programs as well as changes in the discount rate utilized in the fair value calculations.

See Note 8 to our accompanying Condensed Consolidated Financial Statements for additional discussion.

Equity in the Loss of BioMarin/Genzyme LLC

Equity in the loss of BioMarin/Genzyme LLC includes our 50% share of the joint venture's loss for the period. BioMarin/Genzyme LLC's operations consist primarily of certain research and development activities and the intellectual property that are managed by the joint venture, with costs shared equally by BioMarin and Genzyme.

Equity in the loss of the joint venture totaled $0.1 million and $0.7 million for the three and nine months ended September 30, 2013, respectively, compared to equity in the loss of the joint venture of $0.3 million and $1.0 million for the three and nine months ended September 30, 2012, respectively.

Interest Income

We invest our cash, short-term and long-term investments in government and other high credit quality securities in order to limit default and market risk. Interest income totaled $0.6 million and $1.9 million for the three and nine months ended September 30, 2013, respectively, compared to $0.8 million and $1.8 million for the three and nine months ended September 30, 2012, respectively. The increase in interest income during the three and nine months ended September 30, 2013, as compared to the three and nine months ended September 30, 2012 was primarily due to higher cash and investment balances. We expect future interest income to increase due to the October 2013 issuance of $750.0 million of senior subordinated convertible notes which will result in higher cash and investment balances. See Note 20 to our accompanying Condensed Consolidated Financial Statements for additional discussion.

Interest Expense and Debt Conversion Expense

We incur interest expense on our convertible debt and our capital leases. Interest expense for the three and nine months ended September 30, 2013 was $0.5 million and $2.9 million, respectively, compared to $1.8 million and $5.7 million for the three and nine months ended September 30, 2012, respectively. The decrease in interest expense is attributed to the early conversion of $215.0 million and $31.5 million in aggregate principal of the 2017 Notes in March 2013 and August 2013, respectively, as well as the maturity of the 2013 Notes in March 2013. In connection with the early conversion of the 2017 Notes, we recognized debt conversion expense of $1.7 million and $12.2 million during the

three and nine months ended September 30, 2013, respectively. See Note 13 to our accompanying Condensed Consolidated Financial Statements for additional discussion. We expect future interest expense to increase due to the October 2013 issuance of $750.0 million of senior subordinated convertible notes. See Note 20 to our accompanying Condensed Consolidated Financial Statements for additional discussion.

Provision for (Benefit from) Income Taxes

During the three and nine months ended September 30, 2013 we recognized income tax expense of $0.7 million and an income tax benefit of $2.8 million, respectively, compared to an income tax benefit of $6.4 million and $6.8 million during the three and nine months ended September 30, 2012, respectively. Income tax expense for the three and nine months ended September 30, 2013 and 2012 consisted of state, federal and foreign current tax expense, which were offset by deferred tax benefits from federal orphan drug credits, federal R&D credits and California R&D credits. The provisions for the three and nine months ended September 30, 2013 and 2012 were further reduced by the benefit related to stock option exercises during the three and nine months ended September 30, 2013 and 2012. Additionally, the American Taxpayer Relief Act of 2012 (the Relief Act), was enacted on January 2, 2013. The Relief Act reinstated the federal R&D credit retroactively to January 1, 2012. In accordance with ASC Topic 740, we accounted for the effects of change in the tax law in the period that included the enactment date of the change, resulting in the recognition of a deferred tax benefit of $1.2 million related to R&D expenses incurred during 2012 as a discrete item during the nine months ended September 30, 2013, which further increased our income tax benefit for the current period provision. These discrete benefits were offset by a $1.6 million increase in the valuation allowance related to California net operating losses that we believe are likely to expire unutilized. See Note 19 to our Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2012 for additional discussion of the components of our provision for (benefit from) income taxes.

Financial Position, Liquidity and Capital Resources

We expect to fund our operations with our net product revenues from our commercial products, cash, cash equivalents, short-term and long-term investments supplemented by proceeds from equity or debt financings and loans or collaborative agreements with corporate partners, each to the extent necessary. We expect our current product revenue, cash, cash equivalents and short-term and long-term investments will meet our operating and capital requirements for at least the next twelve months based on our current business plans. This expectation could also change depending on how much we elect to spend on our development programs and for potential licenses and acquisitions of complementary technologies, products and companies. We will be highly dependent on our net product revenue to supplement our current liquidity and fund our operations for the foreseeable future. We may in the future elect to supplement this with further debt or equity offerings or commercial borrowing, even after giving effect to our October 2013 senior subordinated convertible note offering.

We consider the unrepatriated cumulative earnings of certain of our foreign subsidiaries to be invested indefinitely outside the U.S. As of September 30, 2013, $109.5 million of our $527.5 million balance of cash, cash equivalents and marketable securities was from foreign subsidiary operations and is intended to fund future foreign operations. In managing our liquidity needs in the U.S., we do not rely on the unrepatriated earnings as a source of funds and we have not provided for U.S. federal or state income taxes on these undistributed foreign earnings.

We are mindful that conditions in the current macroeconomic environment could affect our ability to achieve our goals. Some of the factors that could affect our business include: future changes to healthcare reform in the U.S., a continuation or worsening of global economic conditions, patent expirations of competitive products and the launch of generic competitors, continued government pricing pressures internationally and the potential volatility in foreign currency exchange rates. We will continue to monitor these conditions and will adjust our business processes, as appropriate, to mitigate these risks to our business.

Management's Discussion and Analysis of Financial Condition and Results of Operations – (Continued)

Our financial condition as of September 30, 2013 and December 31, 2012 was as follows (in millions):

	September 30, 2013	December 31, 2012	Change
Cash and cash equivalents	$ 181.6	$ 180.5	$ 1.1
Short-term investments	198.1	270.2	(72.1)
Long-term investments	147.8	116.0	31.8
Cash, cash equivalents and investments	$ 527.5	$ 566.7	$ (39.2)
Current assets	$ 713.5	$ 743.5	$ (30.0)
Current liabilities	167.6	170.4	(2.8)
Working capital	$ 545.9	$ 573.1	$ (27.2)
Convertible debt	$ 78.3	$ 348.2	$(269.9)

Our cash flows for each of the nine months ended September 30, 2013 and 2012 are summarized as follows (in millions):

	2013	2012	Change
Cash and cash equivalents at the beginning of the period	$180.5	$ 46.3	$ 134.2
Net cash provided by (used in) operating activities	(48.3)	5.6	(53.9)
Net cash provided by (used in) investing activities	7.6	(143.3)	150.9
Net cash provided by financing activities	41.8	272.7	(230.9)
Cash and cash equivalents at the end of the period	$181.6	$ 181.3	$ 0.3
Short-term and long-term investments	345.9	351.9	(6.0)
Cash, cash equivalents and investments	$527.5	$ 533.2	$ (5.7)

Cash, Cash Equivalents and Investments

The decrease in cash, cash equivalents and investments during the three months ended September 30, 2013 from December 31, 2012 was primarily attributed to the increase in cash used in operating activities, purchases of property, plant and equipment, the acquisition of Zacharon and payments to holders of the 2017 Notes upon early conversion of the 2017 Notes, offset by proceeds from employee stock option exercises.

Working Capital

Working capital was $545.9 million at September 30, 2013, a decrease of $27.2 million from working capital of $573.1 million at December 31, 2012. The increase in working capital was attributed to the following:

Working capital at December 31, 2012	$573.1
Decreased cash, cash equivalents and short-term investments	(71.1)
Maturity of 2013 Notes on March 29, 2013	23.4
Decreased accounts payable and accrued liabilities	(20.6)
Net increase in other current operating assets	41.1
Working capital at September 30, 2013	$545.9

The decrease in cash, cash equivalents and short-term investments was primarily comprised of $48.3 million of cash used in operating activities, $9.9 million of net cash payments related to the Zacharon acquisition and $12.2 million paid to certain holders of the 2017 Notes in connection with the early conversion of $246.5 million in aggregate principal, offset by proceeds of $54.1 million from employee stock option exercises. The net increase in other current operating assets is primarily attributed to increases of $15.7 million and $20.0 million in accounts receivable and inventory, respectively. The increase in accounts receivable is attributed to timing. The increase in inventory was primarily attributed to the capitalization of Vimizim pre-launch inventory.

Our product sales to government-owned or government-funded customers in certain Southern European countries, including Greece, Spain, Italy and Portugal, are subject to payment terms that are imposed by government authority. Because these customers are government-owned or government-funded, we may be impacted by declines in sovereign credit ratings or sovereign defaults in these countries. A significant or further decline in sovereign credit

ratings or a default in Greece, or in other Southern European countries, may decrease the likelihood that we will collect accounts receivable or may increase the discount rates and the length of time until receivables are collected, which could result in a negative impact to our operating results. Historically we have not experienced a significant level of uncollected receivables and have received continued payments from our more aged accounts. We believe that the allowances for doubtful accounts for these countries are adequate based on our analysis of the specific business circumstances and expectations of collection for each of the underlying accounts in these countries. As of September 30, 2013, approximately 12% of our outstanding accounts receivable relate to such countries. See Note 18 of our accompanying Condensed Consolidated Financial Statements for additional discussion.

Cash Provided by (Used in) Operating Activities

Cash used in operating activities for the nine months ended September 30, 2013 was $48.3 million, compared to cash provided by operating activities of $5.6 million for the nine months ended September 30, 2012. The increase in cash used in operating activities was primarily related to increased research and development expense that drove the increase in our net loss of $114.4 million for the nine months ended September 30, 2013 adjusted for non-cash items such as $37.9 million of depreciation and amortization expenses, $42.6 million of stock-based compensation expense, $21.0 million of net cash outflow related to changes in operating assets and liabilities and $19.2 million of deferred income taxes.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2013 was $7.6 million compared to net cash used in investing activities of $143.3 million during the nine months ended September 30, 2012. Our investing activities have consisted primarily of purchases and sales and maturities of investments and capital expenditures, such as manufacturing equipment and facility improvements. The decrease in net cash used in investing activities for the nine months ended September 30, 2013 was primarily comprised of a $164.8 million increase in net maturities of investment securities, offset by a $9.9 million increase in business acquisitions and a $4.8 million increase in capital expenditures. We expect to make significant capital investments in our Shanbally, Ireland manufacturing facility beginning in 2014 to enable future commercial manufacturing of our products at the facility.

Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2013 was $41.7 million, compared to net cash provided by financing activities of $272.7 million for the nine months ended September 30, 2012. Historically, our financing activities primarily included payments related to our contingent acquisition obligations, payments related to our convertible debt obligations and proceeds from employee stock purchases under the ESPP and employee stock option exercises. The decrease in net cash provided by financing activities for the nine months ended September 30, 2013 was primarily attributed to a decrease of $235.5 million in proceeds from the public offering of our common stock that occurred in June 2012 and an increase of $12.2 million in debt conversion expense, offset by increased proceeds from stock option exercises and ESPP contribution of $16.4 million.

Other Information

In March 2006, we sold approximately $172.5 million of senior subordinated convertible notes due March 2013 (the 2013 Notes), which fully matured on March 29, 2013. The debt was issued at face value and bore interest at the rate of 2.5% per annum, payable semi-annually in cash. The debt did not contain a call provision and we were unable to unilaterally redeem the remaining debt prior to maturity in March 2013. Upon maturity of the 2013 Notes, we issued 1.4 million shares of our common stock pursuant to the terms of the 2013 Notes and paid a bond holder $98,000 in cash for the par value at maturity. See Note 13 to our accompanying Condensed Consolidated Financial Statements for additional discussion.

In April 2007, we sold approximately $324.9 million of senior subordinated convertible notes due April 2017 (the 2017 Notes) of which $78.3 million remains outstanding at September 30, 2013. The debt was issued at face value and bears interest at the rate of 1.875% per annum, payable semi-annually in cash. During the nine months ended September 30 2013, we entered into separate agreements with 16 of the existing holders of the 2017 Notes pursuant to which such holders converted $246.5 million in aggregate principal of the 2017 Notes into 12.1 million shares of our common stock. In addition to issuing the requisite number of shares of common stock pursuant to the 2017 Notes, we also made varying cash payments to each of the holders, totaling an aggregate of $13.9 million, of which $12.2 million

was recognized as Debt Conversion Expense on our Condensed Consolidated Statement of Comprehensive Loss for the nine months ended September 30, 2013. The remaining 2017 Notes are convertible, at the option of the holder, at any time prior to maturity, into shares of our common stock at a conversion price of approximately $20.36 per share, subject to adjustment in certain circumstances. Our debt does not contain a call provision and we are unable to unilaterally redeem the debt prior to maturity in 2017. We also must repay the debt if there is a qualifying change in control or termination of trading of our common stock. If a change of control occurs, we will pay a make whole premium by increasing the conversion rate applicable to the 2017 Notes. See Note 13 to our accompanying Condensed Consolidated Financial Statements for additional discussion.

Our $78.3 million of total convertible debt as of September 30, 2013 will impact our liquidity due to the semi-annual cash interest payments and will impact our liquidity if the holders do not convert on or prior to the scheduled repayments of the debt. Further, depending on market conditions, our financial position and performance and other factors, we may in the future choose to use a portion of our cash or cash equivalents to repurchase our convertible debt or other securities.

On October 15, 2013, the we completed an offering of $750.0 million in aggregate principal of senior subordinated convertible notes consisting of $375.0 million 0.75% Senior Subordinated Convertible Notes due in October 2018 (the 2018 Notes) and $375.0 million 1.50% Senior Subordinated Convertible Notes due in October 2020 (the 2020 Notes). The net proceeds from the offering were approximately $726.4 million, after deducting commissions and estimated offering expenses which will be paid by us. The 2018 Notes and the 2020 Notes accrue interest at annual rates of 0.75% and 1.50%, respectively, which are payable semiannually in arrears on April 15 and October 15 of each year beginning on April 15, 2014. See Note 20 for additional discussion regarding the 2018 and 2020 Notes.

On October 23, 2009, we acquired Huxley Pharmaceuticals Inc. (Huxley), which has rights to Firdapse for a total purchase price of $37.2 million, of which $15.0 million was paid in cash and $22.2 million represented the acquisition date fair value of contingent acquisition consideration payable. In connection with the acquisition, we agreed to pay the Huxley stockholders additional consideration in future periods of up to $41.9 million (undiscounted) in milestone payments if certain annual sales, cumulative sales and U.S. development milestones are met. During 2011, 2010 and 2009, we made milestone payments of $3.0 million, $6.5 million and $1.0 million, respectively, related to the attainment of development milestones.

On February 10, 2010, we acquired LEAD Therapeutics, Inc. (LEAD), which had the key compound now referred to as BMN-673, for a total purchase price of $39.1 million, of which $18.6 million was paid in cash and $20.5 million represented the acquisition date fair value of contingent acquisition consideration payable. We paid $3.0 million of the $18.6 million in cash during December 2009. In connection with the acquisition, we agreed to pay the LEAD stockholders additional consideration in future periods of up to $68.0 million (undiscounted) in milestone payments if certain clinical, development and sales milestones are met. During 2012 and 2010, we paid the former LEAD stockholders $6.0 million and $11.0 million for the attainment of a clinical milestone and regulatory milestone, respectively.

On August 17, 2010, we acquired ZyStor Therapeutics, Inc. (ZyStor), which had the compound now referred to as BMN-701, for a total purchase price of $35.9 million, of which $20.3 million was paid in cash and $15.6 million represented the acquisition date fair value of contingent acquisition consideration payable. In connection with the acquisition, we agreed to pay the ZyStor stockholders additional consideration in future periods of up to $93.0 million (undiscounted) in milestone payments if certain clinical, development and sales milestones are met.

On January 4, 2013, we acquired Zacharon, which focused on developing small molecules targeting pathways of glycan and glycolipid metabolism, for a net cash upfront payment of $9.7 million. In connection with the acquisition, we agreed to pay the Zacharon stockholders additional consideration in future periods of up to $134.0 million (undiscounted) in milestone payments if certain clinical, development and sales milestones are met.

Funding Commitments

We cannot estimate with certainty the cost to complete any of our product development programs. Additionally, except as disclosed under *"Overview"* above, we cannot precisely estimate the time to complete any of our product development programs or when we expect to receive net cash inflows from any of our product development programs. Please see *" Risk Factors"* included in Part II Item 1A of this Quarterly Report on Form 10-Q, for a discussion of the reasons we are unable to estimate such information, and in particular the following risk factors:

- *if we fail to obtain or maintain regulatory approval to commercially market and sell our drugs, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased;*

- *if we are unable to successfully develop and maintain manufacturing processes for our drug products to produce sufficient quantities at acceptable costs, we may be unable to meet demand for our products and lose potential revenue, have reduced margins or be forced to terminate a program;*
- *if we fail to compete successfully with respect to product sales, we may be unable to generate sufficient sales to recover our expenses related to the development of a product program or to justify continued marketing of a product and our revenue could be adversely affected; and*
- *if we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline .*

Our investment in our product development programs and continued development of our existing commercial products has a major impact on our operating performance. Our research and development expenses during the three and nine months ended September 30, 2013 and 2012, and the period since inception of the major programs were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,		Since Program Inception
	2013	2012	2013	2012	
Vimizim	$ 19.9	$ 21.5	$ 61.7	$ 75.0	$ 273.5
Naglazyme	3.0	2.7	9.1	8.4	173.9
Kuvan	3.3	3.3	11.2	11.1	152.0
Firdapse	3.0	0.8	6.0	4.6	31.7
BMN-673	8.5	2.7	18.7	8.1	45.8
BMN-701	9.9	5.1	36.3	17.2	87.9
BMN-111	3.2	2.3	10.9	10.1	42.8
BMN-190	3.2	3.5	9.7	7.9	27.4
PEG-PAL	15.2	5.3	39.4	21.3	152.6
Not allocated to specific major current projects	18.9	19.0	54.5	54.2	Not meaningful
Totals	$ 88.1	$ 66.2	$ 257.5	$ 217.9	

We may elect to increase our spending above our current long-term plans and consequently we may be unable to achieve our long-term goals. This may increase our capital requirements, including: costs associated with the commercialization of our products; additional clinical trials; investments in the manufacturing of Naglazyme, Aldurazyme, Kuvan and Firdapse; preclinical studies and clinical trials for our other product candidates; potential licenses and other acquisitions of complementary technologies, products and companies; and general corporate purposes.

Our future capital requirements will depend on many factors, including, but not limited to:

- our ability to successfully market and sell Naglazyme, Kuvan and Firdapse;
- Genzyme's ability to continue to successfully commercialize Aldurazyme;
- the progress and success of our preclinical studies and clinical trials (including studies and the manufacture of materials);
- the timing, number, size and scope of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals and the costs of post-marketing studies which may be required by regulatory authorities;
- the time and cost necessary to develop commercial manufacturing processes, including quality systems, and to build or acquire manufacturing capabilities;
- the progress of research programs carried out by us;
- our possible achievement of milestones identified in our purchase agreements with the former stockholders of LEAD, ZyStor, Huxley and Zacharon that trigger related milestone payments;

- any changes made to, or new developments in, our existing collaborative, licensing and other commercial relationships or any new collaborative, licensing and other commercial relationships that we may establish; and
- whether our convertible debt is converted to common stock in the future.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to our consolidated financial position or results of operations.

Contractual and Commercial Obligations

We have contractual and commercial obligations under our debt, operating leases and other obligations related to research and development activities, purchase commitments, licenses and sales royalties with annual minimums. Information about these obligations as of September 30, 2013 is presented in the table below (in millions).

	Payments Due by Period					
	2013	2014	2015-2016	2017-2018	2019 and Thereafter	Total
Convertible debt and related interest	$ 0.7	$ 1.5	$ 3.0	$79.0	$ 0	$ 84.2
Operating leases	2.5	10.2	18.8	16.4	20.3	68.2
Research and development and purchase commitments	7.3	18.4	2.9	0.5	0	29.1
Total	$10.5	$30.1	$24.7	$95.9	$ 20.3	$181.5

We are also subject to contingent payments totaling approximately $438.4 million as of September 30, 2013, which are due upon achievement of certain regulatory and licensing milestones if they occur before certain dates in the future. Of this amount, $57.6 million relates to programs that are no longer being developed.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks during the nine months ended September 30, 2013 have not materially changed from those discussed in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2012, which was filed with the SEC on February 26, 2013.

Item 4. Controls and Procedures

(a) Controls and Procedures

An evaluation was carried out, under the supervision of and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, regarding the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of the end of the period covered by this report.

Based on the evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) Change in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during our most recently completed quarter that have materially affected or are reasonably likely to materially affect our internal control over financial reporting. We are utilizing the Committee of Sponsoring Organizations of the Treadway Commission (COSO) 1992 Framework on internal control.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. The risks and uncertainties described below are not the only ones we face. Other risks and uncertainties, including those that we do not currently consider material, may impair our business. If any of the risks discussed below actually occur, our business, financial condition, operating results or cash flows could be materially adversely affected. This could cause the value of our securities to decline, and you may lose all or part of your investment.

We have marked with an asterisk (*) those risk factors below that include a substantive change from or update to the risk factors included in our Annual Report on Form 10-K, for the year ended December 31, 2012 filed with the SEC on February 26, 2013.

***If we fail to obtain or maintain regulatory approval to commercially market and sell our drugs, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished, and the capital necessary to fund our operations will be increased.**

We must obtain and maintain regulatory approval to market and sell our drug products in the U.S. and in jurisdictions outside of the U.S. In the U.S., we must obtain FDA approval for each drug that we intend to commercialize. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products distributed abroad are also subject to government regulation by international regulatory authorities. Naglazyme, Aldurazyme and Kuvan have received regulatory approval to be commercially marketed and sold in the U.S., EU and other countries. Firdapse has received regulatory approval to be commercially marketed only in the EU. Although we announced in November 2012 that our Phase 3 study of Vimizim™, an enzyme replacement therapy for patients with MPS IVA (Morquio Syndrome), had met its primary endpoint, Vimizim has not received regulatory approval in the

U.S., EU or any other jurisdiction and may never receive approval. Also, even if we receive priority review timelines from the FDA for Vimizim, there is no assurance that the FDA will comply with such timelines and there may be delays and ultimately the FDA may decide not to approve Vimizim.

As part of the recent reauthorization of the Prescription Drug User Fee Act (PDUFA), new biologics are included in a new product review program intended to enhance FDA-sponsor communications to lead to greater first-cycle approval decisions. As part of this program, applications for new biologics are subject to either a 12-month standard or 8-month priority review period that begins from the date of application submission. However, since this is a new product review program and no products have completed this new review process, the priority review period may take longer than eight months and the standard review period may take longer than 12 months. Similarly, although the EMA has an accelerated approval process, the timelines mandated by the regulations are subject to the possibility of substantial delays.

In addition, the FDA and its international equivalents have substantial discretion over the approval process for pharmaceutical products. As such, these regulatory agencies may in the end not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval and may require additional data. The FDA has scheduled the Advisory Committee meeting for November 19, 2013 to review the clinical trial data for Vimizim. The FDA and the Advisory Committee will be reviewing a number of risk benefit questions including whether the magnitude and durability of effect demonstrated in the clinical studies are sufficient for a chronic condition and potentially life long therapy. Although the FDA is not bound by the recommendations of an Advisory Committee, it typically follows such recommendations. We cannot provide any assurance as to the timing of, and the determinations to be made by, the FDA or the Advisory Committee following any such meeting. If we fail to obtain regulatory approval for our product candidates, including Vimizim, we will be unable to market and sell those drug products. Because of the risks and uncertainties in pharmaceutical development, our product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain approval. We also rely on independent third-party contract research organizations, or CROs, to file some of our ex-U.S. and ex-EU marketing applications and important aspects of the services performed for us by the CROs are out of our direct control. If we fail to adequately manage our CROs, if the CRO elects to prioritize work on our projects below other projects or if there is any dispute or disruption in our relationship with our CROs, the filing of our applications may be delayed.

From time to time during the regulatory approval process for our products and our product candidates, we engage in discussions with the FDA and comparable international regulatory authorities regarding the regulatory requirements for our development programs. To the extent appropriate, we accommodate the requests of the regulatory authorities and, to date, we have generally been able to reach reasonable accommodations and resolutions regarding the underlying issues. However, we are often unable to determine the outcome of such deliberations until they are final. If we are unable to effectively and efficiently resolve and comply with the inquiries and requests of the FDA and other non-U.S. regulatory authorities, the approval of our product candidates may be delayed and their value may be reduced.

After any of our products receive regulatory approval, they remain subject to ongoing regulation, which can impact, among other things product labeling, manufacturing practices, adverse event reporting, storage, expiration, distribution, advertising and promotion, and record keeping. If we do not comply with the applicable regulations, the range of possible sanctions includes issuance of adverse publicity, product recalls or seizures, fines, total or partial suspensions of production and/or distribution, suspension of marketing applications, and enforcement actions, including injunctions and civil or criminal prosecution. The FDA and comparable international regulatory agencies can withdraw a product's approval under some circumstances, such as the failure to comply with regulatory requirements or unexpected safety issues. Further, the FDA often requires post-marketing testing and surveillance to monitor the effects of approved products. The FDA and comparable international regulatory agencies may condition approval of our product candidates on the completion of such post-marketing clinical studies. These post-marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. If data we collect from post-marketing studies suggest that one of our approved products may present a risk to safety, the government authorities could withdraw our product approval, suspend production or place other marketing restrictions on our products. If regulatory sanctions are applied or if regulatory approval is delayed or withdrawn, the value of our company and our operating results will be adversely affected. Additionally, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will be increased.

If we fail to obtain or maintain orphan drug exclusivity for some of our products, our competitors may sell products to treat the same conditions and our revenues will be reduced.

As part of our business strategy, we intend to develop some drugs that may be eligible for FDA and EU orphan drug designation. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S. The company that first obtains FDA approval for a designated orphan drug for a given rare disease receives marketing exclusivity for use of that drug for the stated condition for a period of seven years. Orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug. Similar regulations are available in the EU with a ten-year period of market exclusivity.

Because the extent and scope of patent protection for some of our drug products is limited, orphan drug designation is especially important for our products that are eligible for orphan drug designation. For eligible drugs, we plan to rely on the exclusivity period under the Orphan Drug Act to maintain a competitive position. If we do not obtain orphan drug exclusivity for our drug products that do not have broad patent protection, our competitors may then sell the same drug to treat the same condition and our revenues will be reduced.

Even though we have obtained orphan drug designation for certain of our products and product candidates and even if we obtain orphan drug designation for our future product candidates, due to the uncertainties associated with developing pharmaceutical products, we may not be the first to obtain marketing approval for any particular orphan indication. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

We may face competition from biological products approved through an abbreviated regulatory pathway.

Our Naglazyme and Aldurazyme products, as well as certain of our product candidates, including Vimizim, are regulated by the FDA as biologics under the Federal Food, Drug and Cosmetic Act, or the FDC Act, and the Public Health Service Act. Biologics require the submission of a Biologics License Application (BLA), and approval by the FDA prior to being marketed in the U.S. Historically, a biologic product approved under a BLA was not subject to the generic drug review and approval provisions of the FDC Act. However, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the PPACA, created a regulatory pathway for the abbreviated approval for biological products that are demonstrated to be “biosimilar” or “interchangeable” with an FDA-approved biological product. In order to meet the standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Such biosimilars would reference biological products approved in the U.S. The law establishes a period of 12 years of data exclusivity for reference products, which protects the data in the original BLA by prohibiting sponsors of biosimilars from gaining FDA approval based in part on reference to data in the original BLA. Our products approved under BLAs, as well as products in development that may be approved under BLAs, could be reference products for such abbreviated BLAs.

To obtain regulatory approval to market our products, preclinical studies and costly and lengthy preclinical and clinical trials are required and the results of the studies and trials are highly uncertain.

As part of the regulatory approval process, we must conduct, at our own expense, preclinical studies in the laboratory and clinical trials on humans for each product candidate. We expect the number of preclinical studies and clinical trials that the regulatory authorities will require will vary depending on the product candidate, the disease or condition the drug is being developed to address and regulations applicable to the particular drug. Generally, the number and size of clinical trials required for approval increase based on the expected patient population that may be treated with a drug. We may need to perform multiple preclinical studies using various doses and formulations before

we can begin clinical trials, which could result in delays in our ability to market any of our product candidates. Furthermore, even if we obtain favorable results in preclinical studies, the results in humans may be significantly different. After we have conducted preclinical studies, we must demonstrate that our drug products are safe and efficacious for use in the targeted human patients in order to receive regulatory approval for commercial sale.

Adverse or inconclusive clinical results would stop us from filing for regulatory approval of our product candidates. Additional factors that can cause delay or termination of our clinical trials include:

- slow or insufficient patient enrollment;
- slow recruitment of, and completion of necessary institutional approvals at, clinical sites;
- longer treatment time required to demonstrate efficacy;
- lack of sufficient supplies of the product candidate;
- adverse medical events or side effects in treated patients;
- lack of effectiveness of the product candidate being tested; and
- regulatory requests for additional clinical trials or pre-clinical studies.

Typically, if a drug product is intended to treat a chronic disease, as is the case with some of our product candidates, safety and efficacy data must be gathered over an extended period of time, which can range from nine months to three years or more. We also rely on independent third-party contract research organizations, or CROs, to perform most of our clinical studies and many important aspects of the services performed for us by the CROs are out of our direct control. If we fail to adequately manage our CROs, or if there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third-party CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could adversely be impacted.

If we continue to incur operating losses for a period longer than anticipated, we may be unable to continue our operations at planned levels and be forced to reduce our operations.

Since we began operations in March 1997, we have been engaged in very substantial research and development and operated at a net loss until 2008. Although we were profitable in 2008 and 2010, we operated at a net loss in 2009, 2011 and 2012. Based upon our current plan for investments in research and development for existing and new programs, we expect to operate at a net loss for at least the next 12 months. Our future profitability depends on our marketing and selling of Naglazyme, Kuvan and Firdapse, the successful continued commercialization of Aldurazyme by Genzyme, the receipt of regulatory approval of our product candidates, our ability to successfully manufacture and market any approved drugs, either by ourselves or jointly with others, our spending on our development programs and the impact of any possible future business development transactions. The extent of our future losses and the timing of profitability are highly uncertain. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

If we fail to comply with manufacturing regulations, our financial results and financial condition will be adversely affected.

Before we can begin commercial manufacture of our products, we, or our contract manufacturers, must obtain regulatory approval of our manufacturing facilities, processes and quality systems. In addition, our pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and international regulatory authorities, before and after product approval. Our manufacturing facilities in the U.S. have been approved by the FDA, the European Commission (EC), and health agencies in other countries for the manufacture of Aldurazyme and Naglazyme. The manufacturing facility located in Shanbally, Cork, Ireland that we purchased in 2011 has not yet been approved by the FDA or EMA. In addition, our third-party manufacturers' facilities involved with the manufacture of Naglazyme, Kuvan, Firdapse and Aldurazyme have also been inspected and approved by various regulatory authorities.

Due to the complexity of the processes used to manufacture our products and product candidates, we may be unable to continue to pass or initially pass federal or international regulatory inspections in a cost effective manner. For the same reason, any potential third-party manufacturer of Naglazyme, Kuvan, Aldurazyme and Firdapse or our product candidates may be unable to comply with GMP regulations in a cost effective manner and may be unable to initially or continue to pass a federal or international regulatory inspection.

If we, or third-party manufacturers with whom we contract, are unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of our products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our financial results and financial condition.

***If we fail to obtain the capital necessary to fund our operations, our financial results and financial condition will be adversely affected and we will have to delay or terminate some or all of our product development programs.**

As of September 30, 2013, we had cash, cash equivalents and short and long-term investments totaling $527.5 million. On October 15, 2013, we completed an offering of senior subordinated convertible notes and received net proceeds of approximately $726.4 million, after deducting commissions and estimated offering expenses payable by us. Notwithstanding the receipt of the net proceeds from this offering, we may require additional financing to fund our future operations, including the commercialization of our approved drugs and drug product candidates currently under development, preclinical studies and clinical trials, and potential licenses and acquisitions. We may be unable to raise additional financing, if needed, due to a variety of factors, including our financial condition, the status of our product programs, and the general condition of the financial markets. If we fail to raise additional financing if we need such funds, we may have to delay or terminate some or all of our product development programs and our financial condition and operating results will be adversely affected.

We expect to continue to spend substantial amounts of capital for our operations for the foreseeable future. The amount of capital we will need depends on many factors, including:

- our ability to successfully market and sell Naglazyme, Kuvan and Firdapse;
- Genzyme's ability to continue to successfully commercialize Aldurazyme;
- the progress and success of our preclinical studies and clinical trials (including studies and the manufacture of materials);
- the timing, number, size and scope of our preclinical studies and clinical trials;
- the time and cost necessary to obtain regulatory approvals and the costs of post-marketing studies which may be required by regulatory authorities;
- the time and cost necessary to develop commercial manufacturing processes, including quality systems, and to build or acquire manufacturing capabilities;
- the progress of research programs carried out by us;
- our possible achievement of milestones identified in our purchase agreements with the former stockholders of LEAD Therapeutics, Inc., ZyStor, Huxley Pharmaceuticals, Inc., and Zacharon Pharmaceuticals Inc. that trigger related milestone payments;
- any changes made to, or new developments in, our existing collaborative, licensing and other commercial relationships or any new collaborative, licensing and other commercial relationships that we may establish; and
- whether our convertible debt is converted to common stock in the future.

Moreover, our fixed expenses such as rent, license payments, interest expense and other contractual commitments are substantial and may increase in the future. These fixed expenses may increase because we may enter into:

- additional licenses and collaborative agreements;
- additional contracts for product manufacturing; and
- additional financing facilities.

We may need to raise additional funds from equity or debt securities, loans or collaborative agreements if we are unable to satisfy our liquidity requirements. The sale of additional securities may result in additional dilution to our stockholders. Furthermore, additional financing may not be available in amounts or on terms satisfactory to us or at all. This could result in the delay, reduction or termination of our research, which could harm our business.

If we are unable to successfully develop and maintain manufacturing processes for our drug products to produce sufficient quantities at acceptable costs, we may be unable to meet demand for our products and lose potential revenue, have reduced margins or be forced to terminate a program.

Due to the complexity of manufacturing our products, we may not be able to manufacture drug products successfully with a commercially viable process or at a scale large enough to support their respective commercial markets or at acceptable margins.

The development of commercially viable manufacturing processes typically is very difficult to achieve and is often very expensive and may require extended periods of time. Changes in manufacturing processes (including manufacturing cell lines), equipment or facilities may require us to complete clinical trials to receive regulatory approval of any manufacturing improvements. Also, we may be required to demonstrate product comparability between a biological product made after a manufacturing change and the product made before implementation of the change through additional types of analytical and functional testing or may have to complete additional clinical studies. Also, if we contract for manufacturing services with an unproven process, our contractor is subject to the same uncertainties, high standards and regulatory controls, and may therefore experience difficulty if further process development is necessary.

Even a developed manufacturing process can encounter difficulties. Problems may arise during manufacturing for a variety of reasons, including human error, mechanical breakdowns, problems with raw materials and cell banks, malfunctions of internal information technology systems, and other events that cannot always be prevented or anticipated. Many of the processes include biological systems, which add significant complexity, as compared to chemical synthesis. We expect that, from time to time, consistent with biotechnology industry expectations, certain production lots will fail to produce product that meets our quality control release acceptance criteria. To date, our historical failure rates for all of our product programs, including Naglazyme, Aldurazyme and Vimizim, have been within our expectations, which are based on industry norms. If the failure rate increased substantially, we could experience increased costs, lost revenue, damage to customer relations, time and expense investigating the cause and, depending upon the cause, similar losses with respect to other lots or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

In order to produce product within our time and cost parameters, we must continue to produce product within our expected success rate and yield expectations. Because of the complexity of our manufacturing processes, it may be difficult or impossible for us to determine the cause of any particular lot failure and we must effectively take corrective action in response to any failure in a timely manner.

Although we have entered into contractual relationships with third-party manufacturers to produce the active ingredient in Kuvan and Firdapse, if those manufacturers are unwilling or unable to fulfill their contractual obligations, we may be unable to meet demand for these products or sell these products at all and we may lose potential revenue. We have contracts for the production of final product for Kuvan and Firdapse. We also rely on third-parties for portions of the manufacture of Naglazyme and Aldurazyme. If those manufacturers are unwilling or unable to fulfill their contractual obligations or satisfy demand outside of or in excess of the contractual obligations, we may be unable to meet demand for these products or sell these products at all and we may lose potential revenue. Further, the availability of suitable contract manufacturing capacity at scheduled or optimum times is not certain.

In addition, our manufacturing processes subject us to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of hazardous materials and wastes resulting from their use. We may incur significant costs in complying with these laws and regulations.

If we are unable to effectively address manufacturing issues, we may be unable to meet demand for our products and lose potential revenue, have reduced margins, or be forced to terminate a program.

Our manufacturing facility for Naglazyme, Aldurazyme and Vimizim is located near known earthquake fault zones, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facility and equipment, or that of our third-party manufacturers or single-source suppliers, which could materially impair our ability to manufacture Naglazyme, Aldurazyme and Vimizim or our third-party manufacturer's ability to manufacture Kuvan or Firdapse.

Our Galli Drive facility located in Novato, California is currently our only manufacturing facility for Naglazyme, Aldurazyme and Vimizim. It is located in the San Francisco Bay Area near known earthquake fault zones and is vulnerable to significant damage from earthquakes. We, and the third-party manufacturers with whom we contract and our single-source suppliers of raw materials, which include many of our critical raw materials, are also vulnerable to damage from other types of disasters, including fires, floods, power loss and similar events. If any disaster were to occur, or any terrorist or criminal activity caused significant damage to our facilities or the facilities of our third-party manufacturers and suppliers, our ability to manufacture Naglazyme, Aldurazyme and Vimizim, or to have Kuvan or Firdapse manufactured, could be seriously, or potentially completely impaired, and our commercialization efforts and revenue could be seriously impaired. The insurance that we carry, the inventory that we maintain and our risk mitigation plans may not be adequate to cover our losses resulting from disasters or other business interruptions.

Supply interruptions may disrupt our inventory levels and the availability of our products and cause delays in obtaining regulatory approval for our product candidates, or harm our business by reducing our revenues.

Numerous factors could cause interruptions in the supply of our finished products, including:

- timing, scheduling and prioritization of production by our contract manufacturers or a breach of our agreements by our contract manufacturers;
- labor interruptions;
- changes in our sources for manufacturing;
- the timing and delivery of shipments;
- our failure to locate and obtain replacement manufacturers as needed on a timely basis; and
- conditions affecting the cost and availability of raw materials.

Any interruption in the supply of finished products could hinder our ability to distribute finished products to meet commercial demand.

With respect to our product candidates, production of product is necessary to perform clinical trials and successful registration batches are necessary to file for approval to commercially market and sell product candidates. Delays in obtaining clinical material or registration batches could delay regulatory approval for our product candidates.

Because the target patient populations for our products are small, we must achieve significant market share and maintain high per-patient prices for our products to achieve profitability.

All of our products target diseases with small patient populations. As a result, our per-patient prices must be relatively high in order to recover our development and manufacturing costs and achieve profitability. For Naglazyme and Vimizim, if approved, we must market worldwide to achieve significant market penetration of the product. In addition, because the number of potential patients in the disease populations are small, it is not only important to find patients who begin therapy to achieve significant market penetration of the product, but we also need to be able to maintain these patients on therapy for an extended period of time. Due to the expected costs of treatment for our products for genetic diseases, we may be unable to maintain or obtain sufficient market share at a price high enough to justify our product development efforts and manufacturing expenses.

If we fail to obtain an adequate level of coverage and reimbursement for our drug products by third-party payers, the sales of our drugs would be adversely affected or there may be no commercially viable markets for our products.

The course of treatment for patients using our products is expensive. We expect patients to need treatment for extended periods, and for some products throughout the lifetimes of the patients. We expect that most families of patients will not be capable of paying for this treatment themselves. There will be no commercially viable market for our products without coverage and reimbursement from third-party payers. Additionally, even if there is a commercially viable market, if the level of reimbursement is below our expectations, our revenue and gross margins will be adversely affected.

Third-party payers, such as government or private health care insurers, carefully review and increasingly challenge the prices charged for drugs. Reimbursement rates from private companies vary depending on the third-party payer, the insurance plan and other factors. Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis.

Reimbursement in the EU must be negotiated on a country-by-country basis and in many countries the product cannot be commercially launched until reimbursement is approved. The timing to complete the negotiation process in each country is highly uncertain, and in some countries we expect that it may exceed 12 months.

For our future products, we will not know what the reimbursement rates will be until we are ready to market the product and we actually negotiate the rates. If we are unable to obtain sufficiently high reimbursement rates for our products, they may not be commercially viable or our future revenues and gross margins may be adversely affected.

A significant portion of our international sales are made based on special access programs, and changes to these programs could adversely affect our product sales and revenue in these countries.

We make a significant portion of our international sales of Naglazyme through special access or “named patient” programs, which do not require full product approval. We expect to also utilize these programs for Vimizim. The specifics of the programs vary from country to country. Generally, special approval must be obtained for each patient. The approval normally requires an application or a lawsuit accompanied by evidence of medical need. Generally, the approvals for each patient must be renewed from time to time.

These programs are not well defined in some countries and are subject to changes in requirements and funding levels. Any change to these programs could adversely affect our ability to sell our products in those countries and delay sales. If the programs are not funded by the respective government, there could be insufficient funds to pay for all patients. Further, governments have in the past undertaken and may in the future undertake, unofficial measures to limit purchases of our products, including initially denying coverage for purchasers, delaying orders and denying or taking excessively long to approve customs clearance. Any such actions could materially delay or reduce our revenues from such countries.

Without the special access programs, we would need to seek full product approval to commercially market and sell our products. This can be an expensive and time-consuming process and may subject our products to additional price controls. Because the number of patients is so small in some countries, it may not be economically feasible to seek and maintain a full product approval, and therefore the sales in such country would be permanently reduced or eliminated. For all of these reasons, if the special access programs that we are currently using are eliminated or restricted, our revenues could be adversely affected.

If we fail to compete successfully with respect to product sales, we may be unable to generate sufficient sales to recover our expenses related to the development of a product program or to justify continued marketing of a product and our revenue could be adversely affected.

Our competitors may develop, manufacture and market products that are more effective or less expensive than ours. They may also obtain regulatory approvals for their products faster than we can obtain them (including those products with orphan drug designation) or commercialize their products before we do. If we do not compete successfully, our revenue would be adversely affected, and we may be unable to generate sufficient sales to recover our expenses related to the development of a product program or to justify continued marketing of a product.

Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our current and future products, which would adversely affect our revenue and results of operations.

We expect that coverage and reimbursement may be increasingly restricted both in the U.S. and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. Governmental and private third-party payers have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the U.S. In some international markets, the government controls the pricing, which can affect the profitability of drugs. Current government regulations and possible future legislation regarding health care may affect coverage and reimbursement for medical treatment by third-party payers, which may render our products not commercially viable or may adversely affect our future revenues and gross margins.

International operations are also generally subject to extensive price and market regulations, and there are many proposals for additional cost-containment measures, including proposals that would directly or indirectly impose additional price controls or mandatory price cuts or reduce the value of our intellectual property portfolio. As part of these cost containment measures, some countries have imposed or threatened to impose revenue caps limiting the annual volume of sales of Naglazyme. To the extent that these caps are significantly below actual demand, our future revenues and gross margins may be adversely affected.

We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. However, future price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our current and future products, which would adversely affect our revenue and results of operations.

***Government health care reform could increase our costs, and would adversely affect our revenue and results of operations.**

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The PPACA is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program.

Several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. For example, the Medicaid rebate rate was increased and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations. Among other things, the PPACA also expanded the 340B drug discount program (excluding orphan drugs), including the creation of new penalties for non-compliance; included a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or “donut hole,” and imposed a new fee on certain manufacturers and importers of branded prescription drugs (excluding orphan drugs under certain conditions). The law also revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of the Medicaid drug rebates paid to states.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

We anticipate that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and an additional downward pressure on the reimbursement our customers may receive for our products. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

We face credit risks from customers that may adversely affect our results of operations.

Our product sales to government-owned or supported customers in various countries outside of the U.S. are subject to significant payment delays due to government funding and reimbursement practices. This has resulted and may continue to result in an increase in days sales outstanding due to the average length of time that we have accounts receivable outstanding. If significant changes were to occur in the reimbursement practices of these governments or if government funding becomes unavailable, we may not be able to collect on amounts due to us from these customers and our results of operations would be adversely affected.

If we are found in violation of federal or state “fraud and abuse” laws, we may be required to pay a penalty or be suspended from participation in federal or state health care programs, which may adversely affect our business, financial condition and results of operation.

We are subject to various federal and state health care "fraud and abuse" laws, including anti-kickback laws, false claims laws and laws related to ensuring compliance. The federal health care program anti-kickback statute makes it illegal for any person, including a pharmaceutical company, to knowingly and willfully offer, solicit, pay or receive any remuneration, directly or indirectly, in exchange for or to induce the referral of business, including the purchase, order or prescription of a particular drug, for which payment may be made under federal health care programs, such as Medicare and Medicaid. Under federal government regulations, certain arrangements, or safe harbors, are deemed not to violate the federal anti-kickback statute. However, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration not intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability, although we seek to comply with these safe harbors. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs.

Federal and state false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Under the Health Insurance Portability and Accountability Act of 1996, we also are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Many states have adopted laws similar to the federal anti-kickback statute, some of which apply to referral of patients for health care services reimbursed by any source, not just governmental payers.

Substantial new provisions affecting compliance also have been adopted, which may require us to modify our business practices with health care practitioners. PPACA, among other things, requires drug manufacturers to collect and report information on payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties. The CMS has issued a final rule that requires manufacturers to begin collecting required information on August 1, 2013 with the first reports due March 31, 2014 (and by the 90th day of each calendar year thereafter) and publication of the reported data in a searchable form on a public website beginning September 30, 2014.

In addition, there has been a recent trend of increased state regulation of payments made to physicians. Certain states mandate implementation of compliance programs, compliance with the Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals, and/or the tracking and reporting of gifts, compensation, and other remuneration to physicians. The shifting compliance environment and the need to implement systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a pharmaceutical manufacturer may violate one or more of the requirements.

While we believe we have structured our business arrangements to comply with these laws, because of the breadth of these laws, the narrowness of available statutory and regulatory exceptions and the increased focus by law enforcement agencies in enforcing such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened , these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. If we are found in violation of one of these laws, we may be subject to criminal, civil or administrative sanctions, including debarment, suspension or exclusion from participation in federal or state health care programs any of which could adversely affect our business, financial condition and results of operation.

We conduct a significant amount of our sales and operations outside of the U.S., which subjects us to additional business risks that could adversely affect our revenue and results of operations.

A significant portion of the sales of Aldurazyme and Naglazyme and all of the sales of Firdapse are generated from countries other than the United States. Additionally, we have operations in several European countries, Brazil, other Latin American countries, Turkey and Asia. We expect that we will continue to expand our international operations in the future. International operations inherently subject us to a number of risks and uncertainties, including:

- changes in international regulatory and compliance requirements that could restrict our ability to manufacture, market and sell our products;
- political and economic instability;
- diminished protection of intellectual property in some countries outside of the U.S.;
- trade protection measures and import or export licensing requirements;
- difficulty in staffing and managing international operations;
- differing labor regulations and business practices;
- potentially negative consequences from changes in or interpretations of tax laws;
- changes in international medical reimbursement policies and programs;
- financial risks such as longer payment cycles, difficulty collecting accounts receivable and exposure to fluctuations in foreign currency exchange rates; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' and service providers' activities that may fall within the purview of the Foreign Corrupt Practices Act.

Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations.

As we continue to expand our existing international operations, we may encounter new risks. For example, as we focus on building our international sales and distribution networks in new geographic regions, we must continue to develop relationships with qualified local distributors and trading companies. If we are not successful in developing and maintaining these relationships, we may not be able to grow sales in these geographic regions. These or other similar risks could adversely affect our revenue and profitability.

If we are unable to protect our proprietary technology, we may not be able to compete as effectively.

Where appropriate, we seek patent protection for certain aspects of our technology. Patent protection may not be available for some of the products we are developing. If we must spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business and financial prospects may be harmed.

The patent positions of biopharmaceutical products are complex and uncertain. The scope and extent of patent protection for some of our products and product candidates are particularly uncertain because key information on some of our product candidates has existed in the public domain for many years. The composition and genetic sequences of animal and/or human versions of Naglazyme, Aldurazyme, and many of our product candidates have been published and are believed to be in the public domain. The chemical structure of BH4 (the active ingredient in Kuvan) and 3,4-DAP (the active ingredient in Firdapse) have also been published. Publication of this information may prevent us from obtaining or enforcing patents relating to our products and product candidates, including without limitation composition-of-matter patents, which are generally believed to offer the strongest patent protection.

We own or have licensed patents and patent applications related to Naglazyme, Kuvan, Aldurazyme and Firdapse and certain of our product candidates, including Vimizim. However, these patents and patent applications do not ensure the protection of our intellectual property for a number of reasons, including without limitation the following:

- With respect to pending patent applications, unless and until actually issued, the protective value of these applications is impossible to determine. We do not know whether our patent applications will result in issued patents.

- Competitors may interfere with our patent process in a variety of ways. Competitors may claim that they invented the claimed invention prior to us or that they filed their application for a patent on a claimed invention before we did. Competitors may also claim that we are infringing on their patents and therefore we cannot practice our technology. Competitors may also contest our patents by showing the patent examiner or a court that the invention was not original, was not novel or was obvious, for example. In litigation, a competitor could claim that our issued patents are not valid or are unenforceable for a number of reasons. If a court agrees, we would not be able to enforce that patent. We have no meaningful experience with competitors interfering with or challenging the validity or enforceability of our patents or patent applications.
- Enforcing patents is expensive and may absorb significant time of our management. Management would spend less time and resources on developing products, which could increase our operating expenses and delay product programs. We may not have the financial ability to sustain a patent infringement action, or it may not be financially reasonable to do so.
- Receipt of a patent may not provide much, if any, practical protection. For example, if we receive a patent with a narrow scope, then it will be easier for competitors to design products that do not infringe on our patent
- The recently enacted America Invents Act, which reformed certain patent laws in the U.S., may create additional uncertainty. Among the significant changes are switching from a “first-to-invent” system to a “first-to-file” system, and the implementation of new procedures that permit competitors to challenge our patents in the U.S. Patent Office after grant.

In addition, competitors may also seek intellectual property protection for their technology. Due to the amount of intellectual property in our field of technology, we cannot be certain that we do not infringe intellectual property rights of competitors or that we will not infringe intellectual property rights of competitors granted or created in the future. For example, if a patent holder believes our product infringes their patent, the patent holder may sue us even if we have received patent protection for our technology. If someone else claims we infringe their intellectual property, we would face a number of issues, including the following:

- Defending a lawsuit, which takes significant time and resources and can be very expensive.
- If a court decides that our product infringes a competitor’s intellectual property, we may have to pay substantial damages.
- With respect to patents, in addition to requiring us to pay substantial damages, a court may prohibit us from making, selling, offering to sell, importing or using our product unless the patent holder licenses the patent to us. The patent holder is not required to grant us a license. If a license is available, it may not be available on commercially reasonable terms. For example, we may have to pay substantial royalties or grant cross licenses to our patents and patent applications.
- We may need to redesign our product so it does not infringe the intellectual property rights of others.
- Redesigning our product so it does not infringe the intellectual property rights of competitors may not be possible or could require substantial funds and time.

It is also unclear whether our trade secrets are adequately protected. Our employees, consultants or contractors may unintentionally or willfully disclose trade secrets to competitors. Enforcing a claim that someone else illegally obtained and is using our trade secrets, as with patent litigation, is expensive and time consuming, requires significant resources and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Furthermore, our competitors may independently develop equivalent knowledge, methods and know-how, in which case we would not be able to enforce our trade secret rights against such competitors.

We may also support and collaborate in research conducted by government organizations, hospitals, universities or other educational institutions. These research partners may be unwilling to grant us any exclusive rights to technology or products derived from these collaborations.

If we do not obtain required licenses or rights, we could encounter delays in our product development efforts while we attempt to design around other patents or may be prohibited from making, using, importing, offering to sell or selling products requiring these licenses or rights. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties. If we are not able to resolve such disputes and obtain the licenses or rights we need, we may not be able to develop or market our products.

If our Manufacturing, Marketing and Sales Agreement (MMS Agreement) with Genzyme were terminated, we could be prevented from continuing to commercialize Aldurazyme or our ability to successfully commercialize Aldurazyme would be delayed or diminished.

Either party may terminate the Manufacturing, Marketing and Sales Agreement (MMS Agreement), between Genzyme and us related to Aldurazyme for specified reasons, including if the other party is in material breach of the MMS, has experienced a change of control, as such term is defined in the MMS agreement, or has declared bankruptcy and also is in breach of the MMS. Although we are not currently in breach of the MMS, there is a risk that either party could breach the MMS in the future. Either party may also terminate the MMS upon one year prior written notice for any reason.

If the MMS Agreement is terminated for breach, the breaching party will transfer its interest in BioMarin/Genzyme LLC, or the LLC, to the non-breaching party, and the non-breaching party will pay a specified buyout amount for the breaching party's interest in Aldurazyme and in the LLC. If we are the breaching party, we would lose our rights to Aldurazyme and the related intellectual property and regulatory approvals. If the MMS Agreement is terminated without cause, the non-terminating party would have the option, exercisable for one year, to buy out the terminating party's interest in Aldurazyme and in the LLC at a specified buyout amount. If such option is not exercised, all rights to Aldurazyme will be sold and the LLC will be dissolved. In the event of termination of the buyout option without exercise by the non-terminating party as described above, all right and title to Aldurazyme is to be sold to the highest bidder, with the proceeds to be split between Genzyme and us in accordance with our percentage interest in the LLC.

If the MMS Agreement is terminated by either party because the other party declared bankruptcy, the terminating party would be obligated to buy out the other party and would obtain all rights to Aldurazyme exclusively. If the MMS Agreement is terminated by a party because the other party experienced a change of control, the terminating party shall notify the other party, the offeree, of its intent to buy out the offeree's interest in Aldurazyme and the LLC for a stated amount set by the terminating party at its discretion. The offeree must then either accept this offer or agree to buy the terminating party's interest in Aldurazyme and the LLC on those same terms. The party who buys out the other party would then have exclusive worldwide rights to Aldurazyme. The Amended and Restated Collaboration Agreement between us and Genzyme will automatically terminate upon the effective date of the termination of the MMS Agreement and may not be terminated independently from the MMS Agreement.

If we were obligated, or given the option, to buy out Genzyme's interest in Aldurazyme and the LLC, and thereby gain exclusive rights to Aldurazyme, we may not have sufficient funds to do so and we may not be able to obtain the financing to do so. If we fail to buy out Genzyme's interest, we may be held in breach of the agreement and may lose any claim to the rights to Aldurazyme and the related intellectual property and regulatory approvals. We would then effectively be prohibited from developing and commercializing Aldurazyme. If this happened, not only would our product revenues decrease, but our share price would also decline.

Based on our strategic alliance with Merck Serono, unless Merck Serono "opts in" to the PEG-PAL program, we will not realize any cost sharing for the development expenses, development milestones, or royalties for ex-U.S. sales.

In May 2005, we entered into an agreement with Merck Serono for the further development and commercialization of Kuvan (and any other product containing 6R-BH4) and PEG-PAL for PKU. Pursuant to that agreement, we received development milestones on Kuvan and receive royalties on sales by Merck Serono. Additionally, we may be entitled to development milestones and royalties related to PEG-PAL. However, Merck Serono has "opted out" of the PEG-PAL development program. Unless and until it elects to opt in, it is not obligated to pay any of the milestones related to the program or to reimburse us for any of the development costs. Additionally, even though Merck Serono has opted out, we do not have any right to commercialize PEG-PAL outside of the U.S. and Japan or to grant anyone else such rights.

Merck Serono may elect to opt in at any time. If Merck Serono opts in to the PEG-PAL development program before the unblinding of the first Phase 3 trial for PEG-PAL, it must pay 75% of the Phase 3 costs incurred prior to the opt-in and the $7,000,000 Phase 3 initiation milestone. If it opts in after unblinding of the first Phase 3 trial for

PEG-PAL, it must pay 100% of the Phase 3 costs incurred prior to the opt-in and the $7,000,000 Phase 3 initiation milestone. Additionally, in all cases after it opts in to the PEG-PAL development program, Merck Serono would be obligated to pay one half of future development costs under the agreement and any further milestones due under the agreement. If Merck Serono does not opt in, it will not have the right to use any of the clinical or other independently developed data.

We cannot determine when or if Merck Serono will opt in to the PEG-PAL development program. If Merck Serono does not opt in, we will not receive any milestones under the agreement nor will there be any sales outside of the U.S. or Japan generating revenue from royalties or otherwise.

If we fail to compete successfully with respect to acquisitions, joint ventures or other collaboration opportunities, we may be limited in our ability to develop new products and to continue to expand our product pipeline.

Our competitors compete with us to attract organizations for acquisitions, joint ventures, licensing arrangements or other collaborations. To date, several of our product programs have been acquired through acquisitions, such as BMN-701 and BMN-673 and several of our product programs have been developed through licensing or collaborative arrangements, such as Naglazyme, Aldurazyme, Kuvan and Firdapse. These collaborations include licensing proprietary technology from, and other relationships with, academic research institutions. Our future success will depend, in part, on our ability to identify additional opportunities and to successfully enter into partnering or acquisition agreements for those opportunities. If our competitors successfully enter into partnering arrangements or license agreements with academic research institutions, we will then be precluded from pursuing those specific opportunities. Since each of these opportunities is unique, we may not be able to find a substitute. Several pharmaceutical and biotechnology companies have already established themselves in the field of genetic diseases. These companies have already begun many drug development programs, some of which may target diseases that we are also targeting, and have already entered into partnering and licensing arrangements with academic research institutions, reducing the pool of available opportunities.

Universities and public and private research institutions also compete with us. While these organizations primarily have educational or basic research objectives, they may develop proprietary technology and acquire patents that we may need for the development of our product candidates. We will attempt to license this proprietary technology, if available. These licenses may not be available to us on acceptable terms, if at all. If we are unable to compete successfully with respect to acquisitions, joint venture and other collaboration opportunities, we may be limited in our ability to develop new products and to continue to expand our product pipeline.

If generic manufacturers use litigation and regulatory means to obtain approval for generic versions of Kuvan, our revenue and results of operations would be adversely affected.

The Hatch Waxman Act permits the FDA to approve abbreviated new drug applications, or ANDAs, for generic versions of branded drugs. We refer to this process as the “ANDA process”. The ANDA process permits competitor companies to obtain marketing approval for a drug with the same active ingredient for the same uses but does not generally require the conduct and submission of clinical efficacy studies for that product. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product is bioequivalent to the branded product based on pharmacokinetic studies. Pursuant to the Hatch Waxman Act, companies were able to file an ANDA application for the active ingredient in Kuvan at any time after December 2011. At present, we have no information that any other party has filed or has conducted the bioequivalency study necessary to file an ANDA for Kuvan.

The Hatch Waxman Act requires an applicant for a drug that relies, at least in part, on our data regarding the safety and efficacy of Kuvan, to notify us of their application and potential infringement of our patents listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Upon receipt of a notice alleging that our patents listed in the Orange Book are invalid or not infringed by the proposed competitor product (paragraph iv notice), we would have 45 days to bring a patent infringement suit in federal district court against the company seeking approval for its product. The discovery, trial and appeals process in such suits can take several years. If we commence such a suit alleging infringement of one or more of our Orange Book listed patents within 45 days from receipt of the paragraph iv notice, the Hatch Waxman Act provides a 30-month stay on the FDA’s approval of the competitor’s application. If the litigation is resolved in favor of the applicant or the challenged patent expires during

the 30-month stay period, the stay is lifted and the FDA's review of the application may be completed. Such litigation is often time-consuming, costly and may result in competition if such patent(s) are not upheld or if the competitor does not infringe such patent(s). However, generic versions of Kuvan would be prohibited until the expiration of orphan drug exclusivity in December 2014 or June 2015 if we receive pediatric exclusivity.

The filing of an ANDA application in respect to Kuvan could have an adverse impact on our stock price and litigation to enforce our patents is likely to cost a substantial amount and require significant management attention. If the patents covering Kuvan were not upheld in litigation or if the generic competitor is found to not infringe these patents, the resulting generic competition following the expiration of orphan exclusivity would have a material adverse effect on our revenue and results of operations.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline.

For planning purposes, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in many cases for reasons beyond our control. If we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and the credibility of our management may be adversely affected and, as a result, our stock price may decline.

We depend upon our key personnel and our ability to attract and retain employees.

Our future growth and success will depend in large part on our continued ability to attract, retain, manage and motivate our employees. The loss of the services of any member of our senior management or the inability to hire or retain experienced management personnel could adversely affect our ability to execute our business plan and harm our operating results.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. In particular, the loss of one or more of our senior executive officers could be detrimental to us if we do not have an adequate succession plan or if we cannot recruit suitable replacements in a timely manner. While our senior executive officers are parties to employment agreements with us, these agreements do not guarantee that they will remain employed with us in the future. In addition, in many cases, these agreements do not restrict our senior executive officers' ability to compete with us after their employment is terminated. The competition for qualified personnel in the pharmaceutical field is intense, and there is a limited pool of qualified potential employees to recruit. Due to this intense competition, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. If we are unsuccessful in our recruitment and retention efforts, our business may be harmed.

Our success depends on our ability to manage our growth.

Product candidates that we are currently developing or may acquire in the future may be intended for patient populations that are significantly larger than any of MPS I, MPS VI, PKU or LEMS. In order to continue development and marketing of these products, if approved, we will need to significantly expand our operations. To manage expansion effectively, we need to continue to develop and improve our research and development capabilities, manufacturing and quality capacities, sales and marketing capabilities, financial and administrative systems and standard processes for global operations. Our staff, financial resources, systems, procedures or controls may be inadequate to support our operations and may increase our exposure to regulatory and corruption risks and our management may be unable to manage successfully future market opportunities or our relationships with customers and other third-parties.

Changes in methods of treatment of disease could reduce demand for our products and adversely affect revenues.

Even if our drug products are approved, if doctors elect a course of treatment which does not include our drug products, this decision would reduce demand for our drug products and adversely affect revenues. For example, if gene therapy becomes widely used as a treatment of genetic diseases, the use of enzyme replacement therapy, such as Naglazyme and Aldurazyme in MPS diseases, could be greatly reduced. Changes in treatment method can be caused by the introduction of other companies' products or the development of new technologies or surgical procedures which may not directly compete with ours, but which have the effect of changing how doctors decide to treat a disease.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities.

We are exposed to the potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceuticals. We maintain insurance against product liability lawsuits for commercial sale of our products and for the clinical trials of our product candidates. Pharmaceutical companies must balance the cost of insurance with the level of coverage based on estimates of potential liability. Historically, the potential liability associated with product liability lawsuits for pharmaceutical products has been unpredictable. Although we believe that our current insurance is a reasonable estimate of our potential liability and represents a commercially reasonable balancing of the level of coverage as compared to the cost of the insurance, we may be subject to claims in connection with our clinical trials and commercial use of Naglazyme, Kuvan, Aldurazyme and Firdapse, or our clinical trials for PEG-PAL, Vimizim, BMN-701, BMN-673, BMN-111 or BMN-190 for which our insurance coverage may not be adequate.

The product liability insurance we will need to obtain in connection with the commercial sales of our product candidates if and when they receive regulatory approval may be unavailable in meaningful amounts or at a reasonable cost. In addition, while we continue to take what we believe are appropriate precautions, we may be unable to avoid significant liability if any product liability lawsuit is brought against us. If we are the subject of a successful product liability claim that exceeds the limits of any insurance coverage we obtain, we may incur substantial charges that would adversely affect our earnings and require the commitment of capital resources that might otherwise be available for the development and commercialization of our product programs.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

We rely significantly on our information technology and manufacturing infrastructure to effectively manage and maintain our inventory and internal reports, to manufacture and ship products to customers and to timely invoice them. Any failure, inadequacy or interruption of that infrastructure or security lapse of that technology, including cybersecurity incidents could harm our ability to operate our business effectively. Our ability to manage and maintain our inventory and internal reports, to manufacture and ship our products to customers and timely invoice them depends significantly on our enterprise resource planning, production management, and other information systems. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. Cybersecurity incidents resulting in the failure of our enterprise resource planning system, production management or other systems to operate effectively or to integrate with other systems, or a breach in security or other unauthorized access of these systems, may affect our ability to manage and maintain our inventory and internal reports, and result in delays in product fulfillment and reduced efficiency of our operations. A breach in security, unauthorized access resulting in misappropriation, theft, or sabotage with respect to our proprietary and confidential information, including research or clinical data could require significant capital investments to remediate any such failure, problem or breach, all of which could adversely affect our business, financial condition and results of operations.

***Our business is affected by macroeconomic conditions.**

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates and overall economic conditions and uncertainties, including those resulting from the current and future conditions in the global financial markets. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass through price increases on to our customers due to the process by which health care providers are reimbursed for our products by the government. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order

to fund our operations. We purchase or enter into a variety of financial instruments and transactions, including investments in commercial paper, the extension of credit to corporations, institutions and governments and hedging contracts. If any of the issuers or counter parties to these instruments were to default on their obligations, it could materially reduce the value of the transaction and adversely affect our cash flows.

For the nine months ended September 30, 2013 approximately 4% of our net product revenues were from the Southern European countries of Italy, Spain, Portugal and Greece. Approximately 12% of our total accounts receivable as of September 30, 2013 related to such countries and we have included an allowance for doubtful accounts for certain accounts receivable from Greece. If the financial conditions of these countries continues to decline, a substantial portion of the receivables may be uncollectable, which would mean we would have to provide for additional allowances for doubtful accounts or cease selling products in these countries, either of which could adversely affect our results of operations. Additionally, if one or more of these countries were unable to purchase our products, our revenue would be adversely affected.

Interest rates and the ability to access credit markets could also adversely affect the ability of our customers/distributors to purchase, pay for and effectively distribute our products. Similarly, these macroeconomic factors could affect the ability of our contract manufacturers, sole-source or single-source suppliers to remain in business or otherwise manufacture or supply product. Failure by any of them to remain a going concern could affect our ability to manufacture products.

Risks Related to Ownership of Our Securities

Our stock price may be volatile, and an investment in our stock could suffer a decline in value.

Our valuation and stock price since the beginning of trading after our initial public offering have had no meaningful relationship to current or historical earnings, asset values, book value or many other criteria based on conventional measures of stock value. The market price of our common stock will fluctuate due to factors including:

- product sales and profitability of Naglazyme, Aldurazyme, Kuvan and Firdapse;
- manufacture, supply or distribution of Naglazyme, Aldurazyme, Kuvan and Firdapse;
- progress of our product candidates through the regulatory process and our ability to successfully commercialize any such products that receive regulatory approval;
- results of clinical trials, announcements of technological innovations or new products by us or our competitors;
- government regulatory action affecting our product candidates or our competitors' drug products in both the U.S. and non U.S. countries;
- developments or disputes concerning patent or proprietary rights;
- general market conditions and fluctuations for the emerging growth and pharmaceutical market sectors;
- economic conditions in the U.S. or abroad;
- broad market fluctuations in the U.S., EU or in other parts of the world;
- actual or anticipated fluctuations in our operating results; and
- changes in company assessments or financial estimates by securities analysts.

In the past, following periods of large price declines in the public market price of a company's securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities. In addition, the current decline in the financial markets and related factors beyond our control, including the credit and mortgage crisis in the U.S. and worldwide, may cause our stock price to decline rapidly and unexpectedly.

***Recent and future regulatory actions and other events may adversely affect the trading price and liquidity of our senior subordinated convertible notes.**

We expect that many investors in, and potential purchasers of, our notes will employ, or seek to employ, a convertible arbitrage strategy with respect to the notes. Investors would typically implement such a strategy by selling

short the common stock underlying our senior subordinated convertible notes and dynamically adjusting their short position while continuing to hold the notes. Investors may also implement this type of strategy by entering into swaps on our common stock in lieu of or in addition to short selling the common stock.

The SEC and other regulatory and self-regulatory authorities have implemented various rules and taken certain actions, and may in the future adopt additional rules and take other actions, that may impact those engaging in short selling activity involving equity securities (including our common stock). Such rules and actions include Rule 201 of SEC Regulation SHO, the adoption by the Financial Industry Regulatory Authority, Inc. of a "Limit Up-Limit Down" program, the imposition of market-wide circuit breakers that halt trading of securities for certain periods following specific market declines, and the implementation of certain regulatory reforms required by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. Any governmental or regulatory action that restricts the ability of investors in, or potential purchasers of, our senior subordinated convertible notes to effect short sales of our common stock or enter into swaps on our common stock could adversely affect the trading price and the liquidity of the notes.

In addition, if investors and potential purchasers seeking to employ a convertible arbitrage strategy are unable to borrow or enter into swaps on our common stock, in each case on commercially reasonable terms, the trading price and liquidity of our senior subordinated convertible notes may be adversely affected.

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

We are incorporated in Delaware. Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to the stockholders. Our anti-takeover provisions include provisions in our certificate of incorporation providing that stockholders' meetings may only be called by our Board of Directors and provisions in our bylaws providing that the stockholders may not take action by written consent and requiring that stockholders that desire to nominate any person for election to our Board of Directors or to make any proposal with respect to business to be conducted at a meeting of our stockholders be submitted in appropriate form to our Secretary within a specified period of time in advance of any such meeting. Additionally, our Board of Directors has the authority to issue shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. The rights of holders of our common stock are subject to the rights of the holders of any preferred stock that may be issued. The issuance of preferred stock could make it more difficult for a third-party to acquire a majority of our outstanding voting stock. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, our Board of Directors approves the transaction. Our Board of Directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our Board of Directors may adopt additional anti-takeover measures in the future.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

10.1^ Amended and Restated Severance Plan and Summary Plan Description effective July 29, 2013, previously filed with the Commission on July 30, 2013 as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference.

31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Link Document

* Filed herewith.
^ Management contract or compensatory plan or arrangement.

Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012, (ii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2013 and 2012, (iii) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and 2012, and (iv) Notes to Condensed Consolidated Financial Statements.

Table of Contents

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOMARIN PHARMACEUTICAL INC.

Dated: October 28, 2013

By /S/ DANIEL SPIEGELMAN
Daniel Spiegelman,
Executive Vice President and Chief Financial Officer
(On behalf of the registrant and as principal financial officer)

EXHIBIT INDEX

10.1^	Amended and Restated Severance Plan and Summary Plan Description effective July 29, 2013, previously filed with the Commission on July 30, 2013 as Exhibit 10.1 to the Company's Current Report on Form 8-K, which is incorporated herein by reference
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. This Certification accompanies this report and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed for purposes of §18 of the Securities Exchange Act of 1934, as amended.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Link Document

* Filed herewith.
^ Management contract or compensatory plan or arrangement.

Attached as Exhibit 101 to this report are documents formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012, (ii) Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2013 and 2012, (iii) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and 2012, and (iv) Notes to Condensed Consolidated Financial Statements.

Exhibit 31.1

CERTIFICATION

I, Jean-Jacques Bienaimé, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioMarin Pharmaceutical Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 28, 2013

/s/ JEAN-JACQUES BIENAIMÉ
Jean-Jacques Bienaimé
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Daniel Spiegelman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of BioMarin Pharmaceutical Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 28, 2013

/s/ DANIEL SPIEGELMAN
Daniel Spiegelman
Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

We, Jean-Jacques Bienaimé and Daniel Spiegelman hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that BioMarin Pharmaceutical Inc.'s Quarterly Report on Form 10-Q for the period ended September 30, 2013, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in such Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of BioMarin Pharmaceutical Inc.

/s/ JEAN-JACQUES BIENAIMÉ
Jean-Jacques Bienaimé
Chief Executive Officer

October 28, 2013

/s/ DANIEL SPIEGELMAN
Daniel Spiegelman
Executive Vice President and Chief Financial Officer

October 28, 2013